REGULATORY PROCESS FOR 01 AND 02 PROCEDURES

In the remainder of this document, we will cover the regulatory process for HACCP procedures in raw processes by following the blocks as depicted by the **diagram** on the next page. There are four main processes that we will cover.

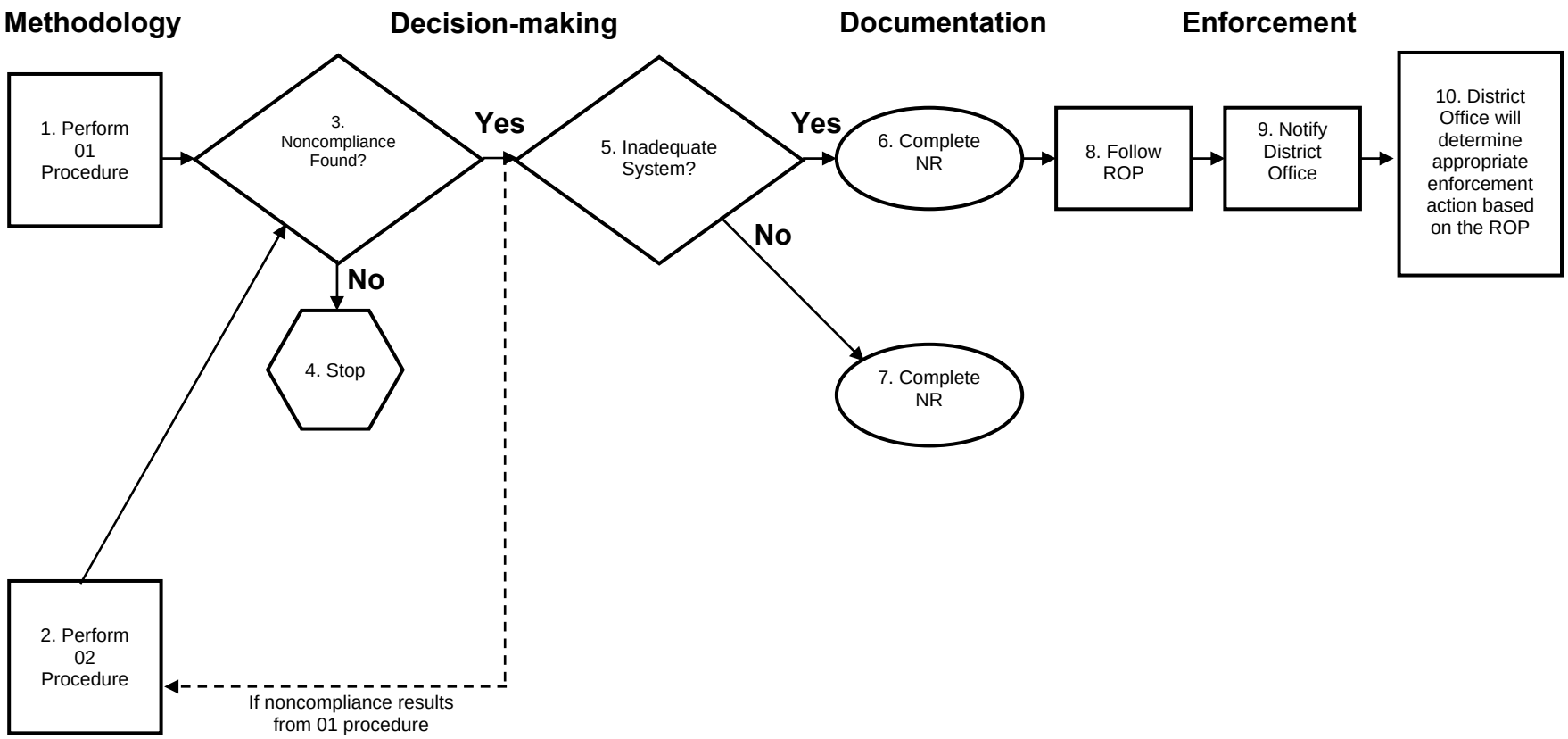
- **Methodology**
- **Decision-making**
- **Documentation**
- **Enforcement**

FSIS Responsibilities

FSIS responsibilities are outlined in **FSIS Directive 5000.1.** You are responsible for understanding and properly performing the procedures as described in this Directive. The information in the Directive follows the regulatory process. The Directive is the foundation for the remainder of this training.

Let's review what is covered in the directive for HACCP verification. This includes verification methodology, which is the HACCP 01 and 02 procedures. Next is a discussion of how to perform verification of the establishment's hazard analysis. Then, the Directive covers how to perform verification of the monitoring, verification, recordkeeping, corrective action and reassessment requirements

Regulatory Process for HACCP 01 and 02 Procedures in 03B - J



Verification Methodology (Blocks 1 & 2)

Perform 01 or 02 Procedure

HACCP 01 and 02 procedures are performed by FSIS personnel to verify that establishments are complying with Part 417. You will focus on the execution or implementation of the HACCP plan when performing your verification procedures.

The Five Regulatory Requirements

There are five 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**
5. **Reassessment**

You will use the 01 and 02 procedures to verify that the establishment complies with these five regulatory requirements.

01 and 02 HACCP Procedures

The 01 and 02 HACCP procedures are performed by inspection personnel to verify ongoing compliance with the regulatory requirements of 9 CFR Part 417 as the establishment executes its HACCP plan for the raw processing categories. The number of HACCP plans and the number of products produced within a processing category has no impact on the number of HACCP procedures that are scheduled for that process. The HACCP 01 and 02 procedures can be performed as scheduled or unscheduled procedures. Each of these procedures has two components:

- **Recordkeeping component**
- **Review and observation component**

In most instances, you will use one of these components. There may be occasions when you use both. For example, you may choose to perform recordkeeping at one CCP and review and observation at another CCP. Or, you may observe something during recordkeeping that may prompt you to perform a review and observation of that CCP.

How to Perform the Two Components

• Recordkeeping

To perform the **recordkeeping** (Rk) component you will review HACCP records to determine if the establishment recorded its tests or measurements at the required frequency, if all required data was recorded, if the data is accurate, if critical limits have been met, and if corrective action was taken when necessary. When you perform the recordkeeping component you are only reviewing records. Typically this review would take place where the records are maintained and may not be at the physical location of the CCP.

Example: *You are performing an 01 procedure and are verifying a monitoring procedure. You decide to perform the recordkeeping component. You examine the records associated with this monitoring procedure. You look at the frequency of the entries and the data recorded, and compare the recorded data to the critical limit at this step.*

• Review and Observation

To perform the **review and observation** (R&O) component you may directly observe plant employees performing the procedures as stated in the HACCP plan (observation) or you may take measurements to see if the values you obtained match those recorded by the establishment (review).

Note: When a you take a measurement, you use the calibrated instrument that the establishment uses for the monitoring or verification activities. For example, you would take a temperature at a CCP using the establishment's thermometer and not your own thermometer because your thermometer may not be calibrated properly. If you take a measurement at the CCP, you need to use the processing monitoring instrument (thermometer) as described in the HACCP plan. The issue here is the ability to show compliance/noncompliance based on the use of a accurate thermometer. If you could show (e.g., on a calibration log) that your thermometer was calibrated prior to being used to verify product temperatures, then you could use government issued thermometer.

Example: *You are performing an 01 procedure and are verifying a monitoring requirement, which in this case is a product temperature check. You decide to perform both parts of the review and observation component. You directly observe the plant employee carry out the product temperature check. Then, you take a product temperature measurement, and compare the result that you obtained to the one just recorded by the plant employee.*

01 Procedure

The 01 procedure is for verifying one or more of the HACCP regulatory requirements as the establishment executes its HACCP plan for raw processes. The 01 procedure is designed to provide a "snapshot" of the HACCP system.

There are three requirements that are **randomly** verified during the 01 procedure: monitoring, verification, and recordkeeping. Corrective Actions and reassessment are not randomly verified as part of the 01 procedure since they are performed as a result of some event that triggers them. For example, you would verify the corrective action requirements are met anytime there is a deviation from a critical limit, a deviation not covered by a specific corrective action, or an unforeseen hazard. Similarly, you would verify the reassessment requirement if the establishment significantly changes its process, or encounters an unforeseen hazard.

You must have a method to randomly select one (or more) of the three requirements to be verified during the performance of the procedure. For example, you may choose to draw pieces numbered one through three from a container. You can use your FSIS, FAIM computer to select random numbers. See appendix 1 for instructions.

*To perform the **01** procedure, you will do the following:*

1. **Randomly** select one (or more) of the three HACCP requirements to verify
2. Select a HACCP plan
3. Select one (or more) of the CCP from the HACCP plan to verify
4. Determine which component (review and observation or recordkeeping) to perform
5. Read the pertinent part of the HACCP plan
6. Perform the verification for **that requirement** for **that CCP**

***01 Example:** Your PS for today lists 03C01. The establishment to which you are assigned has one HACCP plan in this processing category, for marinated chicken. This HACCP plan has 3 CCP. You have 3 cardboard chips labeled monitoring, verification, and recordkeeping, in a coffee can in your office. You decide to pick 2 regulatory requirements to verify. You shake up the can and choose 2 chips, which turn out to be monitoring and recordkeeping. You make a note of this. You decide to verify these requirements at CCP 1 of the HACCP plan. Next you think about which component to perform, and decide to perform the recordkeeping component. You proceed to the HACCP lab to begin to perform the recordkeeping component to verify the monitoring and recordkeeping regulatory requirements at CCP 1 of the marinated chicken process.*

Note: If you determine noncompliance while performing the 01 procedure, you must then perform the 02 procedure.

02 Procedure

The 02 procedure is for verifying **all regulatory requirements** at all of the critical control points in the HACCP plan for a **specific production**. The 02 procedure cannot be completed until the establishment performs the pre-shipment review for that specific production. Because the 02 procedure is performed by examining a specific production, you are additionally determining whether the establishment prevented the distribution of adulterated product.

Note: You follow-up on any 01 procedure that results in a noncompliance determination by performing an 02 procedure on that specific production. You must link the performance of the 02 procedure to the 01 procedure that resulted in the noncompliance determination in PBIS.

Specific production is a term that is used to refer to whatever method the establishment uses to group product. FSIS does not determine the method used to define specific production, this is an establishment's responsibility. You will see a variety of different types of methods used. For example, a poultry slaughter plant might define all the birds from one house as specific production, another might define it by all carcasses produced in one hour on one line. Establishment's might define all product from one formulation batch, one shift's production, or the product in one chiller as a specific production. It is important for you to understand the method used by the establishment to which you are assigned. You can determine this by asking plant management.

There may be times when you are not able to finish reviewing the entire process on the day that the 02 procedure is begun. In this case you should mark the Procedure Schedule as "not performed" on the day that you start your review. When you have completed the review, you need to record on the Procedure Schedule that you completed the 02. If that particular 02 procedure is already scheduled on that day, then mark it according to your determination of compliance/noncompliance. If that particular 02 is not assigned on the day your review is completed, then document the 02 as unscheduled on the Procedure Schedule.

*To perform the **02** procedure, you will do the following:*

1. Verify that **all** of the HACCP requirements have been met for **all CCP** in the HACCP plan for that **specific production**.

