

HACCP VERIFICATION TASK

Objectives

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

1. Identify the regulatory requirements verified with the HACCP verification task.
2. Explain how Inspection Program Personnel (IPP) is to perform the HACCP verification task.
3. Identify issues that represent noncompliance with an establishment's HACCP plan and inadequacy of the HACCP system.
4. Identify the type of issues or concerns that are to be discussed with supervision before determining compliance and completing the HACCP verification task.

Introduction

According to the instructions delineated in FSIS PHIS Directive 5000.1, Chapter III, HACCP, IPP use two types of HACCP tasks – the Hazard Analysis Verification (HAV) task and HACCP verification task – for verifying that an establishment complies with the requirements of 9 CFR Part 417. As discussed earlier course, the HAV task addresses verifying the establishment's hazard analysis, the establishment's support for decisions made in the hazard analysis and HACCP plan including prerequisite programs, and the validation and reassessment regulatory requirements. The directive also provides instructions for performing the HACCP verification task which requires IPP to verify the monitoring, verification, recordkeeping, prerequisite program implementation (when applicable), corrective action, and pre-shipment review regulatory requirements.

There are nine HACCP verification tasks. Each task represents a specific HACCP processing category.

- Slaughter
- Raw Product – Non-Intact
- Raw Product – Intact
- Not Heat Treated – Shelf Stable
- Heat Treated – Shelf Stable
- Fully Cooked – Not Shelf Stable
- Heat Treated but Not Fully Cooked – Not Shelf Stable
- Product with Secondary Inhibitors – Not Shelf Stable

As part of the HACCP recordkeeping requirements, IPP are to verify that the establishment completes the pre-shipment review before the product enters commerce. If IPP cannot complete the HACCP verification task in one day, they are to enter partial findings in PHIS but will not consider the task complete until all applicable mandatory regulatory requirements have been verified, including the pre-shipment review. PHIS will hold that task as incomplete in the inspector's calendar until the inspector documents verification results for all mandatory regulatory requirements.

Routine and Directed HACCP Verification Tasks

IPP are to perform the routine HACCP verification task for the applicable HACCP process category at the frequency in which they appear in the establishment's task list.

PHIS may also add a **directed** HACCP verification task to the establishment's task list in response to certain events or results (e.g. positive pathogen test results or a trend of food safety noncompliances) that suggest the establishment is either not implementing or maintaining control of its food safety system.

IPP are to initiate a **directed** HACCP verification task as a necessary response to finding noncompliance or as instructed by their immediate supervisor, FLS, DO, or Headquarters personnel. In these cases, the IPP are to add a directed instance of the routine HACCP verification task to their task calendar and perform the task.

Performing the HACCP Verification Task

As mentioned earlier, PHIS adds HACCP verification tasks to the establishment's task list based on the HACCP process categories specified in the establishment's profile. IPP then add these tasks to their monthly calendar. To perform the HACCP verification task, IPP are to verify all applicable HACCP regulatory requirements at each process step where a CCP is identified and verify implementation of any prerequisite programs that apply to the selected product by performing the following steps:

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

If the establishment produces multiple types of products within the HACCP category, IPP are to ensure that they verify HACCP implementation for all product types produced in the establishment over the course of time. IPP are to select a product type that the establishment is currently producing.

IPP are to select a specific production of the selected product type, such as the product produced during a specific period, a specific production lot, or other

designated product. IPP are to verify that the establishment has met all applicable HACCP regulatory requirements at each step and any prerequisite programs applicable to that specific production by following the instructions that follows throughout this section.

Specific production is a term that is used to refer to whatever method the establishment uses to group product, e.g., product produced during a specific period of time, a specific production lot, or other designated product. FSIS does not determine the method used to define specific production; this is an establishment's responsibility. IPP will see a variety of different of methods used. For example, a poultry slaughter establishment might define all the birds from one house as a specific production; another might define it by all carcasses produced in one hour on one line.

Establishments might define all products from one formulation batch, one shift's production or time period within a shift, product in one oven or smokehouse, or the product in one chiller as a specific production. It is important for IPP to understand the method used by the establishment to which they are assigned. IPP can determine this by asking establishment management.

2. Review the HACCP plan for the selected product type:

Before performing a HACCP verification task, IPP are to review the relevant HACCP plan to ensure they have full knowledge of its contents. They need to be familiar with the written procedures for monitoring and verification and their frequencies at each CCP in the HACCP plan. IPP are also to be familiar with any prerequisite programs or other control measures that the establishment uses to support that an identified food safety hazard is not reasonably likely to occur. They may also review the HACCP plan again if questions arise during the verification task.

While reviewing the HACCP plan, IPP are to particularly note the most recent date when a responsible establishment representative signed the HACCP plan. If the date is recent, IPP are to pay close attention to the contents of the HACCP plan because a recent date on the HACCP plan may indicate that the establishment has recently revised the monitoring or verification procedures in the HACCP plan.

Note: When IPP identify an addition to or modification of the CCPs in the HACCP plan, they are to note the changes and update the PHIS establishment profile to accurately reflect the revised content of the HACCP plan. IPP are to follow the instructions in FSIS Directive 5300.1 on how to update the HACCP information in the PHIS establishment profile.

9 CFR 417.2(d) requires the establishment is to sign and date the HACCP plan upon initial acceptance, after any modifications, and after the annual

reassessment required by 9 CFR 417.4(a)(3). One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.2(d):

- Establishment management has not signed and dated the HACCP plan.
- Establishment management has not signed and dated the HACCP plan at least once since January 1 of the previous calendar year.
- Establishment management has modified the HACCP plan without updating the signature and date.

3-5. Verify that the monitoring, verification, and recordkeeping HACCP regulatory requirements have been met for **all CCPs** in the HACCP plan for that **specific production**

IPP verify HACCP implementation by verifying that the establishment has met the monitoring, verification, and recordkeeping HACCP regulatory requirements at each CCP. The instructions for verifying each of the HACCP regulatory requirements are discussed later in this section of training.

6. Verify the implementation **of any prerequisite programs** or other programs that apply to the specific production

The implementation of the program and the records generated from the program must demonstrate that the relevant food safety hazard is not reasonably likely to occur on an ongoing basis. Instructions for verifying the implementation of prerequisite programs are discussed later in this section of training.

7. Verify that the corrective action HACCP regulatory requirement has been met

When IPP perform the HACCP verification task and find a deviation from a critical limit or an unforeseen hazard associated with the specific production, they are required to verify that the corrective action regulatory requirements had been met. The instructions for verifying the HACCP corrective action regulatory requirements are discussed later in this section of training.

8. Verify that the **pre-shipment review** requirement for that specific production has been met

The HACCP verification task **cannot be completed** until the establishment performs the pre-shipment review for that specific production. Because the HACCP verification task is performed by verifying the HACCP regulatory requirements for a specific production, IPP are also determining whether the establishment's HACCP system prevented the distribution of adulterated product.

9. Consider any implications of noncompliance and document the HACCP verification task in PHIS

When IPP complete the HACCP verification task, they are to document their findings of compliance or noncompliance in PHIS. Noncompliance is the failure of an establishment to meet one or more HACCP regulatory requirements. In addition to documenting any findings of noncompliance, IPP are to consider all their findings in the context of the establishment's food safety system.

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

HACCP Verification Task Example 2: *The IPP has a Heat Treated – Shelf Stable HACCP verification task scheduled in her PHIS task calendar. The establishment has one HACCP plan for salami sticks in this processing category. She knows from previous experience that this establishment defines specific production as each day's production lot. The establishment performs pre-shipment review each day on the production lot that passes the final CCP, drying. This may take between 4-5 weeks. She proceeds to the HACCP office and determines that one production lot passed the drying CCP today and the pre-shipment review has been completed. She reads the HACCP plan to be familiar with the CCPs. She uses the recordkeeping component in this case because production is complete. She performed her verification and concluded that all of the HACCP requirements were met for all of the CCPs in the HACCP plan for this specific production, including the pre-shipment review. Then, she proceeds to enter her HACCP verification findings in PHIS and marks the task as completed.*

Verifying Compliance with the HACCP Regulatory Requirements

There are **four** regulatory requirements that the establishment must comply with during the day-to-day or ongoing operation of the HACCP system. The regulatory requirements are:

1. **Monitoring**
2. **Verification**
3. **Recordkeeping**
4. **Corrective Actions**

Note: When establishments implement prerequisite programs or other supporting programs to support the decision that the hazard is not likely to occur, the implementation of the program is verified as part of the recordkeeping requirement. The pre-shipment review is also a recordkeeping requirement. Prerequisite programs or other supporting programs and the pre-shipment review will be discussed in individual sections of the training even though they are part of the recordkeeping requirements.

IPP use HACCP verification tasks to verify that the establishment complies with these four regulatory requirements.

This section covers how to verify regulatory compliance and make supportable decisions when performing the HACCP verification tasks. Below is a chart with the HACCP requirements, regulatory references, and the components utilized in verifying compliance.

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

Regulatory References for Verifying the HACCP Requirements

Monitoring

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

Verification

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

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

Recordkeeping

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

417.5(a)3 HACCP Records - Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

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

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

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

417.5(f) Official Review - All records required by this part and all plans and procedures required by this part shall be available for official review and copying

Prerequisite Program Implementation

417.5(a)(1) Supporting Documentation -(a) The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;

Corrective Actions

417.3(a) - The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

- (1) The cause of the deviation is identified and eliminated;
- (2) The CCP will be under control after the corrective action is taken;
- (3) Measures to prevent recurrence are established; and
- (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

417.3(b) - If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

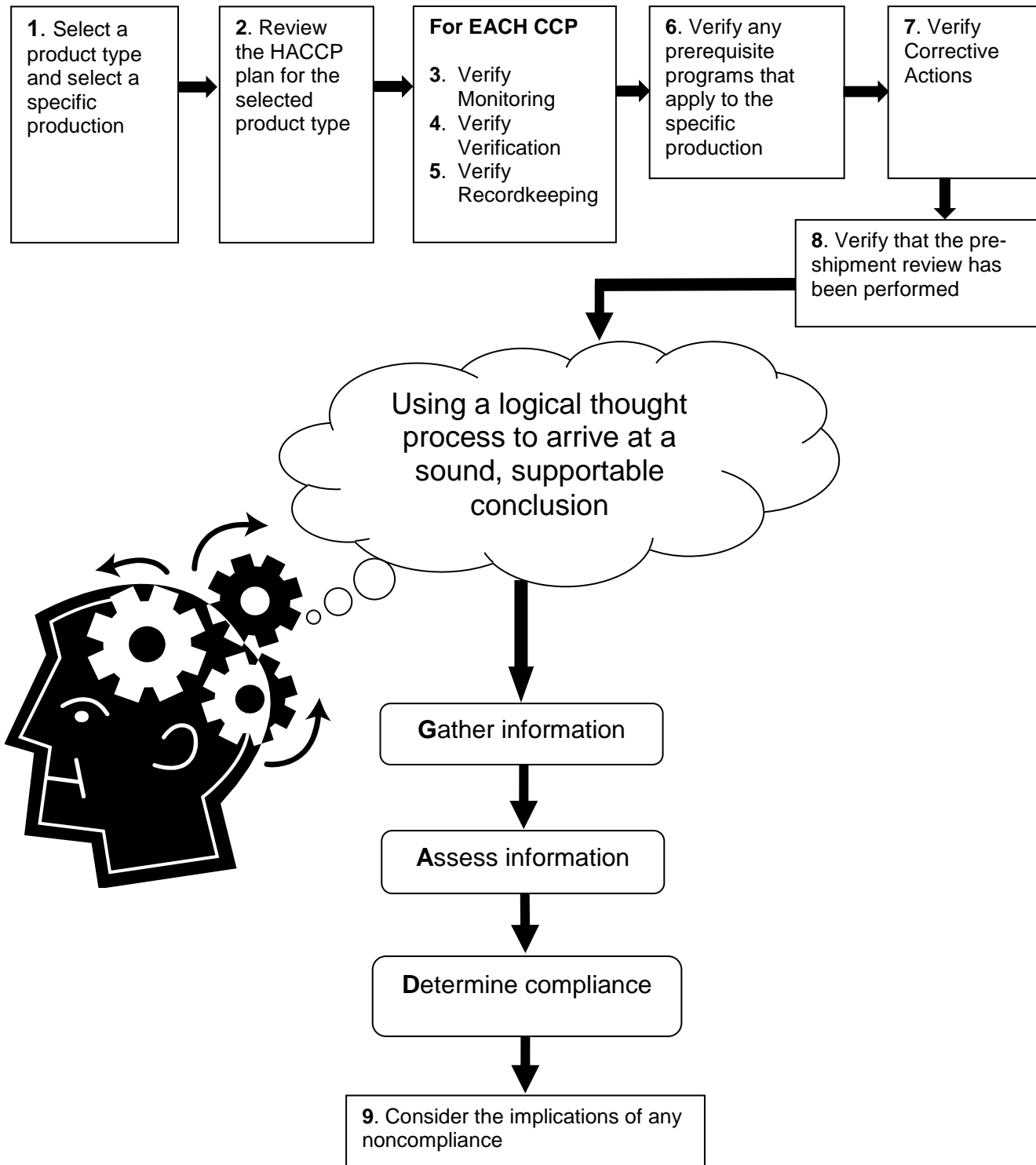
- (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
- (2) Perform a review to determine the acceptability of the affected product for distribution;
- (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
- (4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

Pre-shipment Review

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

HACCP Verification Task Methodology

This thought process should be utilized when verifying all of the HACCP regulatory requirements. The following diagram illustrates the thought process.