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

***02 Example**: Your PS for today lists 03B02. This establishment has one HACCP plan in this processing category, ground beef patties. You know 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. They are not producing patties today, but they did produce them yesterday. You proceed to the HACCP office to begin your verification that all of the HACCP requirements were met for all of the CCP in the HACCP plan for yesterday's production, including the pre-shipment review. You plan to use the recordkeeping component.*

The following table summarizes the concepts we have just covered regarding the 01 and 02 HACCP procedures.

HACCP Procedures – Components Used and Requirements Verified

	COMPONENTS USED BY THE CSI	HACCP REGULATORY REQUIREMENTS VERIFIED
01	• Recordkeeping and/or • Review & Observation	**One or more** of the three regulatory requirements—randomly selected at **one or more CCP.** Corrective Action and Reassessment can be verified using 01 but not randomly.
02	• Recordkeeping and/or • Review & Observation	**All** of the regulatory requirements for **all CCP**, including the pre-shipment review for a specific production

Workshop: Verification Methodology

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

1. Which HACCP procedure is performed to verify all of the HACCP requirements for all CCP in a HACCP plan for a specific production?

2. Which HACCP procedure is performed to verify one or more of the HACCP requirements for one or more CCP in a HACCP plan?

3. What are the five HACCP requirements?

4. What are the two components of HACCP procedures (01 and 02)?

5. What is the purpose of the 01 inspection procedure for HACCP?

6. What is the purpose of the 02 inspection procedure for HACCP?

7. Why can you **not** randomly verify the corrective action and reassessment requirements?

8. When you determine noncompliance during performance of a HACCP 01 procedure, what should be triggered?

9. An establishment has one HACCP plan with 2 CCP (identified 1-2). Describe the steps in performing the HACCP 01 procedure. Then, describe the steps in performing the HACCP 02 procedure.

Verifying Compliance with the Five Regulatory Requirements

This section covers how to verify regulatory compliance and make supportable decisions when performing the HACCP 01 and 02 procedures. The requirements are monitoring, verification, recordkeeping, corrective action, and reassessment. Below is a chart with the five HACCP requirements, regulatory references, and the procedures and components utilized in verifying compliance.

Requirement	Regulatory References	Pro-cedure	Com-ponent
Monitoring	417.2(c)(4) Monitoring Requirement	01 or 02	Rk R&O
Verification	417.2(c)(7) Verification Requirement 417.4(a)(2)(i)(ii)(iii)Verification Activities	01 or 02	Rk R&O
Recordkeeping	417.2(c)(6) Recordkeeping System	01 or 02	Rk
	417.5(a)(1) and (2) Supporting Documentation	01 (02[1])	Rk
	417.5(a)(3) HACCP Records	01 or 02	Rk
	417.5(b) Records Authenticity	01 or 02	Rk R&O
	417.5(d) Computerized Records	01 or 02	Rk
	417.5(e)(1) and (2) Record Retention and Availability	01 or 02	Rk
	417.5(c) Pre-shipment Review	02	Rk R&O (on occasion)
Corrective Action	417.3(a) Deviation from a critical limit 417.3(b) Deviation not covered by a specified corrective action/unforeseen hazard	01[2] or 02	Rk R&O
Reassessment	417.3(b)(4) Deviation not covered by a specified corrective action/unforeseen hazard 417.4(a)(3) Annual Reassessment[3] or Changes in Plant Processes 417.4(b) Hazard Analysis Reassessment	01[2] or 02	Rk

[1] Product acceptability or disposition could be verified using the 02 procedure.
[2] Corrective actions and reassessment can be verified through 01 but not randomly.
[3] Annual Reassessment will be verified with the 03A01 procedure.

Regulatory References for Verifying the Five 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)(1) and (2) 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;
(2) The written HACCP plan, including decision-making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

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(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.

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.

Reassessment

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

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

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

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*

You will verify the monitoring requirement by performing the HACCP 01/02 procedures. You could use either the recordkeeping or review and observation component, or both.

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

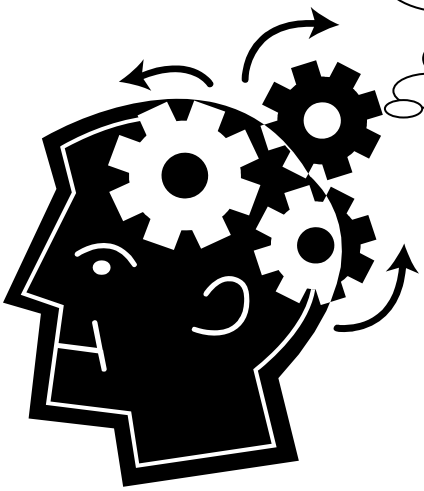
- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements. The diagrams on the following pages illustrate the thought process.

01 HACCP Procedure Methodology

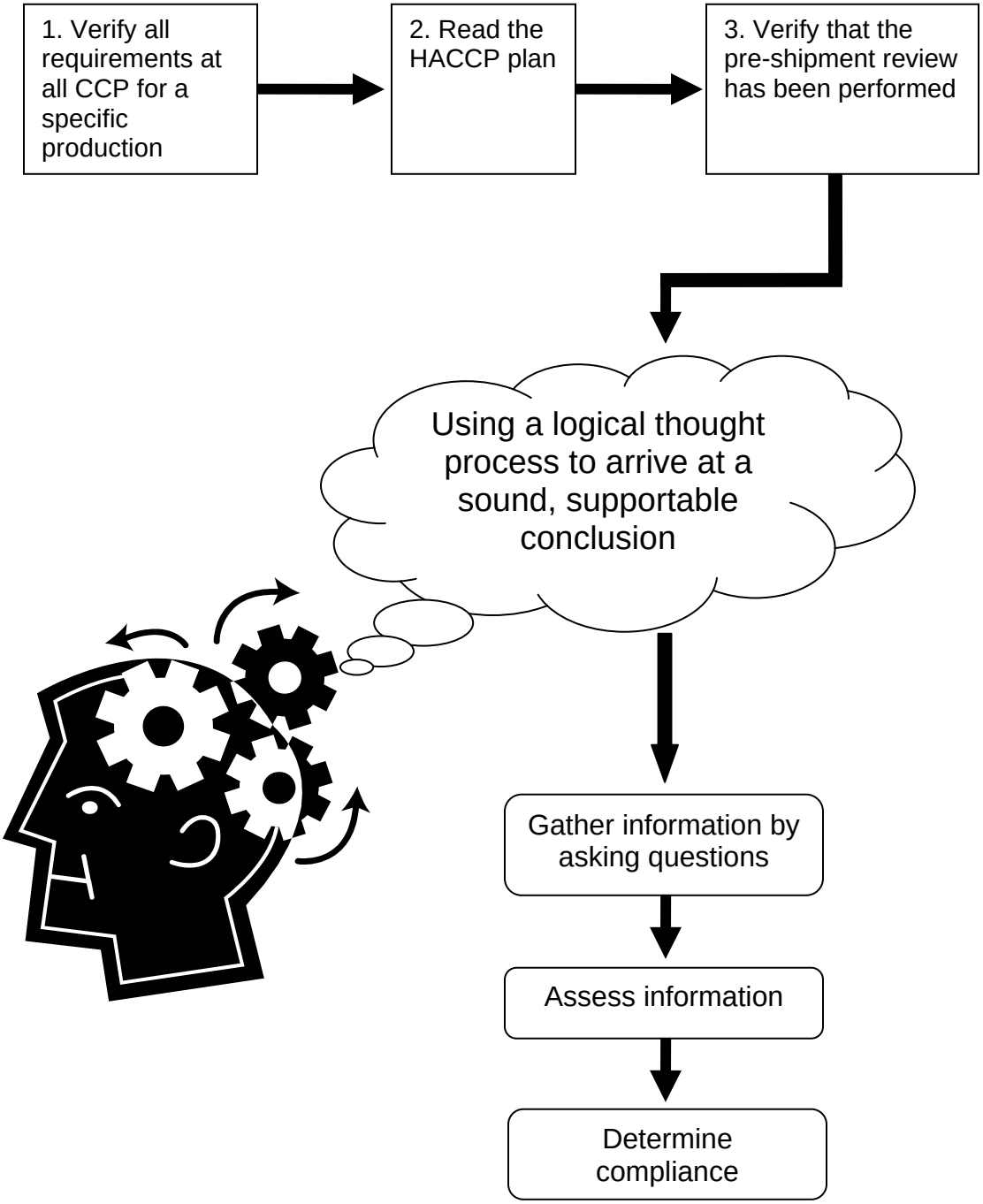
1. Randomly select the requirement to verify
2. Pick a HACCP plan
3. Select one or more CCP to verify
4. Determine which component to perform
5. Read pertinent part of the plan
6. Verify that requirement for that CCP

Using a logical thought process to arrive at a sound, supportable conclusion



- Gather information by asking questions
- Assess information
- Determine compliance

02 HACCP Procedure Methodology



Gather information by asking questions

Verify the regulatory requirements for monitoring by reviewing the HACCP plan, reviewing HACCP records, observing establishment employees performing monitoring activities, and taking measurements at CCP. When verifying the monitoring requirements, 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 CCP listed in the HACCP plan?

4. Are the critical limits met?

Assess the information

To answer these questions you 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 processes, you will determine whether it includes the monitoring procedures and frequencies that are used to monitor each critical control point. It is very important for you to be familiar with the monitoring procedures and frequencies in the current HACCP plan. You 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, you should be able to visualize what is occurring at the CCP. If you cannot visualize what is occurring at the CCP, it could be an indication that the monitoring requirement is not being met.

Monitoring Example 1*: You are performing the 03J01 procedure and have randomly selected to verify the monitoring requirements for the steam pasteurization CCP. You review the establishment's HACCP plan and find 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 your review of the plan, you decide the monitoring procedures and frequencies for this CCP are included in the HACCP plan.

Reviewing HACCP Monitoring Records

You 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 for raw processes.

Monitoring Example 2: *You are performing the 03J01 procedure and have randomly selected to verify the monitoring requirements for the steam pasteurization CCP. Reviewing the records, you find that monitoring personnel have recorded temperatures hourly as per the HACCP plan for this CCP. You determine that the establishment's monitoring recordkeeping for this CCP is in compliance.*

Observing Establishment Employees

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

Monitoring Example 3: *You are performing the 03J01 procedure and have randomly selected to verify the monitoring requirements for the steam pasteurization CCP. You observe the establishment monitoring personnel as they make the temperature determinations and document them on the records for the steam pasteurization CCP. From your observation, you determine that the establishment is in compliance with the monitoring procedure as it is described in the HACCP plan.*

Taking Measurements at Critical Control Points

You may also take measurements at certain critical control points in the raw process.

Monitoring Example 4: *Continuing the 03J01 procedure from the above example, you proceed to the temperature gauges on the steam pasteurization cabinet and take a reading. You then compare your temperature reading with the temperature that was recorded by the establishment monitoring personnel. You determine that the establishment is in compliance because your temperature reading is within the critical limits and compares with the reading as recorded by establishment monitoring personnel.*

Determine Compliance

After you have gathered and assessed all available information pertaining to the monitoring requirement, you must determine regulatory compliance. If you find that the establishment has met all monitoring regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all monitoring regulatory

requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

Noncompliance with the Monitoring Requirement

The following are examples of noncompliance with the monitoring requirement.