Monitoring

The regulation that applies to monitoring is:

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

The establishment is required to develop and implement procedures to monitor each of the CCPs to ensure compliance with the critical limits (9 CFR 417.2(c)(4))

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

The thought process the IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

Gather information by asking questions

When IPP verify HACCP implementation, they are to verify the regulatory requirements for monitoring by reviewing the HACCP plan, reviewing HACCP records, observing establishment employees performing monitoring activities, and taking measurements at CCPs. When verifying the monitoring requirements, IPP should seek answers to the following questions:

1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the critical control points to ensure compliance with the critical limits?
2. Are the monitoring procedures being performed as described in the HACCP plan?
3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?
4. Are the critical limits met?

Assess the information gathered

To answer these questions the IPP should:

- Review the HACCP plan
- Review the HACCP monitoring records
- Observe the establishment employees perform monitoring activities
- Take measurements at critical control points

Now let's review each of these activities in detail.

Reviewing the HACCP Plan

When reviewing the establishment's HACCP plan for raw, ready-to-eat/not ready-to-eat not shelf stable, or shelf stable processes, IPP will determine whether the HACCP plan includes the monitoring procedures and frequencies that are used to monitor each critical control point. It is very important for IPP to be familiar with the monitoring procedures and frequencies in the current HACCP plan. IPP should review the HACCP plan each time the monitoring requirement is verified since the establishment can modify the plan without notifying inspection. When reviewing the monitoring procedures and frequencies in the HACCP plan, the IPP should be able to visualize what is occurring at the CCP. If IPP do not understand how the establishment is performing the monitoring activity at the CCP, they are to seek clarification of the monitoring procedure from establishment management before continuing with the HACCP verification task. If the IPP cannot visualize what is occurring at the CCP, it could be an indication that the monitoring requirement is not being met.

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

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

he decided the monitoring procedures and frequencies for this CCP are included in the HACCP plan.

Reviewing HACCP Monitoring Records

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

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

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

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

Observing Establishment Employees

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

Monitoring Example 5: *An IPP is performing the Slaughter HACCP verification task and verifying the monitoring requirements for the steam pasteurization CCP. She observes the establishment monitoring personnel as they visually observe the temperature gauge on the steam cabinet and document the temperature on the record for the steam pasteurization CCP. From her observation, she*

determines that the establishment is in compliance with the monitoring procedure because it is performed as described in the HACCP plan.

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

Taking Measurements at Critical Control Points

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

Note: IPP should not take independent measurements using complex equipment such as pH meters, water activity, etc. In this case, the IPP should observe establishment employees taking the measurements and recording the results. IPP should have access to the procedures/method of operating and calibrating these process-monitoring instruments.

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

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

her readings compare with the temperature readings recorded by establishment monitoring personnel.

Determine compliance

After the IPP has gathered and assessed all available information pertaining to the monitoring requirement, he/she must determine regulatory compliance. Based on reviewing the monitoring records or based on observing the establishment performing the monitoring procedures, IPP must determine whether the monitoring procedures described in the HACCP plan are being performed in the manner and at the frequencies specified in the HACCP plan. If the IPP finds that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If the IPP finds that the establishment has not met all regulatory requirements, there is noncompliance.

Noncompliance with the Monitoring Requirement

One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.2(c)(4):

- The HACCP plan does not include a written monitoring procedure to ensure that product meets the critical limit at each CCP.
- The establishment employee is not conducting the monitoring procedures as written in the HACCP plan.
- The establishment employees do not implement the monitoring procedures at the frequencies specified in the HACCP plan.
- The IPP takes a measurement at a CCP and finds that the critical limit is not met.
- IPP observe a deviation from the critical limit that was not detected by the establishment monitoring procedure. This finding includes any time IPP observe the deviation in product that has already passed the CCP, product that is at the point of the CCP that would not be selected for monitoring by the establishment, or product that was selected for monitoring but the deviation was not detected by the establishment.

The following are examples of noncompliance with the monitoring requirement.

Monitoring Noncompliance Example 1: *The HACCP plan specifies that monitoring personnel will select three samples from different locations of each batch of product, blend/emulsify the sample, and measure the pH. While performing verification for the monitoring requirement, the IPP observes that the*

monitor took one sample. **The establishment is not conducting the monitoring procedures as specified in the HACCP plan.**

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

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

Monitoring Noncompliance Example 4: *An IPP is performing the poultry Slaughter HACCP verification task and verifying the establishment compliance with the monitoring requirements. The IPP proceeds to the establishment's management office and reviews the HACCP plan. The IPP finds that the establishment incorporated a chilling procedure into its HACCP plan and specifies that trisodium phosphate (TSP) will be used as a prechill antimicrobial spray, chlorine will be added to the chiller water and the post chill carcasses internal temperature will be measure. The critical limits values for those 3 CCPs consecutively are 9% concentration, 20 ppm concentration, and less than 40 F. All critical limits will be monitored hourly. The IPP reviews all the 3 CCPs monitoring records and finds that the monitoring checks for the chlorine concentration were not recorded in the past 3 hours. The IPP determines that **the establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.***

Note: On August 21, 2014 FSIS published a final rule to modernize poultry slaughter inspection that removed the prescriptive time and temperature parameters from the chilling regulatory requirements for all establishments producing ready to cook poultry (RTC) except for ratites. Establishments are required to incorporate procedure for chilling poultry into their HACCP system, e.g., HACCP plan or Sanitation SOP or other prerequisite program (9 CFR 381.66 (b)(3)).

If IPP find a monitoring noncompliance, they are to take a regulatory control action, if necessary, to prevent adulterated product from entering commerce. In addition, IPP are to consider whether the noncompliance may have resulted in adulterated product entering commerce. If they find that adulterated product may have entered commerce, IPP are to notify DO personnel through supervisory

channels immediately (refer to FSIS PHIS Directive 5000.1, Part II, Section X – Subpart B III.B.3).

Note: As per 9 CFR part 418 (Recalls), official establishments are required to prepare and maintain procedures for the recall of all meat and poultry products produced and shipped by the establishment. In addition, the establishments are to notify FSIS (i.e., the District Office) within 24 hours if the establishment believes or has reason to believe that an adulterated or misbranded product received by or originating from the establishment has entered into commerce.

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

Workshop: Monitoring

Refer to the handout to complete the following questions.

1. An IPP is assigned to a small goat slaughter establishment and is performing the Slaughter HACCP Verification task. He is verifying the monitoring requirement for the slaughter food safety standard (zero tolerance for fecal, ingesta, and milk) CCP. Review the HACCP plan and answer the following questions.

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

- a. If the IPP decides to perform the recordkeeping component in verifying the monitoring requirement, what monitoring requirement question would he seek the answer to when reviewing the HACCP plan? What would the answer to the question be?

- b. Review the record below and answer the questions. In reviewing the monitoring records for the recordkeeping component, what questions would the IPP seek the answer to?

Slaughter Number	Feces, ingesta, milk present? (Y or N)*	Performed by	Date: 2-8-12 Time	Corrective Actions and/or Comments
1	N	TDM	0840	
2	N	TDM	0915	
3	N	TDM	0955	
4	N	TDM	1035	
5	N	TDM	1140	
6	N	TDM	1229	
7	N	TDM	1320	
8	N	TDM	1405	
9	N	TDM	1455	

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

- c. Where would he perform the recordkeeping component?

- d. If he decides to perform the review and observation component, how would he proceed?

2. **Case Study** - The following is the monitoring procedure for the pre-evisceration wash as written in a pork slaughter HACCP plan:

QC evaluates 10% of carcasses for visible contaminants. QC monitors washing and antimicrobial equipment to ensure proper adjustment. Concentration of antimicrobial is tested.

Does this monitoring procedure comply with 417.2(c)(4)? Explain your answer.

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

b) The IPP decides to take an internal product temperature. What does the IPP do?

c) The IPP looks at the smokehouse record. What is the IPP looking for?

4. An IPP is performing the Heat Treated Shelf Stable HACCP verification task and has decided to verify the monitoring requirement. He reviews the HACCP plan.

HACCP plan: Beef Sticks, Heat Treated, Shelf-stable			
CCP #	Critical Limits	Monitoring Procedures & Frequencies	HACCP Records
2. Lethality	≥158°F	Select 3 beef sticks at the specified cold spot, measure the internal temperature with a thermocouple thermometer and record the lowest temperature.	Lethality log Corrective action log Calibration log

What do you determine regarding compliance?

Verification

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

The regulations that apply to verification procedures and frequencies are:

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

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

The establishment is required to develop and implement procedures to verify the ongoing effective implementation of the HACCP plan (9 CFR 417.2(c)(7) and 417.4(a)(2)). The verification procedures provide for the calibration of process monitoring instruments, direct observation of monitoring activities and corrective actions, and review of HACCP records unless one or more activity is not applicable in a particular establishment. The verification procedures may also include other activities the establishment develops to verify the effective implementation of the HACCP plan (e.g. microbial sampling of products).

The verification procedures may be particular to each CCP or may apply more broadly across all CCPs. For example, an establishment may use thermometers to monitor several different CCPs. It would not be necessary to have a specific thermometer calibration procedure for each CCP. The establishment could have a single thermometer calibration procedure that covers the HACCP plan as a whole.

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

The thought process the IPP should use when verifying regulatory requirements should include:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

Gather information by asking questions

IPP verify the regulatory requirements for verification by reviewing the HACCP plan, reviewing HACCP records, and observing establishment employees performing verification activities. When verifying the verification requirement, the IPP should seek answers to the following questions.

1. Does the HACCP plan contain verification procedures and frequencies for the calibration of the process-monitoring instruments?
2. Does the HACCP plan contain verification procedures and frequencies for direct observations of monitoring activities and corrective actions?

It is important that the establishment implement corrective actions that meet the requirements of 9 CFR 417.3(a) each time that a deviation from a critical limit occurs, and the requirements of 9 CFR 417.3(b) each time an unforeseen hazard occurs. Since the establishment cannot predict when a deviation from a critical limit or an unforeseen hazard will occur, it would be counterproductive to require that it have specific procedures and frequencies in its HACCP plan for directly observing corrective actions. It is necessary, however, for an establishment to directly observe corrective actions frequently enough to verify that these actions are being performed in a manner that meets the regulatory requirements. Under the regulations (417.4(a)(2)(ii)), the establishment is to document these direct observations of corrective actions in the same manner that it documents other verifications.

3. Does the HACCP plan list verification procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?
4. Does the HACCP plan list product sampling as a verification activity?
5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?
6. Are verification activities conducted as per the HACCP plan?
7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment as specified in the HACCP plan?

Assess information

When assessing the information, the IPP should do the following.

- Review the HACCP plan

- Review HACCP records
- Observe establishment employees performing verification activities

Now let's review each of these activities in detail.

Reviewing the HACCP Plan

When reviewing the HACCP plan, IPP are to determine whether it includes verification procedures such as direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring instrument calibration procedures and frequencies. All three verification activities do not have to occur at each CCP, but all three should be addressed in the HACCP plan. However, if the verification activity is applicable at a CCP and it is not being addressed in the HACCP plan the establishment must have support in accordance with 417.5(a)(2) for not performing the verification activity. The IPP should review the HACCP plan each time the verification requirement is verified since the establishment can modify the plan without notifying inspection personnel.

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

Verification Example 2: *An IPP is performing the Heat Treated – Shelf Stable HACCP verification task in a beef jerky operation. She reviews the establishment's HACCP plan and finds that it specifies quality control personnel will review the water activity records and observe the monitoring procedures at this CCP once per shift. It also specifies that quality control personnel will verify the accuracy of the water activity measuring equipment once per shift by performing a calibration check procedure. Based upon her review of the HACCP plan, she determines that the establishment is in compliance with 417.2(c)(7) and 417.4(a)(2)(i)(ii)(iii).*

It is important to point out here that some HACCP plans might not contain all three verification activities that are found in 417.4(a)(2)(i)(ii)(iii). If an establishment has a CCP that is monitored without the use of process monitoring equipment, there would be no need for process monitoring equipment calibration verification procedures. If the monitoring procedure involves automatic monitoring devices and does not require any human action to accomplish the

monitoring of the critical limit, then direct observation of the automatic portion of the monitoring procedure is not required.

If an establishment only has one employee, it would not be possible for that person to conduct a direct observation of the monitoring activity. In this situation, the HACCP plan would not need to list a direct observation of the monitoring activities.

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

Reviewing HACCP Verification Records

IPP should review the verification records to determine if the establishment is performing the verification procedures at the frequencies specified in the HACCP plan for raw processes.

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

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

Observing Establishment Employees

IPP should observe an establishment employee performing the verification activities listed in the plan to determine if the procedures are being carried out as written in the HACCP plan.

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

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

Note: On-going verification activities should be designed for the establishment verifier to directly observe the establishment employee conducting the monitoring activity. An establishment verifier conducting the same activity as the monitor does not meet the regulatory requirement for the direct observation verification activity described in §417.4(a)(2)(ii). However, the establishment can choose to perform additional verification activities such as taking additional (hands-on) measurements at a CCP.

Product sampling is considered a verification activity **if** the establishment incorporates product sampling into the HACCP plan. It may be used to verify a CCP or it may be used as an overall verification of the HACCP system and not be associated with any one CCP. For example, some establishments may include their *E. coli* O157:H7 testing programs (beef trimmings or ground beef products), or *Lm* testing programs (RTE products that are post-lethality exposed to the environment), or *Salmonella* testing program (beef jerky products) in the HACCP plan. When that is the case, the IPP must verify the testing program is in compliance with the verification requirement (417.4(a)(2)). The establishment may perform end-product sampling. If the establishment does end-product sampling, the verification is not necessarily associated with a single CCP, but it could be an overall verification of all the CCPs from the specific HACCP plan. If the product sampling is part of the verification of the HACCP plan, the IPP should observe the establishment employee collecting samples and following all the

procedures identified in the plan as part of the HACCP verification task when verifying §417.4(a)(2). If the establishment received positive results, the IPP should verify the corrective action requirements of 9 CFR 417.3(a) are met.

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

As mentioned previously, all three of the on-going verification activities must be in the HACCP plan, when applicable. All three of the on-going verification activities must be performed at each CCP when applicable, **unless the establishment can provide justification (support) for not performing the on-going verification activities as required by 417.5(a)(2).**

Determine compliance

After the IPP has gathered and assessed all available information pertaining to the verification requirement, he/she must determine regulatory compliance. If the IPP finds that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If the IPP finds that the establishment has not met all regulatory requirements, there is noncompliance.

Noncompliance with the Verification Requirement

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

- The HACCP plan does not include written verification procedures and frequencies for calibration of any process monitoring instruments used to monitor the CCPs (also noncompliance with 417.2(c)(7)). Calibration methods should be in accordance with accepted procedures or manufacturer instructions.
- The HACCP plan does not include written verification procedures and frequencies for direct observation of monitoring activities (also noncompliance with 417.2(c)(7)).

- The HACCP plan does not include written verification procedures and frequencies for review of records (also noncompliance with 417.2(c)(7)).
- Establishment employees do not implement the verification procedures at the frequencies specified in the HACCP plan.
- The HACCP plan does not include written description of additional verification procedures (if any) and frequencies the establishment uses to verify the effective implementation of the HACCP plan (e.g. microbiological sampling) (also noncompliance with 417.2(c)(7)).
- Establishment employees do not implement the verification procedures as written in the HACCP plan.
- The establishment verification employee does not actually observe the monitoring employee performing the monitoring procedure during the direct observation verification procedure.
- The verification results indicate that the establishment is not implementing the HACCP plan as written, and the establishment has not corrected the situation.

The following are examples of noncompliance with the verification requirement.

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

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

Verification Noncompliance Example 3: *The HACCP plan specifies that one of the verification procedures for the cooking CCP is that the QC supervisor will*

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

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

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

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

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

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

Workshop: Verification

Refer to the handout to complete the following questions.

1. Answer the following questions:
 - a. What are the 3 verification activities that the HACCP regulations specify?

 - b. Must all three occur at each CCP in the HACCP plan? Please explain your answer.

 - c. Would an establishment be in compliance if the same establishment employee performed all three of the verification activities at one CCP?

2. Describe in your own words the difference between FSIS inspection verification and the establishment's verification procedures.

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

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

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

If yes, what is the procedure?

If yes, what is the frequency?

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

If yes, what is the procedure?

If yes, what is the frequency?

- c. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

If yes, what is the procedure?

If yes, what is the frequency?

- d. How would the IPP determine whether process-monitoring calibration activities were being conducted as per the HACCP plan?

If the IPP performs the review and observation component:

If the IPP performs the recordkeeping component:

- e. How would the IPP determine whether direct observation verification activities were being conducted as per the HACCP plan?

If the IPP performs the review and observation component:

If the IPP performs the recordkeeping component:

- f. How would the IPP determine if records generated in accordance with 9 CFR 417.5(a)(3) were being reviewed by the establishment?

If the IPP performs the review and observation component:

If the IPP performs the recordkeeping component:

She requests the Thermometer Calibration Logs and the Product Temperature Logs.

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

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

- g. What do you conclude from the records?

She proceeds to the storage cooler and observes the HACCP coordinator watching the QC personnel perform monitoring, recording the monitoring check, reviewing the Product Temperature Log, and signing the record.

- h. What is your determination regarding compliance based on what she has seen?

4. As part of the Secondary Inhibitors-Not Shelf Stable HACCP verification task, the IPP reviews the HACCP plan to verify that it contains on-going verification procedures and frequencies.

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

- a. How does the IPP proceed with performing the Secondary Inhibitors-Not Shelf Stable HACCP verification task?
- b. What questions will the IPP ask when verifying the verification requirement? Is there noncompliance?

Recordkeeping

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

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

IPP may use the recordkeeping and review and observation components to verify the establishment complies with the recordkeeping regulations. In most instances, they only use the recordkeeping component of the HACCP verification task when they are verifying the recordkeeping requirements. IPP must use the review and observation component to verify that establishment employees make an entry on the record at the time the specific event occurs (record authenticity).

There are several regulations that pertain to **HACCP recordkeeping practices**. The table below summarizes the recordkeeping regulatory requirements.

HACCP Recordkeeping Requirements

Regulatory Recordkeeping Requirement
Recordkeeping system 417.2(c)(6)
HACCP Records 417.5(a)(3)
Record Authenticity 417.5(b)
Computerized Records 417.5(d)
Record Retention 417.5(e)(1) and (2)
Official Review of Records/Plans 417.5(f)

Now let's go into more detail about each requirement as they relate to HACCP plans. These regulations will be covered in **Sections A-F** as follows.

A. Recordkeeping System

The regulatory requirement for a recordkeeping system is:

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

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

Gather information by asking questions

In performing the tasks, IPP should seek the answer to the following questions:

1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?
2. Do the records contain actual values and observations obtained during monitoring?

Assess the information

To verify that the establishment is in compliance with this regulation, IPP should review the following:

- HACCP plan
- HACCP monitoring records

Reviewing the HACCP Plan for the Recordkeeping System Requirement

In reviewing the HACCP plan for compliance with 417.2(c)(6), IPP should verify that it lists the records that will be used to document the monitoring of critical control points.

Recordkeeping Example 1:

HACCP plan: raw boneless skinless chicken breasts					
CCP #	Critical Limits	Monitoring Procedures & Frequencies	HACCP Records	Verification Procedures & Frequencies	Corrective Actions
//////					
2 Chilling	Product temperature not to exceed 40 degrees F	QC personnel will record temperature every 4 hours	Product Temperature Log Thermometer Calibration log	HACCP Coordinator will review the Product Temperature Log and observe QC personnel performing monitoring once per shift	Corrective actions shall meet all requirements of Part 417.3(a)

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

Reviewing HACCP Records for the Recordkeeping System Requirement

When reviewing the HACCP records for compliance with 417.2(c)(6), IPP should verify that it contains the actual values and observations that were obtained during the monitoring of critical control points.

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

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

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the recordkeeping system requirement, they must determine regulatory compliance. If they find that the establishment has met all regulatory requirements for §417.2(c)(6), then there is no regulatory noncompliance. If they find that the establishment has not met all §417.2(c)(6) regulatory requirements, there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with the Recordkeeping System Requirement

The following are examples of noncompliance with 417.2(c)(6).

Noncompliance Example 1: *An IPP is reviewing the HACCP monitoring log for the stabilization CCP in a sliced turkey bologna establishment and finds that monitoring personnel are placing a check mark on Chilling Log instead of the actual thermometer reading as specified in the HACCP plan. **The monitoring personnel are not recording actual values as required in 417.2(c)(6).***

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

B. HACCP Records Requirement

The regulatory requirement for HACCP records is:

9 CFR 417.5(a)(3)—*The establishment shall maintain: Records documenting the monitoring of CCP and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*

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

The thought process IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When reviewing HACCP records for compliance with 417.5(a)(3), IPP should seek the answer to the following questions:

1. Do the records document the monitoring of CCP and their critical limits?
2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?
3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date each record was made?
4. Are the verification procedures and results of those procedures documented?
5. Is the time recorded when the verification activity was performed?
6. Does the record contain the date the record was made?
7. Are the process-monitoring calibration procedures and results being recorded?

Assess the information

To answer these questions, IPP should review:

- HACCP records that document monitoring and verification procedures for CCP and their critical limits
- Documentation of corrective actions taken in response to a deviation from a critical limit, a deviation not covered by a critical limit, or an unforeseen hazard.

When reviewing the HACCP records for compliance with 417.5(a)(3), IPP will verify that the records document the monitoring of CCP and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan and verification procedures and results.

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

Antimicrobial Intervention Log

Date	Lot No.	Time	Solution Conc.	Pressure	Corrective Actions	Monitored by	Verified by *
2-1-2012	1	0730	2.2%	30psi	-	TDM	PP
<i>*direct observation verification-results as per HACCP plan</i>							

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

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

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

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

Recordkeeping Example 6: The IPP is performing the Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task in a smoked bacon operation and is verifying the recordkeeping requirement 417.5(a)(3) at the cooling CCP. The IPP selects the process-monitoring calibration records to review and finds that the establishment personnel have made the following entries:

*Thermometer Calibration Log
Calibrate to 32° F in slush ice water*

Date	Time	Area	Thermometer ID	Personal Thermometer Reading	Adjustment Required	Initials	Comments
2-1-2012	0800	Belly Chilling	2A	32	No	TDM	

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

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the HACCP records requirement, they must determine regulatory compliance. If they find that the establishment has met all regulatory requirements for §417.5(a)(3), then there is no regulatory noncompliance. If they find that the establishment has

not met all regulatory requirements for §417.5(a)(3), there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with the HACCP Records Requirement

One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.5(a)(3):

- Establishment monitoring records do not document all monitoring activities or do not include actual times, temperatures, or other quantifiable values.
- Establishment verification records do not document all verification activities or do not include the results of verification procedures.
- Establishment corrective action records do not document all corrective actions performed by the establishment.

Note: When IPP observe that records are missing, they are to carefully consider whether the record is missing because the establishment employee failed to perform the specified activity or because the employee failed to make the appropriate record entry. If they determine that the employee failed to perform the specified procedure (monitoring, verification, or corrective action), they are to document noncompliance with the applicable regulation (9 CFR 417.2(c)(4), 417.4(a), or 417.3, respectively) rather than 9 CFR 417.5(a)(3). When a deviation from a critical limit occurs, the establishment must implement the corrective actions specified in the HACCP plan. The regulation that applies to the corrective actions will be discussed in a later section.