1. *The HACCP plan specifies that monitoring personnel will examine 20 poultry carcasses for visible fecal contamination off-line at the pre-chill inspection station every hour. While performing verification for the monitoring requirement, you observe that the procedure is being performed on-line with only 10 carcasses per hour.* ***The establishment is not conducting the monitoring procedures as specified in the HACCP plan.***

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. You review the logbook and find that the monitoring checks were recorded every 2 hours. Upon further inquiry, you determine 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.***

3. *The HACCP plan specifies that the concentration of the trisodium phosphate (TSP) rinse will be maintained at a minimum of 8 percent. You observe the concentration gauge on the TSP equipment and find that it reads 6 percent.* ***The critical limit for the CCP is not met.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Workshop: Monitoring

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

1. **Fill in the Blanks: 9 CFR 417.2(c)(4)**—List the _____, and the _____with which those _____will be performed, that will be used to _____ each of the critical control points to ensure compliance with the critical limits

2. You are assigned to a small goat slaughter establishment and are performing the 03J01 procedure. You have randomly chosen to verify the monitoring requirement for the slaughter food safety standard 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 you decide to perform the recordkeeping component in verifying the monitoring requirement, what question would you seek answers to when reviewing the HACCP plan? What would the answers to the question be?

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

Slaughter Number	Feces, ingesta, milk present? (Y or N)*	Performed by	Date: 6-8-04 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 you perform this component?

d. If you were to decide to perform the review and observation component, how would you proceed?

3. **Case Study.** You are a GS-9, Consumer Safety Inspector, assigned to Est. 00038M as the Inspector-in–Charge. Est. 00038M is a small cull beef slaughter facility with a simple processing operation. Today's PBIS schedule includes an 03J01 procedure.

You randomly select to verify that the establishment meets the regulatory requirements for monitoring. After your review of the establishment's written HACCP plan, you confirm that the slaughter process contains only one CCP, which is located in the carcass cooler. The critical limit for this CCP is zero for fecal, milk, or ingesta contamination.

You proceed to the location of the CCP in the carcass cooler and select a random sampling of beef sides. Within your random sample, you note a side of beef that has a two-inch by one-inch streak of ingesta on its left foreshank.

Answer the following questions:

a. Is there evidence of product adulteration?

b. Is there a food safety concern as a result of this situation? Why?

c. What is the regulation that relates to this?

d. What action should you take?

4. **Case Study.** You are a newly promoted GS-8, Consumer Safety Inspector, assigned to Est. 00038M, a large feedlot cattle slaughter facility. You review Est. 00038M's HACCP program for slaughter and you find that there is a designated critical control point in the carcass cooler for monitoring the temperature of carcasses during the chilling process. The establishment's monitoring procedure for this CCP states, "Carcass temperature checks are taken daily to verify that all carcasses are 40º F or below within 8 hours of slaughter processing. Measure the temperatures of five randomly selected carcasses 8 hours after the first carcasses enter the cooler. Temperatures are taken 1 mm under fascia on the inside round." Subsequently, as part of a scheduled 03J01 procedure, you choose to verify that this activity is being performed accordingly.

Later that day, you observe a quality control technician monitoring this CCP by taking temperature measurements of five selected carcasses by inserting the thermometer into the brisket muscle of each carcass. You observe and record the results of these measurements for your personal notes. The five carcass temperatures are 37º F, 39º F, 37º F, 38º F and 37º F. The QC technician records these same temperature results on the HACCP record for the CCP.

a. What is the regulation that applies to this situation?

b. Is there a deviation from the critical limit of this CCP?

c. Are the monitoring procedures being performed as described in the HACCP plan? Explain your answer.

d. Has a noncompliance occurred? If so, what type of noncompliance?

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

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

Is anything missing according to 417.2(c)(4)? If so, what?

Verification

Verification activities are tools the establishment uses to establish 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: The calibration of process-monitoring instruments; direct observations of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with §417.5(a)(3) of this part.*

You will verify the verification requirement by performing the HACCP 01/02 procedures. You could use either the recordkeeping or review and observation component, or both.

The thought process you 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

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

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

2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?

Direct observation of corrective actions is required. The plant cannot predict when a deviation from a critical limit or an unforeseen hazard will occur, so specific procedures and frequencies will probably not be 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 applicable regulatory requirements. Under the 417.4(a)(2)(ii), the establishment is to document these direct observations in the same manner that it documents other verifications.

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)?

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 direct observation verification activities conducted as per the HACCP plan?

7. Are records generated in accordance with 9 CFR 417.5(a)(3) [HACCP records] being reviewed by the establishment?

Assess the information

To answer these questions you should:

- Review the HACCP plan
- Review HACCP records
- Observe establishment employees performing verification activities

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

Reviewing HACCP Plan

When reviewing the establishment's HACCP plan for raw processes, you will 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. You should review the HACCP plan each time the verification requirement is verified since the establishment can modify the plan without notifying inspection.

Verification Example 1: *You are performing the 03J01 procedure in a poultry slaughter operation and have randomly selected to verify the establishment verification requirements for the chilling CCP. You review the establishment's HACCP plan and find 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 your review of the HACCP plan, you determine 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).

Verification Example 2: *You are performing the 03J01 procedure in a very small sheep and goat slaughter operation and have randomly selected to verify the establishment*

verification requirements for the contamination (feces/ingesta/milk) CCP. You review the establishment's HACCP plan and find that it does not provide for direct observation of monitoring procedures. You determine 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

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

Verification Example 3: *You are performing the 03C01 procedure in a poultry cut-up operation and have randomly selected to verify verification requirements for the finished product storage CCP. You review the establishment's HACCP plan and find* ***one*** *of the verification procedures specifies the HACCP Coordinator will observe maintenance personnel perform the monitoring check once per shift. You review several recent room temperature logs and observe that the HACCP Coordinator has recorded results for the verification procedure for each shift. You determine that this requirement is in compliance because the verification procedures are being performed at the frequency specified in the HACCP plan.*

Observing Establishment Employees

You 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 4: *Continuing with the 03C01 procedure from the above example, your review 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 calibrate as necessary. You proceed to the HACCP office, and observe the thermometers being checked for accuracy, and results being recorded on the thermometer calibration log. You determine that this requirement is in compliance because the verification procedure is being carried out as written in the HACCP plan.*

Keep in mind that the establishment employee performing the direct observation ongoing verification procedure should directly observe the employee doing the monitoring activity. An establishment verifier that is performing the same activity as the monitor does not meet the regulatory requirement in 417.4(a)(2)(ii).

Verification Example 5: *Continuing with the 03C procedure, you decide to observe the direct observation verification procedure. You observe the HACCP Coordinator in the finished product storage area, observing the maintenance personnel performing the monitoring check. From your observations, you determine that the direct observation verification procedure requirements are met.*

Product sampling is considered a verification activity if the establishment incorporates it as such 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 in their HACCP plans. When that is the case, you must verify the testing program as part of 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 CCP from the specific HACCP plan. The establishment may do such sampling and choose not to include it in the HACCP plan. If the product sampling is part of the verification of the HACCP plan, you should observe the establishment employee collecting samples and following all the procedures identified in the plan as part of the HACCP 01 and 02 procedures when verifying §417.4(a)(2).

Verification Example 6: *You are performing the 03B01 procedure in a raw ground beef operation and have randomly selected to verify the establishment verification requirements for the finished ground beef temperature CCP. You review the establishment's HACCP plan and find one of the verification procedures specifies the establishment will conduct finished product testing for* E. coli *O157:H7 daily. You observe the HACCP Coordinator take the samples from the finished ground beef. You observe the production lot control procedures. You review several days' records in the laboratory testing log and find negative test results were recorded for each day. You determine that the establishment is in compliance because the verification procedures are being performed as described, and at the frequency stated.*

Determine Compliance

After you have gathered and assessed all available information pertaining to the verification requirement, you must determine regulatory compliance. If you find that the establishment has met all verification regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all verification regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

Noncompliance with the Verification Requirement

The following are examples of noncompliance with the verification requirement.

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. You observe that there is no direct observation verification procedure listed for this HACCP plan. You recall that the regulations require that all three verifications must be listed. One, 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.***

2. *The HACCP plan specifies that the verification procedure for the finished product storage area CCP is that the QC supervisor will calibrate thermometers, that the QC supervisor will observe the plant employee performing the monitoring check, and that the QC supervisor will review the finished product room temperature logs daily. You observe that there is no frequency listed for the calibration of thermometers.* ***The HACCP plan does not list the frequencies at which the calibration verification procedure will be performed.***

3. *The HACCP plan specifies that one of the verification procedures for the product storage area CCP is that the QC supervisor will observe the plant employee performing the monitoring check. You observe that the QC supervisor performs a monitoring check and records it on the product storage area room temperature log as a direct observation verification procedure. You observe that the QC supervisor did not perform a direct observation of the plant 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.***

4. *The HACCP plan specifies that one of the verification procedures for the finished product storage area CCP is that the QC supervisor will review the finished product room temperature logs daily. Your review of the record reveals that there is no documentation of this verification procedure for the last three days.* ***The establishment is not performing the records review verification procedures as specified in the HACCP plan.***

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 stem thermometers daily. You observe that the QC supervisor verifies the accuracy of only about half of the thermometers. When you ask, you are 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.***

6. *The HACCP plan specifies that one of the verification procedures is that finished product will be sampled and tested for* E. coli *O157:H7 once per day. When you review the micro records you observe that there are only results for two samples a week. When you ask about these results you are 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.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Workshop: Verification

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

1. Fill in the Blanks:
9 CFR 417.2(c)(7)—List the _____ procedures, and the _____ 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: The _____ of process-monitoring instruments; _____ of monitoring activities and corrective actions; and the _____ generated and maintained in accordance with §417.5(a)(3) of this part.

2. You are performing the 03C01 procedure in a poultry-boning operation and have randomly selected to verify the establishment verification requirements for the chilling CCP. You proceed to the QC office and review 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 QC will check all thermometers used for monitoring devices for accuracy by immersion in slush ice, and will verify to within 2 degrees F daily All thermometers found to be inaccurate will be calibrated using immersion in slush ice and re-evaluated	Corrective actions shall meet all requirements of Part 417.3(a)

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 you determine whether process-monitoring calibration activities were being conducted as per the HACCP plan?

If you perform the review and observation component:

If you perform the recordkeeping component:

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

If you perform the review and observation component:

If you perform the recordkeeping component:

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

If you perform the review and observation component:

If you perform the recordkeeping component:

You request the Thermometer Calibration Logs and the Product Temperature Logs.

Thermometer Calibration Log			**Calibrate to 32º F in slush ice water**		
Thermometer ID #	Temperature	Adjustment Required?	Date	Time	Initials
A1	32	No	1-2-03	5:23 am	*NM*
A2	32	No	1-2-03	5:25 am	*NM*

Product Temperature Log			**Critical limit 40 or below**	**Date:** 1-2-03
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, 1-2-03*

g. What do you conclude from the records?

You proceed to the storage cooler and observe 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 you have seen?

3. A HACCP plan's CCP at receiving lists as a monitoring activity "the receipt of a letter of guaranty that validated antimicrobial interventions were applied and certificate of analysis (COA) for *E coli* O157:H7 for each product lot." There is no calibration verification procedure listed for this CCP.

Does this meet regulatory requirements? Please explain.

4. You are a Consumer Safety Inspector, assigned to a large market hog slaughter facility.

Walking through the kill floor, you see the QA Supervisor at the critical control point (CCP) monitoring location after the head wash cabinet. He is examining the outer surfaces of a representative sample of swine heads as the heads exit the head wash cabinet. He is alone and appears to be performing the monitoring procedure for the CCP. Usually, you see one of the QA technicians performing this monitoring. Curious, you pause to observe the QA Supervisor's activities.