- Establishment HACCP records (including pre-shipment review) do not include product names, product codes, or other identifying information sufficient to demonstrate which specific production is covered by a particular record.

The following are examples of noncompliance with 417.5(a)(3):

Noncompliance Example 3: An IPP is reviewing the monitoring records for the poultry TSP antimicrobial spray CCP and he finds there is no record of a monitoring procedure being performed in the last 3 hours. The HACCP plan specifies that monitoring at this CCP will take place on an hourly basis. He asks the establishment about these missing records. They provide a signed statement from the monitor stating that the monitoring took place, and that the results were within critical limits, but that the monitor neglected to write this on the record at the time it was done. The IPP concludes that the monitoring took place but it was

not recorded. **The records do not have the monitoring results recorded.**

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

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

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

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

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

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

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

C. Records Authenticity

The regulatory requirement for record authenticity is:

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

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

The thought process IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying that the establishment is in compliance with this requirement, IPP should seek the answer to these questions:

1. Was each entry on the record made at the time the event occurred?
2. Does each entry include the time?
3. Was each entry on the record signed or initialed by the establishment employee making the entry?
4. Does each record include the date?

Assess the information

IPP will review: HACCP records documenting monitoring, verification activities, and corrective action.

When reviewing the HACCP records for compliance with 417.5(b), IPP should verify that each record entry is made at the time the event occurred and includes

the time as part of the entry. In addition, they should verify that the record was signed and initialed by the establishment employee making the entry.

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

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the HACCP record authenticity requirement, they must determine regulatory compliance. If they find that the establishment has met all regulatory requirements for §417.5(b), then there is no regulatory noncompliance. If they find that the establishment has not met all regulatory requirements for §417.5(b), there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with HACCP Record Authenticity

One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.5(b):

- Establishment employees do not make entries in HACCP records at the time that specific events occur.

Note: Some establishments may choose to record HACCP results on “scratch paper” or a “note pad” and then transfer the results to a clean record at a later time (significantly after the event occurred). This practice is allowed, but the initial “scratch paper or note pad” record needs to meet HACCP recordkeeping requirements and must be retained as an official HACCP record. Scratch paper or note pad used during a monitoring procedure is not a HACCP record when the data is transcribed to the

HACCP record immediately when the employee finishes taking the measurements.

- Establishment records do not clearly state the date and time when each entry was made

Note: The establishment may elect not to enter a date or time for every separate entry in the HACCP record when they make several entries at the same time or on the same date. This practice is acceptable as long as the IPP is able to determine the time and date when each entry was made. For example, an establishment may place a single date at the top of a record to cover all entries made during that day.

- Establishment employees do not sign or initial their entries in HACCP records.

The following is an example of noncompliance with 417.5(b):

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

Incoming trimmings log			Critical limit = 38 F or lower			Date: 2-8-12	
Truck ID	Truck condition	Combo ID	Source	Tracking #	Temp	Time	Monitor initials
138	A	-981	Bexel	380001	34	4:56 am	JP
138	A	-982	Bexel	380002	34	5:05 am	JP
8526	B	-020	Donfort	380003	36	7:20 am	GM
8526	B	-021	Donfort	380004	✓		

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

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

D. Computerized Records

The regulatory requirement for computerized records is:

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

Electronic signatures are different from the digitized signature used for signing a credit card purchase. An electronic signature, or digital signature, uses computer technology to ensure the security of records or messages. The person making the record or message uses an electronic “code” to identify himself or herself. The computer, using an electronic “key,” de-codes the record or message. This endorses the identity of the user.

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

The thought process IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying this requirement, IPP should seek the answer to this question:

Are appropriate controls provided to ensure integrity of electronic data and signatures?

Assess the information

To obtain answers to this question, IPP would review the computerized recordkeeping system.

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

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the computerized records requirement, they must determine regulatory compliance. If they find that the establishment has met all regulatory requirements for §417.5(d), then there is no regulatory noncompliance. If they find that the establishment has not met all regulatory requirements for §417.5(d), there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with the Computerized HACCP Records Requirement

The following are examples of noncompliance with 417.5(d):

Noncompliance Example 11: *The establishment uses a computer-based system to monitor and record the temperatures in all processing rooms, coolers, and chillers. The IPP requests information about the controls that the establishment has in place to ensure the integrity of the record. The establishment manager provides him with a record showing that all of the establishment's employees can access the records without any restriction. The IPP asks the establishment manager if the establishment has any controls in place to ensure that record integrity is not compromised and the establishment manager replies, "No one will do anything to the records that will never happen".*

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

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

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

E. Record Retention

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

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

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

The thought process IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

IPP should seek the answer to the following questions.

1. Are the records being maintained for the required amount of time, i.e., 1 year for slaughter and refrigerated products and 2 years for frozen products?
2. Are the records kept on-site for 6 months?
3. If the records are stored off-site after 6 months, can they be retrieved within 24 hours?

Note: Only the HACCP records set out in 9 CFR 417.5(a)(3) may be stored off-site after 6 months. Prerequisite program records and other supporting documentation must be maintained and stored at the establishment.

Assess the information

IPP should verify that the records are being maintained the required amount of time by reviewing **HACCP records**.

If IPP suspect that records stored off-site are not being maintained for the required amount of time, they should contact the Frontline Supervisor for instructions. IPP might request records stored off-site one time to ensure they can be provided, but it would not be necessary for the IPP to routinely request records that are stored off-site to verify this requirement.

Recordkeeping Example 9: *On January 10, 2012 at 1:30 pm, the IPP performed the Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task in a small bacon processing establishment. The establishment has 2 critical control points: CCP 1 to monitor the critical limit of the amount of sodium nitrite added to the formulation, and CCP 2 for the storage temperature of final product. As part of the procedure, the IPP verified the establishment's compliance with the records maintenance requirements. She asked the establishment to provide her with CCP 1 and CCP 2 monitoring, verification, and corrective action records for February 6th of 2011 and November 10th of 2011. The establishment provided her with November's records and informed her that February's records are stored off-site. February's records were provided to the IPP on January 11th at 8.00 am.*

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the records retention and availability requirement, they must determine regulatory compliance. If they find that the establishment has met all regulatory requirements for §417.5(e)(1) and (2), then there is no regulatory noncompliance. If they find that the establishment has not met all regulatory requirements for §417.5(e)(1) and (2), there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with Records Retention and Availability

One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.5(e)(1) and (2):

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

The following are examples of noncompliance with 417.5(e)(1) and (2):

Noncompliance Example 13: *In October, the IPP asks the establishment to provide a sample of the fecal CCP monitoring log records from last January. They give him a folder that contains February's records. He asks the*

establishment about January's records and they tell him they had to clean out the files because they were getting too full. The establishment cannot produce January's records. **The establishment is not maintaining records for the required length of time.**

Noncompliance Example 14: In October, the IPP is reviewing the establishment HACCP records for the Lm sampling component of the post-lethality treatment CCP in a large deli product establishment. She suspects the establishment is not maintaining testing records on-site. She discusses this with her frontline supervisor and then she asks the establishment for the records from May. They tell the IPP that they can give her the records for the past month but they will have to retrieve any other month's records from the corporate headquarters 500 miles away. **The records are not being maintained on-site for 6 months.**

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

F. Official Review Records

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

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

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

The thought process IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying this requirement IPP should seek the answer to this question:

Are all records, plans, and procedures required by Part 417 available for official review?

Assess the information

To obtain the answer to this question, IPP would request HACCP records, HACCP plans, hazard analyses, and supporting documentation including prerequisite programs and records from the establishment.

Some establishments keep their HACCP plans, HACCP records, and other official records in secured areas (locked cabinets or offices). In these cases, IICs are to work with establishment management to develop a method for an establishment employee to provide access to the secured area upon request. IPP are to follow any such established procedure when requesting access to records. IPP only request those records normally required to perform their verification duties. They are not to test the establishment by requesting additional records.

IPP are to contact their supervisor if the establishment **will not** make HACCP plans, HACCP records, or supporting documents available for review.

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

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the availability records requirement, they must determine regulatory compliance. If they find that the establishment has met all regulatory requirements for §417.5(f), then there is no regulatory noncompliance. If they find that the establishment has not met all regulatory requirements for §417.5(f), there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with Official Review of Records

The following are examples of noncompliance with 417.5(f)

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

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

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

Records Misrepresentation

A HACCP system will not work unless consistent, reliable records are generated during the plan's operation. The availability of well-maintained records that contain objective, relevant data, reflecting actual operating conditions benefits **both** industry and regulatory officials. The legitimacy of these records is extremely important.

FSIS views recordkeeping as a serious matter with potentially grave implications if records are falsified or not properly maintained. When enforcement action is required, it is important to distinguish between unintentional (one time or sporadic) errors or isolated cases of sloppy recordkeeping, and errors that reveal a pattern of noncompliance with the procedure or plan, willful errors or omissions, or intentional misinformation. As IPP become familiar with establishment records, and how they appear under ordinary circumstances, they should be able to distinguish between unintentional and willful errors, omissions, and intentional misrepresentation.

When deliberate misrepresentation of records is suspected, IPP should **not** discuss the situation with an establishment employee. They should notify the IIC and document the findings in a memorandum to the files—**not on an NR**. The IIC should use a secure method (email or a telephone off-premises if necessary) to inform the District Office. FSIS does not consider the telephone in the Government office and cellular phones to be secure. The District Manager will provide instructions for further action. If the IIC is not available, the inspector should use a secure method to notify the District Office and follow the District Manager's instructions.

Note: IPP are to follow their chain of command when reporting record misrepresentation to the District Office.

Workshop: Recordkeeping

Refer to the handout to complete the following questions.

1. What recordkeeping requirement must be verified using the review and observation component?

2. **Case Study.** An IPP is verifying the recordkeeping requirement at the pre-visceration antimicrobial rinse CCP as part of the Slaughter HACCP verification task. He reviews the monitoring record for the CCP, which follows.

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

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

- b. What should he do next?

3. How soon, after the monitoring and verification activities, do the results have to be recorded on the establishment records? What is the regulatory reference for this?

4. Evaluate the record below.

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

- a. Is there any noncompliance with recordkeeping requirements here?

- b. If so, what is the regulatory reference?

5. **Case Study.** An IPP is verifying the recordkeeping requirement as part of a Slaughter HACCP verification task and has decided to review the poultry reprocessing slaughter food safety standard CCP. According to the HACCP plan, the frequency for monitoring is hourly and the frequency for direct observation and record review verifications is daily. The shift runs from 0600-1430 with a 30-minute lunch from 1100-1130. The critical limit for the CCP is zero. Evaluate the following record.

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

- a. Do you see any obvious noncompliance with this record? If so, list what it is and give the regulatory references?

- b. Based on what you have observed, could there be more noncompliance? If so, list what it is and give the regulatory references?
- c. What should the IPP do next, if anything?
6. While performing the recordkeeping component of the Heated Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task at a smoked pork chop establishment, the IPP is verifying the record retention requirement. The establishment has been producing this product for two years. The QC Manager gives the IPP a thick file and says that it contains all the HACCP records that the establishment has for these products. The IPP looks at yesterday's record (January 29, 2012), which is on top. The IPP looks through the records in the folder and notes that the oldest date is for June 30, 2011. Is there noncompliance?

Supporting Documentation- Prerequisite Programs and Other Supporting Programs

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

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

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

The establishment is required to maintain documentation to support the decisions in the hazard analysis 9 CFR 417.5(a) (1). If the establishment uses prerequisite programs or other measures to support a decision that a particular hazard is not reasonably likely to occur, **the records of the ongoing implementation of those prerequisite programs or measures is part of the supporting documentation required by 9 CFR 417.5(a)(1).**

9 CFR 417.5(f) requires that all records required under 9 CFR 417 be available for official review by FSIS inspection personnel. IPP are to contact their supervisor if the establishment **will not** make prerequisite programs, prerequisite program records, or other supporting documents available for review.

The thought process IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Prerequisite Program, GMPs or SOPs

Based on the regulatory requirements of 9 CFR 417.2(a)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request, including records from a prerequisite program. IPP should be aware of all monitoring and testing conducted by the establishment and should ask establishment management to share the data that is generated by this monitoring and testing. IPP review this data while performing the HACCP verification task and Review Establishment Data task (refer to FSIS Directive 5000.2) when verifying the requirement for supporting documentation.

When reviewing records, results, and supporting documentation associated with testing, monitoring, and verification activities that are from procedures or prerequisite programs outside the HACCP plan, IPP should determine if the records generated from these programs continue to support the decisions made in the establishment's hazard analysis that the hazard is not reasonably likely to occur in the process. They should also verify that if there is information in the records that requires the establishment to reevaluate or reassess its HACCP plan, the establishment has conducted the reassessment.

Verifying prerequisite programs

When an establishment references a prerequisite program in its hazard analysis as supporting documentation that a food safety hazard is not likely to occur, verify that the establishment:

1. has written procedures that set out the design of the prerequisite program;

Note: There is no regulatory requirement that the prerequisite program has to be written. However, if the program is not written, the establishment would probably not be able to support the decision the hazard is not reasonably likely to occur. (Exceptions: If the establishment addresses the removal, segregation and disposal of SRMs using a prerequisite program, the measures it implements to segregate and dispose of them must be written as stated in 9 CFR 310.22). If the establishment uses the Sanitation SOP to support a decision that a hazard is not reasonably likely to occur, the procedure will be in the written Sanitation SOP.

2. is executing the program as designed, and
3. has evidence that the program is being executed as designed and continues to support decisions made in the hazard analysis (e.g., information on suppliers' interventions, test results from suppliers, results from its own testing, or documents regarding the on-going effectiveness of the program).

Unlike with HACCP plans, IPP **do not** verify compliance with specific regulatory requirements for such activities as monitoring, verification, and recordkeeping. For instance, there are no specific regulations that address monitoring activities or recordkeeping practices for prerequisite programs. Hence, an occasional missed measurement, or failures to initial entries on records, failures to enter the time on records, or a missing entry on the record would not represent noncompliance or would not necessarily mean the prerequisite program is not being implemented effectively. Minor deviations from executing the prerequisite program usually would not create a food safety concern or necessitate action on the product, whereas deviations from the critical limit in a HACCP plan would cause food safety concerns and generally require action on the affected product.

By means of records review and observations, and discussions with the establishment at the weekly meeting, IPP should focus on:

1. the overall program to verify that the establishment:
 - a. implements the procedures as set out in the program's design?
 - b. maintains records to support the implementation of the program, including verification records and results from outside auditors?
 - c. evaluates the implementation of the program?
 - d. has a means to correct implementation problems?
2. any problems that indicate that the prerequisite program may no longer be supporting the decision made in the hazard analysis that a hazard is not likely to occur, and consider questions such as:
 - a. are elements of the program not being implemented?
 - b. are adjustments made to the programs when necessary?
 - c. do the same implementation problems continue to reoccur?
 - d. are there numerous or recurrent mistakes made in the implementation of the program?

Gather information by asking questions

IPP are to verify that establishment employees are implementing the procedures in the prerequisite program and the records generated by the prerequisite program continue to demonstrate that the relevant hazard is not reasonably likely to occur. IPP should seek the answer to the following questions:

1. Is the establishment implementing the procedures in the program as written?
2. Does the establishment maintain records to support the implementation of the program including verification records and results from outside auditors?
3. Do the records show that the prerequisite program continues to support the decision that the relevant hazard is not reasonably likely to occur on an ongoing basis?

Assess the information

To answer these questions, IPP should:

- Review the establishment's hazard analysis,
- Review the records generated by the prerequisite program, and
- Observe establishment employees implementing the procedures in the prerequisite program.

Now let's review each of these activities in detail.

Reviewing the Hazard Analysis

When reviewing the hazard analysis, IPP determine if the establishment uses a prerequisite program or other supporting program to support a decision that a particular hazard is not reasonably likely to occur.

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

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

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

Reviewing Prerequisite Program Records

For each prerequisite program or other program the establishment uses to support a decision that a hazard is not reasonably likely to occur, IPP are to review the records generated by the program for the specific production selected to determine if they continue to support the decision that that the relevant hazard is not reasonably likely to occur on an ongoing basis.

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

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

Note: IPP should discuss the less-than-perfect implementation of prerequisite programs or other supporting programs with establishment management at the weekly meeting. The establishment's response should be documented in the Memorandum of Interview (MOI) the IPP gives to the establishment.

Observing Establishment Employees

For each prerequisite program or other program the establishment uses to support a decision that a hazard is not reasonably likely to occur, IPP are to observe an establishment employee performing the procedures listed in the program to determine if the procedures are being carried out as written in the program.

Prerequisite Program Example 2b: Continuing with example 2a above, the IPP is in the production room and notices that an establishment employee is going to take the last product temperature of the shift at the grinding step. He stops to observe the employee taking the measurement. The establishment employee measures the product temperature as written in the program and documents the

result. The IPP decides to observe the temperature result that the employee recorded. The product temperature result is 40°F and the time of the measurement is recorded. Based on these observations, he determines that the establishment is in compliance with 9 CFR 417.5(a)(1) because it is implementing the program in a manner that supports the hazard analysis decision and the records generated from the program show that relevant hazard is not reasonably likely to occur on an ongoing basis.

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the supporting documentation requirement, they must determine regulatory compliance. There are **three possible outcomes** when verifying whether the on-going implementation of a prerequisite program and the records generated from the program continue to support the decision that a particular hazard is not reasonably likely to occur.

1. Compliance
2. Noncompliance
3. Inability to determine compliance because more information is needed

If IPP find that the establishment has met all verification regulatory requirements, then there is no regulatory noncompliance. If they find that the establishment has clearly not met all supporting documentation regulatory requirements, there is noncompliance.

When IPP determine that there is not enough information available to determine whether the establishment complies with 9 CFR §417.5(a) (1), they should notify establishment management. This provides the establishment with an opportunity to support the decisions made, or to reassess the hazard analysis and make decisions that it can support. After allowing the establishment the opportunity to provide additional support, if IPP are still uncertain whether the implementation of the prerequisite program and the records generated from a prerequisite program support the decisions in the hazard analysis, they are to discuss the issue with their supervisor.

If IPP have concerns about the **design** of the procedures or programs an establishment is using to support decisions in the hazard analysis, they should contact the Policy Development Division (PDD) or an EIAO through supervisory channels. EIAOs conduct comprehensive food safety assessments in establishments to verify that the design of the food safety systems in operation meet regulatory requirements.

Noncompliance with the Supporting Documentation Requirement When Using a Prerequisite Program or Other Supporting Program

One or more of the following findings evidence that the establishment has not met the requirement of 9 CFR 417.5(a) (1):

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

The following are examples of noncompliance with the supporting documentation requirement.

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

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

The establishment will have 5 SRM removal stations.

- *Station one (located in the kill floor next to the head inspection area): the establishment's trained employee will remove the palatine and the lingual tonsils from the head and the tongue.*
- *Station two (located in the auger room): the establishment's trained employee will remove the brain by a suction apparatus and dispose the skull in the marked SRM containers.*
- *Station three (located in the kill floor after the viscera inspection): The entire intestine including the distal ileum will be condemned and disposed in the marked SRM containers.*
- *Station four (located on the kill floor before the final trim rail): the spinal cord will be removed entirely by specified marked tools (orange handle).*
- *Station five (located in the boning room): the vertebral column will be removed by specified marked tools (orange handle) and disposed of in the marked SRM containers.*

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

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

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

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

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

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

The IPP asked the establishment manger to provide her with all prerequisite program records for the past 5 days. The manager provided her with the following records informing her that these are all the records that he has.

Pre requisite program form A					
Date	Station #	Time	finding	Corrective actions	signature
01-01-2012	1	6 am	No finding	N/A	JOHN SMITH
01-01-2012	1	11.30 am			
01-01-2012	2	6.30 am			
01-01-2012	2	12.30 pm			
01-01-2012	3	7.00 am	No finding		JOHN SMITH
01-01-2012	3	1.00 pm			
01-01-2012	4	7.30 am			
01-01-2012	4	1.30 am			
01-01-2012	5	8.00 am			
01-01-2012	5	2.00 pm	No finding		JOHN SMITH

Pre requisite program form A					
Date	Station #	Time	finding	Corrective actions	signature
01-05-2012	1	6 am	No finding	N/A	JOHN SMITH
01-05-2012	1	11.30 am			
01-05-2012	2	6.30 am			
01-05-2012	2	12.30 pm			
01-05-2012	3	7.00 am	No finding	N/A	JOHN SMITH
01-05-2012	3	1.00 pm			
01-05-2012	4	7.30 am			
01-05-2012	4	1.30 am			
01-05-2012	5	8.00 am			
01-05-2012	5	2.00 pm			

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

because the establishment has failed to implement its procedures for removal of SRMs. The IPP decided to discuss this noncompliance with her supervisor to identify further enforcement actions.

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

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

Workshop: Supporting Documentation- Prerequisite Programs and Other Supporting Programs

Refer to the handout to complete the following questions.

1. An IPP is performing the Raw Non-Intact HACCP verification task, he reviews the hazard analysis and finds that the establishment implements a prerequisite program for metal detection to support the decision they made in the hazard analysis that the physical hazard/metal (broken needles) is not reasonably likely to occur. He reviews the metal detection program and finds that the establishment maintains a daily record of the metal detection results. He asks the establishment manager to provide him with the prerequisite program record for the day the specific production was produced. The establishment manager could not produce the record. Thus, the IPP asks him for the metal detection records from the previous 4 working days. The establishment manager could only provide the IPP with a record from one day stating, "These are all of the records I have".
 - a. Is there any noncompliance with the support documentation recordkeeping requirements in this scenario?

 - b. What should he do next?

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

 - b. What should she do next?

Corrective Actions

Before we elaborate on the corrective action requirements, let's review the difference between a deviation from a critical limit and a HACCP noncompliance.

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

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

When IPP verify HACCP implementation, they are to verify that establishments meet the corrective action requirements whenever an event occurs that requires corrective action. For instance, whenever IPP determine through their own observations or through the review establishment records (e.g. monitoring records) that a deviation from a critical limit or other unforeseen hazard has occurred, they are to verify that the establishment implements corrective actions that meet the regulatory requirements. IPP verify that corrective action requirements are met while performing the HACCP verification task. If necessary, IPP are to initiate a directed HACCP verification task to document their verification of corrective action requirements when a routine HACCP verification task is not available (e.g., all of the routine tasks have either been scheduled or already performed for the month).

Note: IPP may not be able to verify corrective action requirements during a routine HACCP verification task if no corrective action is required for that specific production.

A. Corrective Actions in Response to a Deviation from a Critical Limit

When a deviation from a critical limit occurs, the establishment must implement the corrective actions specified in the HACCP plan. The regulation that applies to corrective actions taken in response to a deviation from a critical limit is:

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

The thought process that IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

To verify compliance with the corrective action regulatory requirements, IPP should seek the answer to the following questions:

1. Did the establishment identify and eliminate the cause of the deviation?
2. Did the corrective actions ensure that the CCP is brought under control?
3. Were measures implemented to prevent recurrence of the deviation?
4. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?

Assess the information

When seeking answer to these questions, the IPP should:

- Observe the establishment executing the corrective actions.
- Review the corrective action records associated with the deviation from the critical limit.
- Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(a) to determine whether the corrective actions taken by the establishment in response to the deviation from the critical limit meet the requirements.

Now let's have a look at each of these in more detail.

Observing the Establishment Execute Corrective Actions

In observing the establishment executing corrective actions, the IPP should verify that the appropriate affected product has been identified.

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

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

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

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

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

a new SOP for removing the machine from the area during wet cleanup. Based on these observations, he determines that the establishment has identified and eliminated the cause of the deviation.

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

Corrective Action Example 1, Part 3: *Continuing with the above example, the IPP continues to observe the establishment's actions in the production area. The establishment brings in a replacement unit for the metal detector. The packaging line supervisor checks the replacement unit with the seeded sample, and the equipment responds appropriately. The IPP observes production resume. The packaging line supervisor notifies him that they will perform the monitoring checks at an increased frequency of once per hour for one week. Based on these observations, he determines that the establishment has the CCP under control.*

He would observe the execution of corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce.

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

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

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

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

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

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

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

- Other establishment HACCP monitoring or verification records,
- SSOP records,

- Establishment testing results, and
- The records of any related prerequisite programs.