When he completes the check, he writes his initials in the 'Verified by' column on the Head Wash CCP HACCP record then writes in the current time (0820 hours) and today's date next to his initials. A previous entry indicates a QA technician had made a monitoring check at 0720 hours. Puzzled by the QA Supervisor's actions, you ask, "Did you just complete your daily verification check for monitoring this CCP?" and he replies, "Yes."

You decide to review the written HACCP plan and proceed to the QA office. You review the plan and confirm that the monitoring procedures for the CCP after the head wash cabinet are performed every two hours. The verification procedures for monitoring the CCP are 'Once per shift the QA supervisor will review all logs and observe trained QA personnel monitoring for visible contamination.'

a. Are the direct observation verification procedures being performed as described in the HACCP plan? Please explain.

b. Has a noncompliance occurred?

c. What is the regulation that applies to this situation?

Recordkeeping

You will verify some of the recordkeeping requirements when performing the HACCP 01 procedure. Other recordkeeping requirements are verified when performing the HACCP 02 procedure.

You will verify these requirements by reviewing the following:

- **HACCP plan**
- **HACCP records**
- **Hazard analysis**
- **Supporting documentation**
- **Decision-making documents**

In most instances, you will only use the recordkeeping component of the HACCP procedures when you are verifying the recordkeeping requirement. On occasion, you may use the review and observation component. For example, you may use the review and observation component to verify recordkeeping requirements by observing the establishment actually performing the pre-shipment review.

The thought process you 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.

There are several regulations that pertain to HACCP recordkeeping and you should verify as many of these requirements as are applicable and possible. Below is a table summarizing the recordkeeping regulatory requirements and procedures used to verify compliance.

HACCP Recordkeeping Requirements and the Procedures Used to Verify Compliance

Regulatory Recordkeeping Requirement	HACCP Procedure Performed
Recordkeeping system 417.2(c)(6)	01 or 02
Supporting Documentation 417.5(a)(1) and (2)	01
HACCP Records 417.5(a)(3)	01 or 02
Record Authenticity 417.5(b)	01 or 02
Computerized Records 417.5(d)	01 or 02
Record Retention and Availability 417.5(e)(1) and (2)	01 or 02
Pre-shipment Review 417.5(c)	02

The **recordkeeping component** of the 01 and 02 procedures will be used the majority of the time for verifying the recordkeeping requirements. You may occasionally use **review and observation for verifying pre-shipment review.**

Product acceptability or disposition could be verified using the 02 procedure.

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

A. Recordkeeping System

The regulatory requirement for recordkeeping 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.*

You will verify the recordkeeping requirement by performing the HACCP 01/02 procedures.

Gather information by asking questions

In performing the procedures, you should be seeking answers 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, you should review the following:

- HACCP plan
- HACCP monitoring records

• Reviewing the HACCP Plan for Recordkeeping Requirements

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

• Reviewing HACCP Records for Recordkeeping Requirements

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

Recordkeeping Example 1: *You are performing the 03J01 procedure in a poultry slaughter operation and randomly select to verify the recordkeeping requirement. You review the HACCP plan to verify that it lists the records used to document monitoring of critical control points and you find the following records listed for the fecal CCP: Plant Finished Product Standards Form, Antimicrobial Log, Equipment Maintenance Log, and Corrective Action Log. You also review the Fecal Monitoring Log and observe that monitoring personnel have recorded the actual time, test results, and initials. Based*

*upon your review, you determine that the establishment is in compliance with **this part** of the recordkeeping requirements of 417.2(c)(6) at this CCP.*

***Recordkeeping Example 2:** You are performing the 03C01 procedure in a small pork fabrication operation and have randomly selected to verify the establishment recordkeeping requirements for the only CCP, product storage. You review the establishment's HACCP plan and find that it lists the records used to document monitoring of critical control points, including the room temperature log, calibration log, and the corrective action log. You also find the monitoring procedure specifies that maintenance personnel observe the product storage area thermometer every two hours, and record results on the room temperature log. You review the room temperature logs and observe that the maintenance personnel have recorded actual temperatures and times on the form, and initialed each result. Based upon your review, you determine that the establishment is in compliance with **this part** of the recordkeeping requirements of 417.2(c)(6) at this CCP.*

Determine Compliance

After you have gathered and assessed all available information pertaining to the recordkeeping system requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements for §417.2(c), then there is no regulatory noncompliance. If you find that the establishment has not met all §417.2(c) regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the Recordkeeping System Requirement

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

1. *You are reviewing the HACCP monitoring log for the chilling CCP in a large beef slaughter establishment and find that monitoring personnel are placing a check mark on the Cooler Temperature 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).***

2. *You are reviewing the HACCP plan for a very small swine slaughter plant and you notice 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 CCP.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

B. Supporting Documentation Requirements

The regulatory requirements for supporting documentation are:

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;
(2) The written HACCP plan, including decision-making documents associated with the selection and development of CCP and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

You will verify this requirement by performing the HACCP 01 procedure, using the recordkeeping component.

The thought process you 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.

Note: As part of the requirement above, establishments will have documentation that address the requirement in 417.4(a). 417.4 specifies that "every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis." You should determine compliance with the requirement of this regulation, by verifying that the establishment has the necessary documentation required in 9 CFR 417.5(a)(2). This verifies that the HACCP plan is theoretically sound.

You should use sound judgment in requesting supporting documents and should not just arbitrarily ask for them. You should ask for supporting documents if you have reason to believe that an establishment decision was not an appropriate one.

Prerequisite Program-GMP and SOP

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. You 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. You do this while performing the 01 HACCP procedure when verifying the recordkeeping 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 plans, you should not apply the same criteria as they would when verifying the regulatory requirements of HACCP plans. For example, these records associated with monitoring and testing may include occasional instances of less than perfect control without resulting in threat to product safety. However, records generated from these programs must continue to support the decisions made in the establishment's hazard analysis.

You should assess the overall effectiveness of the testing results and monitoring results to verify the overall effectiveness of the procedures or programs. You should verify that if there is information in the records that requires the establishment to reevaluate the effectiveness of the Sanitation SOPs or reassess its HACCP plan, the establishment has done so. If the establishment has gathered information that indicates the Sanitation SOPs are not longer effective in preventing direct contamination or adulteration of product, there is noncompliance with 9CFR 416.14. If the establishment has gathered information that indicates the HACCP plan should be reassessed and has not done so, there is noncompliance with 9 CFR 417.4.

If you have concerns about the design or results from testing, procedures or programs, contact the Policy Development Division (PDD) or an EIAO through supervisory channels. The EIAO needs to conduct a comprehensive food safety assessment in the establishment to verify that the design of the food safety systems in operation meet regulatory requirements.

If the establishment does not provide these records when they are requested, you should document this as noncompliance with the requirements specified in 9 CFR 417.5(a)(1) or as per 5000.1.

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;

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 (9 CFR 417.5) (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).

NOTE: If you have questions regarding the design of the hazard analysis, contact the DO.

Unlike with HACCP plans, inspection program personnel **do not** verify compliance with specific regulatory requirements for such activities as monitoring, verification, and recordkeeping. Deviations from compliance with a prerequisite program usually would not create a food safety concern or necessitate action on the product, whereas deviations from the controls in a HACCP plan 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, you should focus on:

1. the overall program to verify that the establishment is implementing it as designed and consider such questions as:

a. is the establishment implementing the procedures as set out in the program's design?

b. does the establishment maintain records to support the implementation of the program, including verification records and results from outside auditors?

c. does the establishment evaluate the implementation of the program?

d. does the establishment have means to correct implementation problems?

2. any problems that indicate that the prerequisite program may no longer be supporting the decisions made in the hazard analysis that a hazard is unlikely 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 problem continue to reoccur?

d. are there numerous or recurrent mistakes made in the implementation of the program?

If you find, based on records or observations, that the prerequisite program is not continuing to support the decision made in the hazard analysis that a food safety hazard is not likely to occur in the process (i.e., the program is not being executed), document a noncompliance with 9 CFR 417.5(a)(1), as per FSIS Directive 5000.1, and verify that the establishment:

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

2. provides data supporting the decisions made during this reassessment required in 9 CFR 417.5(a)(1).

Gather information by asking questions for supporting documentation

In verifying these recordkeeping requirements, you should seek to answer the following questions:

1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis?

2. Does the establishment have the decision-making documents associated with the selection of each CCP?

3. Do the documents explain why the establishment selected that location for the CCP?

4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?

5. Does the establishment have scientific, technical, or regulatory support for the critical limit?

6. Does the support appear credible?

7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?

8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?

9. If the establishment has supporting documents for these decisions, does the documentation support the decisions?

Assess the information

When assessing the information gathered you will review the following:

- Hazard analysis with supporting documentation
- HACCP plan
- Decision-making documents associated with the selection and development of the CCP and critical limits
- Supporting documentation for the verification procedures and frequencies
- Supporting documentation for the monitoring procedures and frequencies

Some examples of supporting documentation that an establishment might provide include:

- Scientific journal articles
- Regulations
- Pathogen modeling
- Processing authority
- Research
- Historical data

There are **three possible outcomes** for verification of these requirements.

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

Note: There are situations in which you need more information to determine whether the establishment is meeting the requirements of 9 CFR 417.2. If the establishment is monitoring its critical limit every hour, and the only supporting documents that are available are the monitoring records for the past year, you might need more information to determine whether the HACCP plan complies with 9 CFR 417.2. You could issue a

30-day reassessment letter requesting the establishment to reassess its HACCP plan. (The 30-day reassessment letter will be discussed in a later section.) You have not been trained to assess the scientific and technical information that an establishment might have to support the HACCP system. You do have resources available to assist you in evaluating this information. You can contact the District Office or the Policy Development Division for assistance.

• Reviewing the Hazard Analysis with Supporting Documentation

You should review the hazard analysis along with the supporting documentation to verify that the establishment has the documentation to support the decisions made in the hazard analysis.

Recordkeeping Example 3a: *You are reviewing the hazard analysis in a raw ground beef patty operation. You review the establishment's hazard analysis documentation, and the process flow diagram. You find that all of the steps in the actual plant operations are described in the flow diagram, and each step is addressed in the hazard analysis. You find the hazard analysis considers potential biological, chemical, and physical food safety hazards at each step. Where potential food safety hazards are identified, the establishment has made a determination about whether they are reasonably likely to occur or not, and recorded the basis for that decision.*

You observe 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 "plant records show that there has been no incidence of foreign materials in products received in the plant." You decide to request the supporting documentation for this decision. The establishment provides a copy of a procedure for physical examination of raw material receiving, and the raw material receiving examination log. You observe that there are no significant findings of foreign material. You determine that this requirement for the recordkeeping system is in compliance in that the hazard analysis appears to have been conducted appropriately, and that the establishment has the documentation to support the decisions made in the hazard analysis.

Recordkeeping Example 3b*: While performing the 03B01 procedure for raw ground beef patties to verify the recordkeeping requirements for supporting documentation, you review the records from product testing conducted outside the HACCP plan or Sanitation SOP. During this review, you find that the establishment received a positive* E. coli *O157:H7 result from beef trimmings that were destined for grinding.*
You then review the establishment's corrective action records to verify the requirements of 417.3 were met.