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

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

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

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

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

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

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

Corrective Action Example 2, Part 5 - verifying 417.3(a)(4): *Continuing with example 2, the establishment has held and segregated the affected product, and provided a processing authority with its cooling data points (time/temperature combinations) for the deviation. The processing authority has plotted the data into a pathogen-modeling program and used other scientific literature to determine that there would be no outgrowth of *Clostridium botulinum* and no more than one log increase in *Clostridium perfringens*, based on the cooling*

curve that the product experienced. The report from the processing authority, which indicates that the product is safe for distribution, is attached to the corrective action log. The IPP determines that the establishment has prevented product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce. The IPP determines that the requirements for 417.3(a) have been met. The IPP verifies all the regulatory requirements at all CCPs for that specific production, determines that the establishment has carried out the pre-shipment review for that particular specific production, and records the results in PHIS as a directed Fully Cooked-Not Shelf Stable HACCP verification task.

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

Reviewing the Corrective Action Records

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

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

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the corrective action requirement, they must determine regulatory compliance. If they find that the establishment has met all corrective action regulatory requirements in 9 CFR 417.3(a), then there is no regulatory noncompliance. When IPP document compliance with the corrective action requirement, they are to briefly describe their observations that support a finding of compliance as described in FSIS PHIS Directive 5000.1. If they find that the establishment has not met all corrective action regulatory requirements, there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with the Corrective Action Requirements

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

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

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

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

*“TSP concentration control dial was increased to 9% at 0805. Chlorine in the chiller was increased from 20 to 40 ppm and the post-chill chlorinated rinse cabinets were turned on at 0810.” These actions are consistent with the corrective actions regulations but she finds no documentation and observes no evidence that the establishment attempted to **identify the cause of the deviation from the critical limit.***

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

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

after the actions were taken.

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

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

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

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

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

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

Note: Remember; anytime there is a deviation from a critical limit, the IPP will verify that the corrective actions taken by the establishment meet the requirements of the regulation. In addition, the IPP will verify the establishment's support when product is retreated with critical operating parameters different from the ones stated in the HACCP plan and determine whether they are

effective in controlling or preventing the relevant hazard. For instance, in the noncompliance example above, there is a potential issue with increased bacterial resistance to heat if the original heat treatment did not destroy the target microorganism.

IPP are to take regulatory control action to prevent adulterated product from entering commerce when it becomes apparent that the establishment intends to release product but cannot demonstrate that it is not adulterated. For example, if the establishment signs the pre-shipment review before performing necessary corrective actions. Once the establishment has signed pre-shipment review, FSIS considers the product to be in commerce. IPP are to retain the affected product before it leaves the establishment if they find evidence that the establishment's intended actions would result in adulterated product entering commerce.

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

B. Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action, or an Unforeseen Hazard

The regulation that applies when a deviation not covered by a specific corrective action or an unforeseen hazard occurs is:

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

The thought process IPP should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

IPP should answer the following questions to determine whether the corrective action requirements have been met:

1. Did the establishment segregate and hold **all** affected product?
2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?
3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce?
4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?

Assess the information

When seeking answer to these questions, the IPP should:

- Review the corrective action records associated with the deviation not covered by a specific corrective action or unforeseen hazard and observe the establishment executing the corrective actions.
- Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(b) (1) and (2) (3)(4) to determine whether the corrective actions taken in response to the deviation from the critical limit meets all of these requirements.
- Observe the establishment segregating and holding the affected product to verify that the establishment segregated and held **all** affected product.
- Observe the establishment evaluating the affected product to verify that only acceptable product is released.
- Review the corrective action records; determine if a reassessment was performed.

Now let's look at each of these in more detail.

Reviewing the Corrective Action Records

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

Corrective Action Example 3, Part 1: *An IPP is performing the Slaughter HACCP verification task in a poultry slaughter establishment. She finds that an event has occurred earlier in the shift, in which the establishment monitoring personnel found metal shavings on the carcasses exiting from the chill system. The establishment decided that the metal would constitute a food safety hazard. The establishment has no CCP for metal contaminants in the chill system. She reviews the corrective action log dated 2-1-2012 and finds the following entry for this incident:*

All carcasses exiting the chill system held by QA in vats and placed in the cooler. Carcasses were visually examined by production personnel for the presence of metal. Metal shavings were removed from affected carcasses. All carcasses will be deboned and resulting product run through a metal detector system. The HACCP plan will be reassessed by 2-3-2012. Based upon her review of the records, she determines that the recorded actions meet the requirements of 417.3(b).

Observing the Establishment Execute Corrective Actions

She would observe the establishment executing corrective actions to verify that all affected product is segregated and held.

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

She would observe the establishment evaluating the affected product to verify that only acceptable product is released.

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

Determine if a Reassessment was Performed and Documented

IPP verify that establishments perform a reassessment when an unforeseen hazard occurs (9 CFR 417.3(b)(4)), provide supporting documentation for decisions made during the reassessment (9 CFR 417.5(a)(1)), and make a record of the reassessment by documenting 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 (9 CFR 417.4(a)(3)(ii)) while performing the directed HACCP verification task.

Note: IPP are to verify the reassessment requirement as part of the HAV task. However, if during the performance of the HACCP verification task, IPP discover that the establishment performed a reassessment that is not documented in accordance with 9 CFR 417.4(a)(3)(ii), IPP are to document the noncompliance under the HACCP verification task being performed if a HAV task is not being performed.

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

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

Note: She would also verify the support for the decisions in the HACCP plan during the directed HACCP verification task performed as a result of the unforeseen hazard, e.g., the documentation the establishment receives from its supplier stating what antimicrobial treatment is applied to the trimmings that are received, and the specified reduction in the number of pathogens achieved,

documentation for the selection and placement of the CCP and the support for monitoring and verification procedures and frequencies at the receiving CCP, etc.

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the corrective action requirement, they must determine regulatory compliance. If they find that the establishment has met all corrective action regulatory requirements in 9 CFR 417.3(b), then there is no regulatory noncompliance. When IPP document compliance with the corrective action requirement, they are to briefly describe their observations that support a finding of compliance as described in FSIS PHIS Directive 5000.1. If they find that the establishment has not met all regulatory requirements for corrective action, there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance with the Corrective Action Requirements

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

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

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

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

Noncompliance Example 1, Part 2: If the personnel collecting the birds coming out of the chill system had misunderstood which chiller was affected and held

product from the wrong chill system, the establishment would have **held product but it would not be the affected product**.

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

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

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

Noncompliance Example 2: *An IPP is performing the Raw Non-Intact HACCP verification task in a small beef grinding operation and he is verifying the establishment recordkeeping requirements for all CCPs. He reviews a recent corrective action log that documents a large fecal smear observed on the boneless bull meat chucks as they were being prepared for grinding. Currently, the establishment does not have a CCP for visual observation of raw materials. Under preventive measures on the corrective action log, “none needed” is recorded. He asks whether they considered this an unforeseen hazard, and whether they performed a reassessment of the hazard analysis and HACCP plan. The QC manager replies, “No, because this was the only time we’ve observed this.” **A deviation not covered by a specific corrective action or an unforeseen hazard occurred, and a reassessment was not conducted.***

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

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

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

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

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

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

Workshop: Corrective Action

Refer to the handout to complete the following questions.

1. An IPP is reviewing a HACCP record and observes that a result of 3% is recorded as a monitoring check. The critical limit at this CCP is “at least 6%.”
 - a. At this point in the review, is this a deviation from a critical limit and/or a HACCP noncompliance?

 - b. Continuing with the above, if the establishment’s records indicate that **all** corrective actions met the requirements of 417.3(a), is there a HACCP noncompliance?

2. The HACCP plan specifies that the CCP for product temperature will be monitored by checking product at three locations in the cooler each hour, and recording all results. An IPP reviews the temperature log and observes that at each monitoring check there are only two temperatures recorded. All results are within critical limits.
 - a. Based only on the information given, is this a deviation from a critical limit, an unforeseen hazard, or a HACCP noncompliance?

 - b. Would the IPP expect to see all corrective actions in section 417.3(a) taken for this situation? Please explain.

3. An IPP is making observations in the poultry boning room, when she observes that there is a commotion among employees at the automatic breast deboning equipment. Investigating, she observes that a full set of viscera has been hung up on the equipment, and intestinal contents are spread all over. The employees shut off the line. Because she reviewed the HACCP plan this morning, she realizes that there is no CCP that addresses this situation.
 - a. Which regulation would apply in this situation?

- b. At this point, is there a HACCP noncompliance?
- c. What should the IPP do next?

The IPP observes the employees gather all of the chicken breasts from the area, put them into inedible containers, and begin cleaning up. She returns to her other duties, and later she goes to the QA office and asks for documentation of the actions taken.

HACCP CORRECTIVE ACTION OR UNFORESEEN HAZARD REPORT		XYZ Corporation
Date: 1-2-2012		
Product and amount affected: 397 lbs chicken breasts		
Describe the unforeseen hazard, including cause: <i>At 8:30 am viscera present in box of breasts got onto equipment causing major contamination. We stopped the line, disposed of product and did a full cleanup AB 8:50 am.</i>		
Describe how the affected product was segregated and held: <i>All product from line or near line disposed of as inedible AB 8:50 am.</i>		
Describe how the product was reviewed to determine acceptability for distribution: <i>In addition, we did a visual inspection of all product that we had not yet run from that lot, and reinspected a sample of the product already produced. No other defects found AB 9:15 am.</i>		
Describe measures taken to prevent a reoccurrence and/or to eliminate the cause: <i>Production employees were instructed to observe dumping of raw materials more closely. We have contacted the supplying establishment and their written reply attached. The next load of product from that supplier will be given 100 % reinspection before use CD 2:00 pm.</i>		
State whether HACCP plan reassessed, conclusions, and any changes: <i>Yes, hazard analysis done, no changes to the HACCP plan. A new SOP for supplier certification/acceptability added for purchasing/receiving CD 3:00 pm 1-3-12.</i>		
<u>Adel Brezil</u> 1-3-12 Plant Management, date	<u>Craig Darrow</u> 1-3-12 QA Manager, date	Example: For Training Use Only

- d. Do the establishment's recorded corrective actions meet all of the corrective action regulatory requirements?
- e. What else should the IPP do in this situation?

4. An IPP has recently rotated assignments and his new patrol includes a pork fabrication operation. Today's schedule includes the Raw Non-Intact HACCP verification task. He observes that there is a metal detector in use on the pork cuts before they enter the tenderizer injector. He reviews the HACCP plan and hazard analysis, and he sees that the hazard analysis identifies metal, but finds it is not likely to occur. The HACCP plan does not have a CCP for metal detection.

What might the IPP conclude at this point?

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

HACCP CORRECTIVE ACTION OR UNFORESEEN HAZARD REPORT		<u>IJK Corporation</u>
Date: 3-2-12		
Product and amount affected: <i>25 lb boneless pork loin</i>		
Describe the unforeseen hazard, including cause: <i>At 9:00 am the metal detector rejected product, which was carefully examined by QC, what looks like a syringe needle was found EF 10:05 am.</i>		
Describe how the affected product was segregated and held: <i>We disposed of the piece as inedible EF 10:05 am</i>		
Describe how the product was reviewed to determine acceptability for distribution: <i>All product from that same load was run back through the metal detector but nothing else was found EF 1:00 pm.</i>		
Describe measures taken to prevent a reoccurrence and/or to eliminate the cause: <i>We have contacted the supplying establishment XYZ and notified them that if it happens again we will no longer purchase from that supplier GH 11:00 am.</i>		
State whether HACCP plan reassessed, conclusions, and any changes: <i>Yes. Established a new CCP for metal detection. See new version of HACCP plan, dated 3-2-12 GH 1:00 pm.</i>		
<u>Eric Fazoli</u> 3-2-12 Plant Management, date	<u>Gerry Harroldson</u> 3-2-12 QA Manager, date	Example: For Training Use Only

b. Did the establishment meet corrective action requirements?

c. Is there a HACCP noncompliance?

d. What else should the IPP do?

5. Read each of the following statements and then summarize in your own words what the HACCP noncompliance is. What regulation would you cite on the NR?
- a. The HACCP plan lists a monitoring procedure for the temperature of the hot water pasteurization spray as “visual checking the temperature gauge three times per shift.” The critical limit is 180° F or above. The IPP reviews the monitoring log.

Hot Water Pasteurization Spray, critical limit 180° F or above			Date: 1-2-12
Time	Temp	Monitor	Comments
6:45 am	182	OP	
9:30 am	175	OP	
12:00	183	OP	

The IPP asks the monitor whether any corrective actions were done after the second check and the reply is “none.” She asks for the associated corrective action log and is told that there is none. What is the noncompliance and the regulatory reference?