There was documentation on the corrective action record of a reassessment of the hazard analysis and HACCP plan. While reviewing the hazard analysis and HACCP plan, you requested supporting documents for the decisions made in the hazard analysis and HACCP plan during the reassessment. The establishment provided supporting documentation when it was requested. You verify that the documents provided are adequate to support these decisions. You are able to determine that the supporting documentation supported the decisions made during the reassessment. You determine that there is compliance with these requirements.

• Reviewing the HACCP Plan and Supporting Documentation

In reviewing the HACCP plan and supporting documentation for compliance with 417.5(a), you should verify that the establishment has the documents to support the selection of each CCP and why that location was selected. In addition, you should verify that there is a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazard. There should also be credible scientific, technical, or regulatory support for the critical limit at the CCP and there should be documents supporting the monitoring and verification procedures and their frequencies identified in the HACCP plan.

Recordkeeping Example 4: *You are reviewing the HACCP plan in a beef slaughter operation. You review the HACCP plan, hazard analysis, and supporting documentation for the steam pasteurization CCP to verify that it meets the requirement in 417.5(a)(1) and (2). You find that the hazard analysis describes the rationale for the location and critical limits of the CCP. The supporting documentation includes scientific articles by researchers at various institutions supporting the location and the critical limits for the steam pasteurization CCP. Based upon your review, you determine that the establishment is in compliance with 417.5(a(1)and (2)).*

Determine Compliance

After you have gathered and assessed all available information pertaining to the supporting documentation requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements for §417.5(a) (1) and (2), then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for §417.5(a) (1) and (2), there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the Supporting Documentation Requirement

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

1. *You are reviewing the hazard analysis for a large beef slaughter establishment and find that it identifies the hazard of* E. coli *O157:H7 at the dehiding step but the establishment did not judge that it was reasonably likely to occur. You ask for documents supporting the decision and the establishment tells you it has none.* ***The establishment has no supporting documentation to support why it is not necessary to establish controls for food safety hazards identified in the hazard analysis.***

2. *You are reviewing the HACCP plan for a large beef slaughter establishment and find that it has a CCP for* E. coli *O157:H7 at the steam pasteurization step prior to chilling. The verification procedures specify that maintenance will calibrate the temperature recording device once a week prior to operations. You ask the establishment for documentation supporting this frequency of calibrating the temperature recording device and they finally produce some technical documents from the manufacturer that states the temperature recording device should be calibrated daily.* ***The establishment has no documentation supporting the verification procedure and frequency.***

3. *The hazard analysis addresses the biological hazards of* Salmonella *and* E. coli *O157:H7 in raw materials received and has determined that they are likely to occur. There is no CCP identified in the HACCP plan to address these hazards. When you request decision-making documents to support this determination the establishment is not able to provide any.* ***The establishment has no supporting documents associated with the decision-making process for the selection of the CCP.***

4. *The HACCP plan has a critical limit to control* Salmonella *and* E. coli *O157:H7 for irradiation of raw ground patties of 0.045 kGy. The plant is not able to provide any supporting documentation for this radiation dose.* ***The establishment has no scientific, technical, or regulatory support for the critical limit.***

5. *The HACCP plan has a monitoring procedure for checking the finished product chilling medium by hand thermometer at the beginning of each shift. The plant is not able to provide any supporting documentation for this procedure or frequency.* ***The establishment has no documentation supporting the monitoring procedures and frequencies.***

6. *The hazard analysis has identified that* E. coli *O157:H7 is likely to occur and established a CCP to control this hazard. The establishment provides as supporting documentation for its critical limit some charts from a microbial pathogen computer modeling program. Upon examination you observe that the parameters used in the predictive model do not match the ones used by the establishment in its process.* ***The establishment has documentation, but the documentation does not support the decisions made.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

C. 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.*

You will verify compliance with this regulation by performing either the 01 or the 02 procedure. You would use the recordkeeping component to verify this regulation.

The thought process you 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), you should seek answers 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

You will 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.

Recordkeeping Example 5: *You are performing the 03J01 procedure in a pork slaughter operation and randomly select to verify the recordkeeping requirement in 417.5(a)(3) for the pre-evisceration carcass rinse CCP. You review the HACCP records for this CCP and find 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 **
2-1-2003	*1*	*0730*	*2.2%*	*30psi*	*-*	*TDM*	*PP*
**direct observation verification-results as per HACCP plan*							

Based upon your records review, you determine that the establishment is in compliance with this part of the recordkeeping requirements of 417.5(a)(3).

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

Recordkeeping Example 6: *You are performing the 03B02 procedure in a raw pork sausage operation and as part of your procedure you are verifying all requirements for all CCP for a specific production. As part of your review, you examine all HACCP records produced. You observe that each of the records includes the actual values, the production code and the product name, where applicable, and that each record includes the date. Based on your review, you decide that the plant is in compliance with this part of the recordkeeping requirement.*

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

Recordkeeping Example 7: *You are performing the 03J01 procedure in a poultry slaughter operation and randomly select to verify the recordkeeping requirement in 417.5(a)(3) for the carcass chilling CCP. You review the HACCP records for this CCP and find that the verification personnel have made the following entries:*

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

Date	*Time*	*Area*	*Thermometer ID*	*Personal Thermometer Reading*	*Adjustment Required*	*Initials*	*Comments*
2-1-2003	*0800*	*Carcass Chilling*	*2A*	*32*	*No*	*TDM*	

Based upon your records review, you determine that the establishment is in compliance with this part of the recordkeeping requirements for the chilling CCP. You would then proceed to verify other recordkeeping requirements.

Determine Compliance

After you have gathered and assessed all available information pertaining to the HACCP records requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements for §417.5(a)(3), then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for §417.5(a)(3), there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the HACCP Records Requirement

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

1. *You are reviewing the monitoring records for the poultry TSP antimicrobial spray CCP and you find 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. You ask 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. You conclude that the monitoring took place but it was not recorded.* ***The records do not have the monitoring results recorded.***

2. *You are reviewing the poultry chiller CCP monitoring records and find that the temperatures have been recorded on the monitoring log but no times are recorded. Upon further investigation, you are provided evidence that the monitoring checks were performed at the proper times.* ***The records do not include the actual times that monitoring is performed.***

3. *You are reviewing the monitoring records for the carcass wash CCP in a poultry establishment and you find 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.***

4. *You are reviewing the HACCP records for the finished product storage CCP in a small sheep slaughter operation and notice 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.***

5. *From the above example, you notice that the product temperature log from the previous shift does not have the date on it.* ***The records do not include the date the record was completed.***

6. *You are reviewing the verification records for the organic acid pre-evisceration rinse CCP in a large swine slaughter operation and you notice 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 are being performed.* ***The verification procedures and results are not being recorded.***

7. *You are reviewing the corrective actions for the fecal CCP in a poultry slaughter operation and you notice the plant monitoring procedure at 0700 had a fecal finding and the following procedure at 0710 also had a fecal finding. You look at the corrective action log and find no record of any corrective actions. You request 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.***

8. *You are reviewing the records for the thermal organic acid rinse CCP prior to chilling in a beef slaughter operation and you find 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 every shift startup. You request more information and the establishment provides you with evidence that the calibration was performed.* ***The results of calibration of process monitoring instruments are not recorded.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

D. 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.*

You will verify this requirement as part of the 01 or 02 procedure. You could use either the recordkeeping or review and observation component, or both.

The thought process you 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

In verifying that the establishment is in compliance with this requirement you will seek answers 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

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

When reviewing the HACCP records for compliance with 417.5(b), you 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, verify that the record was signed and initialed by the establishment employee making the entry.

Recordkeeping Example 8: *You are performing the 03C01 procedure in a poultry cut-up operation and have randomly selected to verify the establishment recordkeeping requirements for the product storage CCP. You review the establishment's HACCP plan and find that the verification procedure is that QC personnel will check the product storage area temperature recording device (continuous process monitoring instrument) every two hours, and record the results on the chart. You review the chart and observe that the QC personnel have recorded actual time and temperature results for each entry, and initialed each entry, and that the date is recorded at the top of the form. You notice that it is almost time for the next check and so you remain in the area and observe that the QC employee performs the check and records the results at the time of the check. You determine 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 you have gathered and assessed all available information pertaining to the HACCP record authenticity requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements for §417.5(b), then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for §417.5(b), there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with HACCP Record Authenticity

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

- *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. You observe this record:*

Incoming trimmings log	Critical limit = 38 F or lower		Date: 7-8-04				
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	✓		

You observe the next truck unloaded. The plant 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. You determine 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.***

E. 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 you might make when you sign for 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 themselves. The computer, using an electronic "key," de-codes the record or message. This endorses the identity of the user.

This requirement will be verified by performing the 01 or 02 procedure

The thought process you 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 you should seek the answer to this question:

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

Assess the information

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

Recordkeeping Example 9: *An establishment enters all HACCP activity results into hand-held computer devices. Network access is for QA employees only. Each employee has a unique log-in 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 you have gathered and assessed all available information pertaining to the computerized records requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements for §417.5(d), then there

is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for §417.5(d), there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the Computerized HACCP Records Requirement

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

1. *The establishment uses a computer-based system to monitor and record the temperatures in all processing rooms, coolers, and chillers. You request information about controls to ensure the integrity of the records, which the establishment is not able to provide.* ***The establishment does not have controls in place to ensure the integrity of the electronic records.***

2. *The establishment uses a computer-based system to monitor and record the temperatures in all processing rooms, coolers, and chillers. You observe that on a warm day a processing room employee adjusts the computer settings so that the alarm will not keep going off. You observe 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.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

F. Record Retention and Availability

The regulatory requirement for record retention and availability is:

> ***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.*

You will verify this requirement as part of the 01 or 02 procedure.

The thought process you 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

You should seek answers 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, and available upon request?

3. If the records are stored off-site after 6 months, can they be retrieved within 24 hours?

Assess the information

You should verify that the records are being maintained the required amount of time by reviewing:

- **HACCP records.**

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

Determine Compliance

After you have gathered and assessed all available information pertaining to the records retention and availability requirement, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements for §417.5(e)(1) and (2), then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for §417.5(e)(1) and (2), there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with Records Retention and Availability

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

1. *In October, you ask the establishment to provide a sample of the fecal CCP monitoring log records from last January. They give you a folder that contains February's records. You ask the establishment about January's records and they tell you 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.***

2. *In October, you are reviewing the establishment HACCP records for the sampling component of the steam pasteurization CCP in a large beef plant. You suspect the establishment is not maintaining records on site. You discuss this with your frontline supervisor and then you ask the establishment for the records from May. They tell you that they can give you 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.***

3. *You are new to this assignment at a large poultry plant and are performing records maintenance verification as part of 03J01. You wonder about whether the establishment is able to retrieve records stored offsite and discuss this with your supervisor. You decide to ask the establishment to provide a sample of records from 7 months in the past. They tell you that after 6 months they store them at corporate headquarters. You request they retrieve the records from corporate headquarters. You receive the records 5 days later.* ***The establishment cannot retrieve the records within 24 hours when stored off-site.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

G. 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.*

FSIS considers product to be **"produced and shipped"** when the establishment completes pre-shipment review. Verifying that the establishment has completed pre-shipment review enables you to know whether the company has taken full and final responsibility for applying its HACCP controls to the product that it has produced.