- b. The HACCP plan has a monitoring procedure for measuring internal product temperature of fresh pork sausage chubs. The IPP reviews the temperature log and observe a deviation recorded. He reviews the associated corrective action log and finds that the establishment recorded the cause of the deviation, eliminated the cause, and ensured that the CCP was in control before continuing production. His review also reveals that the establishment implemented an effective preventive measure. The corrective action report does not contain any record of what was done with the product that was produced while the critical limit was out of control. He reviews shipping records and observes that the product has been distributed. The establishment cannot produce any further records to demonstrate the safety of this product. What is the noncompliance and the regulatory reference?

6. The results of a sample of sliced turkey ham the establishment sent to the lab for analysis was positive for *Salmonella*. The sampled lot of product was placed on hold pending laboratory analysis. The establishment evaluated the product for acceptability for distribution and determined to recook it. It performed a reassessment of the HACCP plan. That is the information the IPP observed recorded in the corrective action log as part of a directed Fully Cooked-Not Shelf Stable HACCP verification task he or she performed as a result of learning about the positive result. Does this meet the requirements of 417.3(b)? Explain your answer.

Pre-Shipment Review Requirement

The regulatory requirement for pre-shipment review is:

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

The purpose of a pre-shipment review is to ensure that adulterated product is not released into commerce. Therefore, the establishment must review the records associated with the production of specific product to ensure completeness, including the determination that all critical limits were met, and if appropriate, corrective actions were taken, including proper disposition of the product. To meet 9 CFR 417.5(c), the establishment's pre-shipment review must include the review of **all** records, including any prerequisite program and disposition records, used to determine whether the product is safe and not adulterated.

Establishments have a lot of flexibility in how they conduct the pre-shipment review. For instance, establishments can perform the review of their records in stages and by multiple employees. They are not required to gather all the records together and review them all at once prior to shipping the product in commerce. The establishment has the responsibility to evaluate its production and recordkeeping systems to determine how the review of the applicable records will be accomplished during the pre-shipment review procedure.

Note: When IPP have submitted a finished product sample to an FSIS lab to be tested for an adulterant, the establishment cannot complete the pre-shipment review until negative results are received. In addition, the establishment would not meet 9 CFR 417.5(c) if it completed the pre-shipment review before receiving test results for adulterants from samples it has submitted to its own lab. The establishment could review all the applicable records that are available, hold or control the product until acceptable test results are received from its lab, then perform the final review and release the product.

There is no regulatory requirement for an establishment to conduct a pre-shipment review when the product moves from one process category to another in same establishment, e.g., carcasses from the slaughter process moving to further processing (cut-up or boning).

FSIS considers product to be **“produced and shipped”** when the establishment completes the pre-shipment review even if the product is still at the

establishment. Verifying that the establishment has completed the pre-shipment review enables IPP to know whether the company has taken full and final responsibility for applying its HACCP system controls to the product that it has produced.

When IPP verify the establishment's implementation of its HACCP system, they are to review the records for the specific production to verify that the establishment has conducted the pre-shipment review in accordance with 9 CFR 417.5(c). Occasionally, when IPP perform the HACCP verification task, they are to observe the establishment employee performing the pre-shipment review procedure using the review and observation component of the task. The inspector in charge (IIC) determines how often (the frequency) IPP are to verify 9 CFR 417.5(c) using review and observation in a multiple inspector establishment. The front line supervisor (FLS) determines how often IPP use review and observation to verify 9 CFR 417.5(c) in a single inspector assignment.

IPP should understand that the pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the **control** of the producing establishment.

The thought process that IPP should use when verifying regulatory requirements includes:

- gathering information
- assessing the information; and
- Determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

IPP should seek the answer to the following questions:

1. Has the establishment reviewed all the records associated with the production of the product, including any prerequisite program records that are part of the HACCP system, prior to shipment?

Note: Some prerequisite programs may not apply to a specific production. In addition, most procedures in the Sanitation SOP are not associated with a specific lot of product. If a prerequisite program or the Sanitation SOP procedure is not product specific and does not have a bearing on whether product is adulterated, the establishment does not need to review the records associated with program or Sanitation SOP as part of pre-shipment review. However, if the prerequisite program or Sanitation SOP procedure is associated with a

specific lot of product (e.g., test results for adulterants) establishments need to review the prerequisite program and Sanitation SOP records when conducting pre-shipment review. IPP are to be aware of the establishment's HACCP system associated with the production of a specific product so that they can understand which programs are part of the HACCP system and which bear on the determination whether product is adulterated

2. Has the pre-shipment review been signed and dated by an establishment employee?

Assess the information

To answer these questions, the IPP should review the pre-shipment review records.

Pre-shipment Review Compliance Example: An IPP is performing the Slaughter HACCP verification task in a poultry slaughter establishment, and verifying the establishment's compliance with the pre-shipment review requirement. The IPP has already observed that the establishment performs pre-shipment review by looking at and signing and dating each CCP record and prerequisite program records associated with a shift's production. The establishment has two CCPs (final wash and carcass chilling) and 3 prerequisite programs: chiller chlorine program, antimicrobial online reprocessing program, and a salmonella testing program. The IPP reviews the Sanova antimicrobial rinse CCP log and the chilling CCP log from yesterday's shift and finds that all the results were entered, no corrective action was needed, and the establishment's QC supervisor had signed and dated at the bottom of the record. He also reviews the 3 prerequisite program records and finds the same results. Based on his observations; he determines that the establishment is in compliance with 9 CFR 417.5(c).

Determine Compliance

After IPP have gathered and assessed all available information pertaining to the pre-shipment review requirement, they must determine regulatory compliance. If the IPP finds that the establishment has met all pre-shipment review regulatory requirements in 9 CFR 417.5(c), then there is no regulatory noncompliance. If the IPP finds that the establishment has not met all regulatory requirements for pre-shipment review, there is noncompliance. More information about making compliance determinations is provided in another section of the training.

Noncompliance examples with Pre-Shipment Review Requirement 417.5(c)

One or more of the following findings evidence that the establishment does not comply with 9 CFR 417.5(c):

- The establishment ships product in commerce without performing a pre-shipment review.
- The establishment transports product to another location prior to pre-shipment review and cannot demonstrate that it maintains control of the product.
- An establishment employee does not sign and date the pre-shipment review.
- An establishment employee does not review the appropriate HACCP records associated with the production covered by the pre-shipment review. The appropriate HACCP records typically include the records of any monitoring activities, verification activities, corrective actions and records from prerequisite programs that are part of the HACCP system that were created during the production period covered by the pre-shipment review.

If IPP find that the establishment employees failed to review a prerequisite program or SSOP record associated with the production of a specific product during the pre-shipment review and electronically or manually signed and dated the pre-shipment review, they are to issue an NR citing **both** 9 CFR 417.5 (a)(1) and 417.5(c) as the regulations with which the establishment failed to comply.

IPP are to determine noncompliance with 9 CFR 417.5(a) (3) if the pre-shipment review records do not identify the specific production to which they apply (e.g., product codes, lot codes, product name, and production periods)

The following are examples of noncompliance with 417.5(c).

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

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

*noncompliance with 417.5(c) **AND** 417.5(a)(1) and documents the noncompliance in PHIS.*

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

Note: If a noncompliance trend is occurring because an establishment does not review its prerequisite programs as part of the pre-shipment review, IPP are to discuss the issue with their immediate supervisor and determine whether a further review is necessary by an Enforcement Investigation and Analysis Officer.

Workshop: Pre-shipment Review

Refer to the handout to complete the following questions.

1. The establishment must accomplish the pre-shipment review prior to the specific production leaving the physical premises. True or False?

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

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

Summary – Verifying the HACCP Regulatory Requirements

Table 1 below summarizes the Steps that IPP perform during the HACCP verification task. **Table 2** and **Table 3** on the following pages provide a quick reference for the questions that IPP should seek answers to when verifying each of the HACCP Implementation regulatory requirements.

Table 1
HACCP Verification Task Summary

Step 1: Select Product Type and Specific Production	Select product type within the process category	Ensure all product types within process category are verified over time.
	Select specific production.	Select product type that the est. is currently producing.
	Verify all HACCP regulatory requirements at each CCP by following Steps 3-9	
Step 2: Review the HACCP Plan for the Selected Product Type	Understand the monitoring and verification procedures and frequencies	
	Note the most recent signature date (must be entered into PHIS)	417.2(d)
	Note changes to the HACCP plan and update the establishment profile	
Step 3: Verify Monitoring	Per Directive 5000.1	417.2(c)(4)
Step 4: Verify Verification	Per Directive 5000.1	417.2(c)(7), 417.4(a)(2)(i)(ii)(iii)
Step 5: Verify Recordkeeping	Per Directive 5000.1	417.2(c)(6), 417.5(a)(3), 417.5(b), 417.5(d), 417.5(e)(1), 417.5(e)(2), 417.5(f)-Note: contact supervisor if records are not made available
Step 6: Verify Implementation of Prerequisite program (PRP)/Other Control Measures Used to Support Hazards Not Reasonably Likely to Occur (NRLTO)	Per Directive 5000.1	417.5(a)(1)
	Review PRP records for the specific production, Observe program implementation, Verify implemented as written, and Verify records continue to support decision that hazard is NRLTO	Contact supervisor if records are not made available per 417.5(f)
	Consider whether implemented in a manner that supports the Hazard Analysis decisions	
	Contact supervisor if uncertain whether implementation or records support the decision in the Hazard Analysis	
Step 7: Verify Corrective Action (CA)	Per Directive 5000.1 Initiate a directed HACCP verification task to verify CA when no routine HACCP verification task is available	417.5(c), 417.3(a), 417.3(b)
Step 8: Verify Pre-shipment Review	Per Directive 5000.1	417.5(c)
Step 9: Consider the Implications of any noncompliance	Document findings of compliance and noncompliance. Associate any previous noncompliances. Use systems based thinking per Directive 5000.1	417.6

If IPP find that adulterated product may have entered commerce, they are to notify the DO personnel through supervisory channels immediately.

Table 2—Monitoring, Verification, and Recordkeeping Requirements

Step 3 Monitoring	Step 4 Verification	Step 5 Recordkeeping
<p><u>9CFR 417.2(c)(4)</u></p> <p>1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCP to ensure compliance with the critical limits?</p> <p>2. Are the monitoring procedures being performed as described in the HACCP plan?</p> <p>3. Are the monitoring procedures being performed at the frequencies for the CCP listed in the HACCP plan?</p> <p>4. Are the CL met?</p>	<p><u>9CFR 417.2(c)(7) 417.4(a)(2)(i)(ii)(iii)</u></p> <p>1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?</p> <p>2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities & corrective actions?</p> <p>3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?</p> <p>4. Does the HACCP plan list product sampling as a verification activity?</p> <p>5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?</p> <p>6. Are direct observation verification activities conducted as per the HACCP plan?</p> <p>7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?</p>	<p><u>Recordkeeping Requirement – 9CFR 417.2(c)(6)</u></p> <p>1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?</p> <p>2. Do the records contain actual values & observations obtained during monitoring?</p> <p><u>HACCP Records Requirement – 9CFR 417.5(a)(3)</u></p> <p>1. Do the records document the monitoring of CCP and critical limits?</p> <p>2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment’s HACCP plan?</p> <p>3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date each record was made?</p> <p>4. Are verification procedures and results documented?</p> <p>5. Is the time recorded when the verification activity was performed?</p> <p>6. Does the record contain the date the record was made?</p> <p>7. Are process-monitoring calibration procedures & results recorded?</p> <p><u>Records Authenticity Requirement – 9CFR 417.5(b)</u></p> <p>1. Was each entry on the record made at the time the event occurred?</p> <p>2. Does each entry include the time?</p> <p>3. Was each entry on the record signed or initialed by the establishment employee making the entry?</p> <p>4. Does each record include the date?</p> <p><u>Computerized Records Requirement – 9CFR 417.5(d)</u></p> <p>Are appropriate controls provided to ensure integrity of electronic data and signatures?</p> <p><u>Record Retention and Availability Requirement – 9CFR 417.5(e)(1) and (2)</u></p> <p>1. Are the records being maintained for the required amount of time, i.e., one year for slaughter and refrigerated products and two years for frozen, preserved, or shelf-stable products?</p> <p>2. Are the records kept on-site for 6 months?</p> <p>3. If the records are stored off-site, can they be retrieved in 24 hours?</p> <p><u>Official Review of Records – 9 CFR 417.5(f)</u></p> <p>Are all records, plans, and procedures required by Part 417 available for official review?</p>