For a pre-shipment review, the establishment must review the records associated with the production of specific product. There is no regulatory requirement for an establishment to conduct pre-shipment review when the product moves from one process category to another. Verify an establishment's pre-shipment review of its records by performing the 02 procedure. You should occasionally perform a verification check by observing the establishment employee perform the pre-shipment review. Once the observation verification has been performed, this regulatory requirement can be verified using the recordkeeping component.

You should understand that 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 you 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

You should seek answers to the following questions:

1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?

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

Assess the information

You should review the pre-shipment review records.

Determine Compliance

After you have gathered and assessed all available information pertaining to the pre-shipment review requirement, you must determine regulatory compliance. If you find that the establishment has met all pre-shipment review regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for pre-shipment review, there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with Pre-Shipment Review Requirement

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

1. *You are performing the 02 procedure on a specific production that has left the control of the establishment. You request 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.***

2. *You are performing the 02 procedure, and you decide to perform the review and observation component by observing the establishment employee complete the pre-shipment review. You observe a plant employee review the records associated with the production of the product, but not sign or date any record to indicate the review is complete.* ***The establishment performs pre-shipment review but does not sign and date the records.***

You will document any recordkeeping noncompliance in accordance with our discussion of documentation and enforcement in a later section.

• Records Misrepresentation

Familiarity with an establishment's procedures and compliance history will help separate honest errors from deliberate record misrepresentation. When deliberate misrepresentation of records is suspected, do **not** discuss the situation with an establishment employee. Notify the IIC and document the findings in a memorandum to the files—**not on an NR**. The IIC should use a secure phone (off-premises if necessary) to call 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 phone to notify the District Office and follow the District Manager's instructions.

Workshop: Recordkeeping

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

1. Fill in the blanks for the following regulatory references:

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

9 CFR 417.5(a)—The establishment shall maintain the following _____ documenting the establishment's HACCP plan:
(1) The written _____ _____, prescribed in §417.2(a) of this part, including all supporting documentation;
(2) The written HACCP plan, including _____ documents associated with the _____ and _____ of CCP and _____ _____, and documents supporting both the _____ and _____ procedures selected and the _____ of those procedures.

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

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

9 CFR 417.5(c)—Prior to _____ product, the establishment shall _____ the records associated with the _____ of that product, documented in accordance with this section, to ensure completeness, including the determination that all _____ _____ were met and, if appropriate, _____ actions were taken, including the proper _____ of product. Where practicable, this review shall be _____, _____, and _____ 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.

2. Indicate the procedure, or procedures, used to verify compliance with the following regulatory requirements. Possible answers are:
a. 01
b. 02
c. 01 or 02

Recordkeeping—417.2(c)(6) _____

Supporting Documentation—417.5(a) _____

HACCP Records—417.5(a)(3) _____

Record Authenticity—417.5(b) _____

Computerized Records—417.5(d) _____

Record Retention and Availability—417.5(e)(1) and (2) _____

Pre-Shipment Review—417.5(c) _____

3. What recordkeeping requirement can be verified using the review and observation component?

4. When verifying the recordkeeping requirement, how many of the regulatory requirements should you verify?

5. **Case Study.** You select to verify the recordkeeping requirement at the pre-evisceration antimicrobial rinse CCP as part of a 03J01 procedure. You review the monitoring record for the CCP, which follows.

Pathogen Reduction Log							
Date	*Lot No.*	*Time*	*Solution Conc.(%)*	*Pressure (psi)*	*Corrective Actions*	*Monitored by*	*Verified by **
2-1-2003	*1*	*0730*	*OK*	*OK*	*-*	*TDM*	*PP*
**direct observation verification-results as per HACCP plan*							

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

b. What would you do next?

6. **Case Study.** You are reviewing the HACCP plan for a large beef slaughter establishment and find that it has a CCP for control of *E. coli* O157:H7 at the hot water carcass rinse prior to chilling. The critical limit for the hot water wash is 140º F. You are not certain that this temperature is adequate to reduce *E. coli* O157:H7; therefore, you ask the establishment for scientific support that this temperature is effective in reducing *E. coli* O157:H7. The establishment provides you with a scientific study paper from researchers at a major university that supports the use of hot water washes with a minimum of 165º F as a method to effectively reduce the numbers of *E. coli* O157:H7. You ask the establishment for supporting documents for making 140º F the critical limit at the CCP. They tell you that the critical limit was put at 140º F because that was the maximum output temperature for the plant boiler.

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

7. 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?

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

9. **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
2/15/2003	PM	Carcass Cooler	2B	32°F	No	TDM	

a. Is there any noncompliance with recordkeeping requirements here?

b. If so, what is the regulatory reference?

10. **Case Study.** You are verifying the recordkeeping requirement as part of a 03J01 procedure and select 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 0. 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 noncompliance with this record? If so, list what it is and give the regulatory references?

b. What would you do next, if anything?

11. You are 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.

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

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 part 417: monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance.

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

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.*

This requirement cannot be randomly verified because corrective action occurs when something triggers it (a deviation from a critical limit). **Anytime** there is a deviation from a critical limit you will **always** verify that the corrective actions taken by the establishment meet the requirements of the regulation. This will be done as part of the 01 or 02 procedure. The recordkeeping component or the review and observation component can be used to verify these requirements.

The thought process you 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, you will seek answers 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 answers to these questions, you 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 in response to the deviation from the critical limit meets all of these 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, you 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 your patrol assignment at 10:30 am, you are notified by the plant management that there has been a deviation of the metal detection critical limit. You thank the plant manager for voluntarily notifying you about this situation. You know that you must verify that the corrective action requirements are met, and realize you could do this by performing the review and observation component. You review the establishment's HACCP plan and find 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.*

You find that the corrective actions are "all parts of 417.3 will be met." You proceed to the production area and review the metal detection control log, and find the deviation noted at the 10:04 am monitoring check. The form notes that the equipment failed to detect the seeded sample. You note that the form states that at the 8:00 check the equipment was operating properly. You observe that the establishment has product identified and segregated. You inspect the amount and the codes of segregated product and compare them to the codes on the monitoring record. You ask the packaging line supervisor about the segregation of product and are informed that all product produced after the 8:00 am check has been identified and segregated. You determine that the plant has segregated the appropriate affected product.

You 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, you continue to observe the establishment's actions in the production area. You observe 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 you that the unit is malfunctioning, and that it will not be used until it is repaired. Later, the establishment informs you 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, you determine that the establishment has identified and eliminated the cause of the deviation.*

You 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, you continue 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. You observe production resume. The packaging line supervisor notifies you that they will perform the monitoring checks at an increased frequency of once per hour for one week. Based on these observations, you determine that the establishment has the CCP under control.*

You 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, you return to the production area. You observe a monitoring check on the metal detector. Next you observe 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, you determine that the establishment has prevented product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce.*

You 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. You review the establishment's HACCP plan and find that a verification procedure has been added, to observe that the machine is placed in a dry room during cleanup. You go to the production area. You notice that the original metal detector, the one that malfunctioned, is back in place. You observe that the metal detector appears to be working. You review the monitoring records and observe that the monitoring had been done at the increased frequency for one week, as proposed. Later, you observe that the machine is removed to a dry room during cleanup. Based on these observations, you determine that the establishment has established preventive measures.*

• Reviewing the Corrective Action Records

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

Corrective Action Example 1, part 6: *Continuing with the above example, you review the establishment's corrective action log for this deviation. You compare the recorded corrective actions with what you have observed, and with the requirements of 417.3(a), and find 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. You observe the record that shows the proposed maintenance repairs were performed. You determine that this requirement is met, and you record 03B01 as an unscheduled procedure, and mark it as (a) performed.*

Determine Compliance

After you have gathered and assessed all available information pertaining to the corrective action requirement, you must determine regulatory compliance. If you find that the establishment has met all corrective action regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all corrective action regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the Corrective Action Requirements

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

1. *You are reviewing monitoring records for the TSP CCP in a poultry slaughter operation and you find that at 0800 the recorded TSP concentration was below the critical limit of 8%. You proceed 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 50 ppm and the post-chill chlorinated rinse cabinets were turned on at 0810."

   These actions are consistent with the corrective actions regulations but you find no documentation and observe no evidence that the establishment attempted to ***identify the cause of the deviation from the critical limit.***

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. You find 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.***

3. *Continuing the example above, you review the corrective action records again and find 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.***

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.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

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.*

This requirement cannot be randomly verified because corrective action occurs when something triggers it (i.e., an unforeseen hazard or a deviation not covered by a corrective action. If an unforeseen hazard or a deviation not covered by a critical limit occurs, **always** verify that the regulatory requirements are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR 417.3(b).

These requirements should be verified as part of the HACCP 01 or HACCP 02 procedures.

The thought process you 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

You 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 answers to these questions, you should:

- Review the corrective action records associated with the deviation 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 and, if so, verify that the establishment has supporting documentation for decisions made during the reassessment.

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

• Reviewing the Corrective Action Records

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

Corrective Action Example 2, part 1: *You are performing the 03J02 procedure in a poultry slaughter establishment to follow-up on an event that 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. You review the corrective action log dated 2-1-2003 and find 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. HACCP plan will be reassessed by 2-3-2003.

Based upon your review of the records, you determine that the recorded actions meet the requirements of 417.3(b).

• Observing the Establishment Execute Corrective Actions

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

Corrective Action Example 2, part 2: *Continuing from the previous example in which there were metal shavings on the product, you verify that the establishment segregates and holds the affected product by going to the chiller and the cooler to observe the product. At the chiller, you find no product exiting the chiller since operations ceased an hour earlier. You find the affected product held by a QA tag and segregated in the cooler. Based upon your observations, you determine that the establishment has adequately held and segregated affected product.*

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

Corrective Action Example 2, part 3: *Continuing from the previous example in which there were metal shavings on the product, you observe 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, you inspect several samples of boneless product and find no trace of metal contamination. Based upon your observations the establishment took necessary measures to ensure that only acceptable product was released.*

• Determine if a reassessment was performed

Verify that the establishment performed the reassessment and has supporting documentation for decisions made during the reassessment.

Corrective Action Example 3: *During a routine review of an establishment's HACCP plan for raw ground beef, you observe a notation that the HACCP plan has been reassessed, and updates made. You further observe that the establishment has added a CCP for 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. You decide to investigate further and ask for more information, and any supporting documentation, from plant management. You learn that this reassessment was conducted as a result of an unforeseen hazard. You are 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. You are 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 HACCP plan. You are shown documentation the plant received from its supplier stating which antimicrobial treatment products received, and the specified reduction in the number of*

pathogens achieved. You determine 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. You determine that the establishment is in compliance, and you record 03B01 as an unscheduled procedure, and mark it as (a) performed.

Determine Compliance

After you have gathered and assessed all available information pertaining to the corrective action requirement, you must determine regulatory compliance. If you find that the establishment has met all corrective action regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for corrective action, there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the Corrective Action Requirements

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

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

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.***

3. *If the plant 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.***

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.***

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).*

6. *You are performing the 03B01 procedure in a small beef grinding operation and have randomly selected to verify the establishment recordkeeping requirements for all CCP. You review 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 plant does not have a CCP for visual observation of raw materials. Under preventive measures on the corrective action log, "none needed" is recorded. You ask 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.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Workshop: Corrective Action

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

1. Fill in the blanks:

9 CFR Part 417.3(a) – The written HACCP plan shall identify the corrective action to be followed in response to a _____ from a _____. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The _____ of the deviation is _____ and _____; (2) The CCP will be _____ _____ after the corrective action is taken; (3) Measures to _____ _____ are established; and (4) No product that is _____ to _____ or otherwise adulterated as a result of the deviation enters _____.