Table 3- Prerequisite Program Implementation, Corrective Action, Pre-shipment Review Requirements, and System Thinking

<p>Step 6 Prerequisite Program Implementation</p>	<p>Step 7 Corrective Actions</p>	<p>Step 8 Pre-shipment Review</p>
<p><u>Supporting Documentation Requirement – 9 CFR 417.5(a)</u>¹</p> <p>1. Is the establishment implementing the procedures in the program as written?</p> <p>2. Does the establishment maintain records to support the implementation of the program, including verification records and results from outside auditors?</p> <p>3. Do the records show that the prerequisite program continues to support the decision that the relevant hazard is not reasonably likely to occur on an ongoing basis</p>	<p><u>Corrective actions in response to a deviation from a critical limit – 9 CFR 417.3(a)</u></p> <p>1. Did the establishment identify and eliminate the cause of the deviation?</p> <p>2. Did the corrective actions ensure that the CCP is brought under control?</p> <p>3. Were measures implemented to prevent recurrence of the deviation?</p> <p>4. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?</p> <p><u>Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action or an Unforeseen Hazard – 9CFR 417.3(b)</u></p> <p>1. Did the establishment segregate and hold all affected product?</p> <p>2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?</p> <p>3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce?</p> <p>4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?</p>	<p><u>Pre-shipment Review Requirement – 417.5(c)</u></p> <p>1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?</p> <p>2. Has the pre-shipment review been signed and dated by an establishment employee?</p> <hr/> <p>Step 9 Consider the Implications of any noncompliance and Document</p> <p>1. Is there a pattern of repeated failure to implement the HACCP procedures as written?</p> <p>2. Is there reason to believe that the establishment's food safety system is not effectively preventing or controlling the applicable food safety hazards?</p> <p>3. Has product been prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or rendered injurious to health?</p> <p>4. Has the establishment produced adulterated products or shipped adulterated products in commerce?</p>

Note: The Corrective Action requirement is verified at **each occurrence**. For example, when the IPP is performing the HACCP verification task and the IPP notices that the establishment had a deviation from a critical limit, the IPP would verify that the corrective action requirements had been met.

FSIS Verification

The IPP performs the HACCP verification task by verifying **all** requirements **at all CCPs for a specific production**, including the pre-shipment review. The HACCP implementation requirements verified at each CCP include monitoring, verification, recordkeeping, and corrective action. Furthermore, when establishments implement prerequisite programs or other supporting program to support the decision that a hazard is not reasonably likely to occur, they are verified as part of the recordkeeping requirement. The pre-shipment review is also part of the recordkeeping requirement. The IPP may use either component or both components when performing the HACCP verification task.

To perform the HACCP verification task, the IPP will:

1. Select the product type and specific production; review the HACCP plan for the selected product type
2. Verify that all four HACCP implementation requirements have been met for all CCPs in the HACCP plan for that specific production. The IPP must understand what the establishment has defined as their specific production that will be shipped.
3. Verify the pre-shipment review requirement for that specific production is met. The IPP must observe at least once how the establishment meets the requirements in §417.5(c) prior to being able to properly perform the HACCP verification task.
4. Observe the records reviewed by the establishment during its defined pre-shipment review process to determine if all the relevant records reviewed associated with that specific production meet the regulatory requirements.

Corrective Actions are verified as part of the HACCP verification task at **each** occurrence.

Example: *The IPP is performing the Secondary Inhibitors-Not Shelf Stable HACCP verification task and proceeds to verify all the requirements at all the CCPs for a lot of Westphalian hams. The establishment has three CCPs, one at drying, one at smoking, and one at storage. The IPP seeks to answer the questions in **Table 2 and 3** to ensure that all the HACCP regulatory requirements have been met for all the CCPs. The establishment has a prerequisite program at the receiving step to inhibit growth of pathogen. The IPP decides to use the recordkeeping component at the drying and smoking CCPs. For the storage temperature CCP, the IPP decides to use the review and observation component since there has been some inconsistency in the cooler temperatures lately. The IPP proceeds to check the records of the prerequisite program at the receiving step to see if the operational parameters have been met. After that, the IPP goes*

to the storage area to take a temperature measurement and compare it to the continuous recording thermometer (process monitoring instrument). The IPP also checks the records at this CCP to verify that the results meet the regulatory requirements. There have been no corrective actions associated with this lot of product so the IPP cannot verify this requirement. Later in the shift, the IPP goes to the QA office to check records to determine whether the establishment has carried out the pre-shipment review for that particular lot.

Implications of any Noncompliance in PHIS – HAV and HACCP Verification Tasks

As discussed throughout this module, IPP are to verify HACCP regulatory requirements by performing the HACCP verification tasks that appear on the establishment's task list. The HACCP verification tasks will appear on the establishment's inspection task list according to the specific HACCP process categories (listed in 9 CFR 417.2(b)) entered in the establishment profile in PHIS. IPP are also to initiate directed HACCP verification tasks when they observe noncompliance (sometimes referred to as stumble-on situation) or are instructed to do so by their supervisor.

When IPP complete the HACCP verification task, they are to document their findings of compliance or noncompliance in accordance with FSIS PHIS Directive 5000.1 – Chapter V. If IPP cannot complete the whole HACCP verification task in one day, they are to enter partial findings in PHIS and then complete the task later.

In addition to documenting any findings of noncompliance, IPP are to consider all their findings in the context of the establishment's food safety system. IPP are to think about the broader implications of their findings regardless of whether they identify specific regulatory noncompliance. Documenting individual regulatory noncompliances is important, but to protect public health, IPP are also to identify those establishments where vulnerabilities in the food safety system may result in increased food safety risks.

IPP are to consider the following questions:

1. Are there potential shortcomings in the establishment's decisions regarding hazards that are reasonably likely to occur in its production process?
2. Is there a pattern of repeated failure to implement the HACCP procedures as written?

3. Is there reason to believe that the establishment's food safety system is not effectively preventing or controlling the applicable food safety hazards?
4. Has product been prepared, packed, or held under insanitary conditions where it may have become contaminated with filth or rendered injurious to health?
5. Has the establishment produced adulterated products or shipped adulterated products in commerce?
6. Do the establishment's records show any pattern or trend of increasing microbial levels or provide any other indication of an increasing potential for failure of the food safety system or product adulteration?

IPP also consider whether their findings indicate systemic or ongoing problems with the establishment's food safety system, and whether those problems could result in the establishment producing adulterated or misbranded products. If IPP have concerns that there may be systemic problems with the establishment's food safety system, or there is reason to believe that product may have become adulterated, IPP are to bring the issues to the attention of their supervisor immediately.

Food Safety Systems Thinking Workshop

General Instructions

Work through this workshop as a group. Select a group leader. The leader should monitor the time and focus of the group, and ensure the discussion involves each member of the group. Answer the workshop questions.

Description of the Establishment's Production Process and Scenario

You are Phyllis Isaacs, the GS-12 PHV IIC, assigned to Novosibar Poultry INC, which is a 4-line SIS (Streamline Inspection System) poultry slaughter and processing establishment. The establishment slaughters on two shifts and processes approximately 260,000 young chickens a day. The chickens have an average weight of 4.5 lbs. The establishment implements a prerequisite program for on-line reprocessing and uses a post evisceration Syntrx antimicrobial rinse prior to the chiller.

In addition to whole birds and giblets, the establishment produces tray packs of wings, drums, thighs, chicken breasts, and tenders. After packaging, the boxed product is shipped under refrigeration to wholesale and retail outlets.

Shortly after operations started, an inspector on line 2 requests that you look at a couple of birds she had the helper take off the line. You notice a couple of small black specks on the legs of the carcasses. After you question this inspector, and all of the other on-line inspectors, you observe some carcasses and determine that the presence of the black specks is infrequent occurrence, isolated to line two, and that the bird washers further down the line seem to be removing the specks.

1. At this point, what do you conclude from your findings?

Several hours later, one of the GS-08 floor inspectors informs you that he found "several small smearable black specks" on four of the ten birds from line 2 while performing a pre-chill Finished Products Standard (FPS) test. He determined that this substance appeared to be falling off of the rails and onto the carcasses. He also informs you that the FPS test passed and therefore the establishment did not seem to be worried about the black specks. Moments later, the other GS-08 floor inspector informs you that the line inspectors on line 2 had informed her that "the birds were covered with a powdery black substance" and that they wanted to see you.

You proceed to the slaughter floor to investigate the line inspectors' concern. You observe several carcasses and determine that approximately 45% of them have varying degrees of a powdery, smearable black substance on them. You look up at the rails and notice a build-up of this same substance on the rails and the chain's trolley wheels.

2. Based on your findings, are there components of the establishment's food safety system that you think need to be evaluated/reviewed/verified? If so, what components and why would you want to review or verify them?

3. Would you take any action based on the above findings? If so, what type of action? If there is regulatory support for your action, please identify the regulations.

At this point, you review the establishment's FPS and SSOP records:

- The pre-chill and post-chill FPS records show higher than normal levels of extraneous material.
- Today's pre-operational SSOP record document the sanitation crew's effort to reduce some minor rust build-up on the line 2 rail by foaming it with an approved cleaner, rinsing it with water and then having the maintenance department apply an approved oil lubricant to the rail.
- Today's operational SSOP record has two entries that state that there has a problem with a black powdery build-up on the rails and trolley wheels and that "this same substance was falling onto the carcasses." The record also states that the establishment "wiped the rails with rags soaked in a lubricant" during breaks in production. The last entry indicated that the establishment planned to perform a more thorough wiping of the rail at lunch (which was still

9 CFR Part 417--Hazard Analysis and Critical Control Point (HACCP) Systems

Sections:

- 417.1 Definitions.
- 417.2 Hazard Analysis and HACCP plan.
- 417.3 Corrective actions.
- 417.4 Validation, Verification, Reassessment.
- 417.5 Records.
- 417.6 Inadequate HACCP Systems.
- 417.7 Training.
- 417.8 Agency verification.

Sec. 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action - Procedures to be followed when a deviation occurs.

Critical control point - A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit- The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard- Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System- The HACCP plan in operation, including the HACCP plan itself.

Hazard - SEE Food Safety Hazard.

Preventive measure - Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument - An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official-The individual with overall authority on-site or a higher level official of the establishment.

Sec. 417.2 Hazard Analysis and HACCP Plan.

(a) *Hazard analysis.* (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 processed, in the absence of those controls.

(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.

(3) Food safety hazards might be expected to arise from the following:

- (i) Natural toxins;
- (ii) Microbiological contamination;
- (iii) Chemical contamination;
- (iv) Pesticides;
- (v) Drug residues;
- (vi) Zoonotic diseases;
- (vii) Decomposition;
- (viii) Parasites;
- (ix) Unapproved use of direct or indirect food or color additives; and
- (x) Physical hazards.

(b) *The HACCP plan.* (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

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

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter

pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

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

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under Sec. 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Sec. 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Sec. 417.4(a)(2)(iii) and the recordkeeping requirements of Sec. 417.5 of this part.

Sec. 417.4 Validation, Verification, Reassessment.

(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.

(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 CCPs, 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.

(2) *Ongoing verification activities.* Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) *Reassessment of the HACCP plan.* (i) 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.

(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; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Sec. 417.5 Records.

- (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:
- (1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;
 - (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.
 - (3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.
- (b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and includes the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.
- (c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.
- (d) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) *Record retention.* (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

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

Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

- (a) The HACCP plan in operation does not meet the requirements set forth in this part;
- (b) Establishment personnel are not performing tasks specified in the HACCP plan;
- (c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;
- (d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or
- (e) Adulterated product is produced or shipped.

Sec. 417.7 Training.

(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 Sec. 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 Sec. 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Sec. 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
- (b) Reviewing the CCP records;

- (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
- (d) Reviewing the critical limits;
- (e) Reviewing other records pertaining to the HACCP plan or system;
- (f) Direct observation or measurement at a CCP;
- (g) Sample collection and analysis to determine the product meets all safety standards; and
- (h) On-site observations and record review.

9 CFR PART 418—RECALLS

Sections:

418.1 [Reserved]

418.2 Notification.

418.3 Preparation and maintenance of written recall procedures.

418.4 Records.

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 418.1 [Reserved]

§ 418.2 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

§ 418.4 Records.

All records, including records documenting procedures required by this part, must be available for official review and copying.