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) _____ 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 _____ 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 _____ 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 _____ into the HACCP plan.

2. You are reviewing a HACCP record and observe 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 your 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?

3. 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. You review the temperature log and observe 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 you expect to see all corrective actions in part 417.3(a) taken for this situation? Please explain.

4. You are making observations in the poultry boning room, when you observe that there is a commotion among employees at the automatic breast deboning equipment. Investigating, you observe that a full set of viscera has gotten hung up on the equipment, and intestinal contents are spread all over. The employees shut off the line. Because you reviewed the HACCP plan this morning, you realize 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 would you do next?

You observe the employees gather all of the product from the area, put it into inedible containers, and begin cleaning up. You return to your other duties, and later you go to the QA office and ask for documentation of the actions taken.

HACCP CORRECTIVE ACTION OR UNFORESEEN HAZARD REPORT XYZ Corporation
Date: *1-2-03*
Product and amount affected: *397 lbs chicken breasts*
Describe the unforeseen hazard, including cause:
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.

Describe how the affected product was segregated and held:
All product from line or near line disposed of as inedible AB 8:50 am.

Describe how the product was reviewed to determine acceptability for distribution:
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.

Describe measures taken to prevent a reoccurrence and/or to eliminate the cause:
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.

State whether HACCP plan reassessed, conclusions, and any changes:
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.

Adel Brezil 1-3-03 — Plant Management, date
Craig Darrow 1-3-03 — 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 would you do in this situation?

5. You have recently rotated assignments and your new patrol includes a pork fabrication operation. Today's schedule includes the 03C02 procedure. You observe that there is a metal detector in use on the pork cuts before they enter the tenderizer injector. You review the HACCP plan and hazard analysis, and you see 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 do you conclude at this point?

Later that day, you learn that the metal detector has rejected product. You review the corrective action log.

HACCP CORRECTIVE ACTION OR UNFORESEEN HAZARD REPORT IJK Corporation
Date: *5-2-03*
Product and amount affected: *25 lb boneless pork loin*
Describe the unforeseen hazard, including cause:
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.

Describe how the affected product was segregated and held:
We disposed of the piece as inedible EF 10:05 am

Describe how the product was reviewed to determine acceptability for distribution:
All product from that same load was run back through the metal detector but nothing else was found EF 1:00 pm.

Describe measures taken to prevent a reoccurrence and/or to eliminate the cause:
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.

State whether HACCP plan reassessed, conclusions, and any changes:
Yes. Established a new CCP for metal detection. See new version of HACCP plan, dated 5-2-03 GH 1:00 pm.

Eric Fazoli 5-2-03 — Plant Management, date
Gerry Harroldson 5-2-03 — QA Manager, date

Example: For Training Use Only

a. What regulation applies to this situation?

b. Did the establishment meet corrective action requirements?

c. Is there a HACCP noncompliance?

d. What else would you do?

6. 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 has a monitoring procedure for the temperature of the hot water pasteurization spray of checking the temperature three times per shift. The critical limit is 180º F or above. You review the monitoring log.

Hot Water Pasteurization Spray, critical limit 180º F or above			Date: 1-2-03
Time	Temp	Monitor	Comments
6:45 am	182	OP	
9:30 am	175	OP	
12:00	183	OP	

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

b. The HACCP plan has a monitoring procedure for product temperature of fresh pork sausage chubs. You review the temperature log and observe a deviation recorded. You review the associated corrective action log and find that the establishment recorded the cause of the deviation, eliminated the cause, and ensured that the CCP was in control before continuing production. Your 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. You review shipping records and observe 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?

7. You are observing a QC technician doing a poultry slaughter food safety standard test, and the QC technician identifies fecal contamination on one of the sample carcasses. You observe the QC technician notify the establishment supervisor that a deviation had occurred at the CCP and observe plant corrective actions to ensure that they comply with 9 CFR 417.3(a) and with the plant's HACCP plan specifications.

Plant personnel perform the following actions:

1. Remove the affected carcass for reprocessing;
2. Determine that the vent machine was out of adjustment and get maintenance to readjust it;
3. Retain all product between the vent machine (after it is readjusted) and the chiller for rework;
4. Increase the overflow in the chill system for product in the chill system since the last monitoring check;
5. Wash all product exiting the chiller with chlorinated water;
6. Have a QC technician check the product exiting the chill system for visible fecal material;
7. Document all of the above actions on the corrective action log.

The corrective action log states:
"At 10:42 am, visible fecal material was identified on a carcass from line 1. The vent machine was found to be out of adjustment and was readjusted. All product from the last monitoring check to product at the point of the vent machine was retained for rework. Product already in the chill system was reconditioned by washing in chlorinated water after exit from the chill system, and was checked for visible fecal material by a QC technician. Overflow in the chill system was increased for 2 hours, which will flush out contaminated water."

After observing the corrective actions and reading the entries on the corrective action log, answer the following questions:

a. Does noncompliance exist? If so, what were the noncompliances?

b. What regulatory requirements were not met?

c. What actions should you take next, if any?

Reassessment

Reassessment (Annual and Changes in Plant Processes) and Establishment Training Requirements

The regulations that apply to the reassessment of the HACCP plan and establishment training are:

***9 CFR 417.4(a)(3)**--Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with §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 §417.2(c) of this part.*

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

***9 CFR 417.2(d)**—Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. The 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 section 417.4(a)(3) of this part

The establishment can reassess its HACCP plan, or plans, any time during the calendar year to meet the annual reassessment requirement. This requirement does not require the establishment to reassess every 12 months. To demonstrate that the annual reassessment has been performed, the establishment is required to sign and date the HACCP plan.

You verify that the establishment is meeting the annual reassessment and training requirement **once** a year as close as possible to the anniversary of the date that FSIS implemented HACCP (January 25-26th) by reviewing its HACCP plan(s).

You perform procedure 03A01 to verify **both** the annual reassessment and establishment training requirements. Use the HACCP system— basic compliance checklist (FSIS Form 5000-1), but only the parts which pertain to the annual reassessment (top of form and last block on form). Complete 1 checklist per HACCP plan, but only enter **one** unscheduled 03A01 on the Procedure Schedule per HACCP element or processing category (03B, 03C, 03J, etc.) that covers product the plant produces, regardless of how many HACCP plans the plant has under that HACCP element or processing category, or how many checklists you complete.

For example, if the plant has a slaughter HACCP plan (03J), three raw ground product HACCP plans (03B), and two raw not ground product HACCP plans (03C), you would record a total of three unscheduled 03A01 procedures in the PBIS procedure results screen. This number represents each of the three HACCP processing categories that cover products the establishment produces, even though the establishment has six HACCP plans. If the establishment has **ONE HACCP plan** that FSIS verifies **using two HACCP elements** or processing categories (such as 03J and 03C), then inspection program personnel are to record **two** unscheduled 03A01 procedures in the PBIS procedure results screen.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

HACCP SYSTEMS BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME		ESTABLISHMENT NO.	PROCESS
PRODUCTS COVERED BY PROCESS			
IMPLEMENTATION DATE	NEW PRODUCT	REASSESSMENT DATE *(Yearly: Check for dated signature only)*	
Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1.			

ACCEPTANCE AND REASSESSMENT (417.2 (d)) The responsible establishment official did not sign and date the HACCP plan (1) upon initial acceptance, or	
(2) at least annually thereafter upon required plan reassessment.	
MODIFICATION The HACCP plan was modified, and the responsible establishment official did not sign and date the plan (417.2 (d) (2) (ii)).	

Note: The establishment **is not** required to have documentation that the individual that performed the reassessment and any modification to the HACCP plan successfully completed a HACCP training course.

The establishment must reassess the adequacy of the HACCP plan whenever a change occurs that could affect the hazard analysis or alter the HACCP plan, but it is not required to document such reassessments, unless the reassessment reveals that modification of the plan is necessary. If reassessment reveals that the HACCP plan no longer meets regulatory requirements, the HACCP plan must be modified immediately, and signed and dated.

The thought process you 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 compliance with §417.4(a)(3), §417.7 and §417.2(d), you should consider the following questions:

1. Did the establishment perform the annual reassessment of its plan or plans at some point during the previous calendar year?

2. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?

3. Has any change occurred that could affect the hazard analysis or HACCP plan?

4. Did the establishment reassess?

5. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, was the HACCP plan modified immediately?

6. Did the establishment sign and date the HACCP plan or plans during the previous calendar year and upon any modification to the plan?

7. Has the individual who reassessed the HACCP plan, or who modified the plan, completed training or a course in the seven principles of HACCP including a segment on the development of a HACCP plan for specific product and review of records?

Assess the information

To verify compliance with §417.4(a)(3) and §417.2(d), you should review:

- Reassessment records, if available.

- HACCP plan.

Verify that the annual reassessment has been performed by an individual having the training required by §417.7 and that the establishment has considered any significant changes or developments in its slaughter and/or raw product processes that could affect the hazard analysis or alter the HACCP plan.

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Reassessment Example 1: *On 1-28-2007, you are performing the 03A01 procedure in a turkey slaughter operation. Because it is close to the anniversary of the date that FSIS implemented HACCP (January 25-26th), you decide to verify the annual reassessment and training requirements. You review the HACCP plan and verify that the annual reassessment was last performed and signed off on 1-1-2006. You learned in your HACCP training that the establishment reassessment requirement is based upon the calendar year and not upon a 12-month period. The person who signed the plan has been identified as someone who completed a HACCP training course meeting the requirements in §417.7. Therefore, you determine that the establishment is in compliance with the annual reassessment and training requirements since reassessment was performed in 2006 and the person that reassessed the plan was HACCP trained.*

When the establishment is in compliance, enter “a” (for performed) on the procedure schedule for the unscheduled 03A01 procedure and file the completed checklist (FSIS form 5000-1) in the government file.

If changes have occurred that could affect the hazard analysis or HACCP plan, you should verify that the plant did perform a reassessment. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, you should verify that the HACCP plan was modified immediately.

Reassessment Example 2: *You are a CSI in a small beef slaughter operation which has just recently begun to slaughter bob veal calves. On 5-10-07, you decide to review the HACCP plan to determine if a reassessment was performed and, if so, were any changes made to the HACCP plan as a result of that reassessment. You find that*

reassessment was last performed and signed off on 5-1-2007. You also note that, as a result of the reassessment, the HACCP plan was changed by adding a CCP for chemical hazards at receiving. The supporting documentation for adding the CCP states the establishment had begun slaughtering bob veal calves. There were several sources of data in the supporting documentation that showed bob veal calves to be a much greater risk for residue violations. Based on your review, you determine that the establishment is in compliance with the reassessment requirement as a result of process changes.

Determine Compliance

After you have gathered and assessed all available information pertaining to the reassessment and training requirement, you must determine regulatory compliance. If you find that the establishment has met all reassessment and training regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all reassessment regulatory training requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the Reassessment Requirements in §417.4(a)(3)

The following are examples of noncompliance with §417.4(a)(3):

1. *On 2-2-2007, you are performing the 03A01 procedure and are reviewing the HACCP plan to verify it meets the annual reassessment and training requirements. The HACCP plan is signed and dated 11-11-2005. You question the HACCP coordinator and determine that the last reassessment was in November of 2005.* ***The annual reassessment requirement was not met.***

2. *In mid October of 2007, a large beef slaughter establishment reassessed its HACCP plan in light of the new data showing* E. coli *O157:H7 is more prevalent than previously thought. On 11-6-07, you are reviewing the hazard analysis and find that* E. coli *O157:H7 was judged to be a hazard reasonably likely to occur at dehiding and evisceration. However, in reviewing the HACCP plan you find no CCP to address the hazard.* ***In this case, reassessment revealed that the HACCP plan no longer met the requirements of 417.2(c) and the plan was not immediately modified.***

When the establishment has not signed and dated each of its HACCP plans during the calendar year or signed and dated it upon modification, enter a check mark on the checklist. If the establishment does not meet the annual reassessment requirement or comply with the training requirement under 417.7 for each of its HACCP plans, enter the “m” noncompliance result code on the procedure schedule (PS) and complete the NR citing both 417.4(a)(3) and 417.2(d)(iii) for failing to meet the annual reassessment requirement, or 417.2(d)(ii) for failing to sign and date upon modification, or 417.7 for failing to meet the training requirement. Attach the completed checklist to the copy of the NR and maintain the copy in the government file.

Additional information for documenting noncompliance will be provided during discussion of documentation and enforcement in a later section.

Reassessment of the Hazard Analysis

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

You will have to rely on your knowledge of the operation and the changes that occur within that operation. You would verify this requirement using the 01 procedure.

The thought process you 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 compliance with §417.4(b), you must answer the following questions:

1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur?

2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?

3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

4. Has the individual who reassessed the hazard analysis met the training requirement prescribed in §417.7?

Assess the information

You would review the hazard analysis.

FSIS knows of no process that inherently has no hazards. If you encounter an establishment with no HACCP plan, you should notify the District Office. You should verify food safety to ensure the process is not producing adulterated product.

Determine Compliance

After you have gathered and assessed all available information pertaining to the reassessment requirement, you must determine regulatory compliance. If you find that the establishment has met all reassessment regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements for reassessment, there is noncompliance. You will receive more information about making compliance determinations in a later section.

• Noncompliance with the Reassessment Requirements in §417.4(b)

1. The establishment has a process with no HACCP plan, changes occurred that could affect whether a food safety hazard exists, and the establishment did not conduct a reassessment of the hazard analysis.

2. Changes occurred that could affect whether a food safety hazard exists, reassessment was conducted, the reassessment revealed that a food safety hazard exists, and no HACCP plan was developed. This is actually noncompliance with §417.2(b)(1) because the reassessment was conducted in accordance with §417.4(b).

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

The Hazard Analysis and HACCP Plan

This section covers how to perform your HACCP duties to verify that an establishment has performed a hazard analysis as prescribed in §417.2(a) and developed or designed a HACCP plan that meets the requirements of §417.2(c). The hazard analysis is a key element in the HACCP system. The purpose of the hazard analysis is to create a list of food safety hazards that are reasonably likely to occur in the production process. This list is used in developing the HACCP plan. The hazard analysis and HACCP plan are building blocks of the HACCP system.

You verify that an establishment has performed a hazard analysis and developed a HACCP plan when the hazard analysis has identified one or more food safety hazard that reasonably likely to occur in the process during the performance of the 03A01 procedure. You should use the thought process and methodology described below when verifying the hazard analysis and HACCP plan. You will verify compliance by reviewing the flow charts, the hazard analysis, the HACCP plan, and HACCP records.

Before reviewing the hazard analysis, you should understand that a food safety hazard is defined in §417.1 as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. You must review the hazard analysis to determine if it considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe. The hazard must be one that would be identified by a reasonable consideration of the food, how it was processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the planet) does not mean that the hazard analysis must address that hazard. If you have a concern about whether relevant hazards have been considered, you may decide to discuss issues with the establishment or seek guidance through the Policy Development Division.

You can use the HACCP System—Basic Compliance checklist (FSIS Form 5000-1) to assist in assessing compliance with Part 417 in a **new establishment**, when the establishment has developed a **new HACCP plan** for a new product or process or when you become aware that a major revision has been made to an existing HACCP plan.

1. Did the establishment conduct a hazard analysis or have one conducted for it?

2. Did the establishment's analysis start by identifying all hazards that may occur?

3. Does the hazard analysis identify preventive measures the establishment can apply to the food safety hazards?

4. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment?

5. Does the hazard analysis identify the intended use or the consumers of the finished product?

6. Does the result of the establishment's hazard analysis reveal one or more food safety hazards that are reasonably likely to occur?

7. Does the establishment have a written HACCP plan for each of its products?

8. Has the establishment conducted validation activities to determine if a HACCP plan can function as intended?

Note that Section 417.4(a)(1) provides more detail about the requirement for initial validation. "…The establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan." Validation data for any HACCP plan must include some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. This is necessary because validation must demonstrate not only that the HACCP plan is theoretically sound, but also that the establishment can implement it and make it work on a day-to-day basis.

9. Do the establishment's records include multiple results that verify the monitoring of CCP and conformance with critical limits?

10. Does the establishment have subsequent results that support the adequacy of corrective action in achieving control at a CCP after a deviation from a critical limit has occurred?

You also verify that the establishment training requirement as prescribed in §417.7 is met when the establishment implements a new HACCP plan or hazard analysis during the performance of procedure 03A01. At next weekly meeting after the new plan is in place, you are to ask establishment management about the individual's training who developed the HACCP plan. Since documentation that the individual attended HACCP training is not required, you must use the gather, assess, and determine (GAD) thought process. Ask:

- Has the person who developed the HACCP plan successfully completed training that included instruction on the 7 principles of HACCP?
- Did the training include a segment on the development of a HACCP plan for a specific product?
- Did the training include a segment on the review of records?

Document the discussion from the weekly meeting with establishment management in Memorandum of Interview (MOI). Give a copy of the MOI to establishment management and keep a copy in the government file. If the establishment use an individual that does not having the training prescribed in §417.7 to develop its HACCP plan, there is noncompliance. Document this noncompliance on an NR under the 03A01 procedure entering the "m" noncompliance result code on the procedure schedule.

Determining Basic Compliance

When a plant is determined to be in compliance, the answer to all questions on the checklist is "no." The statements on the checklist are worded as they are so that if a plant meets the basic (design) requirements, nothing needs to be marked on the checklist. When you determine that the plant is compliance, enter the unscheduled 03A01 procedure on the procedure schedule as "a" (performed) and file the completed

checklist in the government office. However, if basic noncompliance is identified an NR is issued. The checklist is stapled to the inspection copy of the NR.

When basic noncompliance is identified while conducting the 03A01procedure, you must know the appropriate regulatory actions to take. Whenever new federally inspected meat or poultry plants come under inspection, or when a plant starts producing a product under a new processing category and/or has created **a new HACCP plan that has not yet been in operation**, the following actions are appropriate if basic noncompliance is identified while performing procedure 03A01 –

1. The basic compliance checklist is completed. This document is to be attached to the copy of the NR filed in the Inspection office.
2. An NR is generated under procedure code 03A01 using the “m” noncompliance result code.
3. The establishment is not permitted to start the production of products under the noncompliant HACCP plan. In these situations, FSIS should not let the plant even start the production. The District Office should be notified of this action.
4. If the establishment has not yet received the grant of inspection, it is not under PBIS and no NR is issued. In this instance, the grant of inspection is withheld.

If the plant **has been producing the products covered under the plan**, contact the DO for further instructions. A withholding action should **not** immediately be taken because the plant has already been producing products. You are expected to take appropriate actions to ensure that no product that may be harmful to the consumer enters commerce, regardless of how long the establishment has been producing product under the conditions in question. Once you have taken necessary action to ensure product safety, you should contact the District Office.

30-Day Letter

You should issue a 30-day letter when you need more information to determine whether the establishment is meeting the requirements of §417.2. The 30-day letter gives the establishment an opportunity to support the decisions made or to reassess the hazard analysis and HACCP plan and make supportable decisions. Provide your Frontline Supervisor with a copy of the 30 day letter. If the establishment fails to provide you with the requested information within 30 days, contact the District Office, via supervisory channels, for instructions on further actions. Do ***not*** use a 30-day letter when there is noncompliance.

You must use good judgment when assessing an establishment’s supporting documentation. If you determine that the lack of supporting documentation results in an imminent food safety issue, follow the Rules of Practice. For example, if the establishment has a critical limit for chilling poultry carcasses to 50°F with no time limit, and it has no support for this critical limit, then the 30-day letter is ***not*** appropriate.

You should discuss your supporting documentation concerns with establishment management, and contact the Policy Development Division if technical guidance is needed.

Workshop: Reassessment and Hazard Analysis

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

1. Fill in the blanks:

9 CFR 417.4(a)(3)—Reassessment of the HACCP plan. Every establishment shall reassess the _____ of the HACCP plan at least annually and whenever any _____ occur that could affect the _____ _____ or alter the _____ 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 §417.7 of this part. The HACCP plan shall be _____ _____ whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

2. On 2-1-2008, you are performing the 03A01 procedure in a turkey slaughter operation to verify the annual reassessment requirement (close to the anniversary date of implementation). You review the HACCP plan and find that the annual reassessment was last performed and signed off on 1-1-2007.

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

3. You are performing the 03B01 procedure at a raw ground beef patty operation. You observe employees adding dry seasoning ingredients at the mixer. You are familiar with this plant, and this is the first time that you have observed any non-meat ingredients being used. After verifying that other consumer protection requirements have been met, you go to the HACCP office and review the HACCP plan. You find no documentation that this change to the product formula has triggered a reassessment.

a. What would you do next?

b. Why would you do that?

c. Is there a HACCP noncompliance?

d. If so, what regulations apply to this situation?

4. You are a relief processing inspector and have been assigned to cover a large beef slaughter and processing establishment. You find that the plant has been issued a 30-day reassessment letter. Please review the letter on the next page. IN YOUR OWN WORDS, briefly answer these questions.

a. What was the reason for issuing this letter?

b. What did FSIS ask the establishment to do?

c. What did FSIS ask the establishment to provide?

d. What should the FSIS inspector do after 30 days?

"date"
Mr. Plant Manager
Manager, Est. 00038 M
"address"

Example, for
Training use only

Dear Mr. Plant Manager,

FSIS has become concerned that the design of your HACCP plan is not adequate to ensure the safety of the products produced.

Your HACCP plan is required to adequately address the food safety hazards that are reasonably likely to occur with your operation. This includes the requirement in 9 CFR 417.5(a)(1) & (2) for supporting data and decision-making documents associated with the selection and development of critical control points (CCP). Without decision-making documents to support the design, FSIS is not able to determine if the HACCP plan meets the requirements in 417.2. Accordingly, in information obtained from your HACCP plan and your hazard analysis, you have made the selection of room temperature as the critical limit of your CCP for controlling microbiological pathogens on carcasses. There is no documentation, either historical data or other scientific or technical information, available in your HACCP plan, or in other establishment documents provided, to indicate a relationship between the temperature of the cooler and the control of microbiological pathogens on meat carcasses.

Under 9 CFR 417.5(a)(1) & (2), each establishment shall maintain records documenting the establishment's HACCP plan, including all supporting documentation for the written hazard analysis, and all decision-making documents for the written HACCP plan. This supporting and decision-making documentation must include relevant scientific, technical or historical data as well as information supporting any relationship associated with the selection and development of your CCP. This would also include supporting documentation to demonstrate that the preventive measures stated in your HACCP plan are adequate to control microbiological pathogens on meat carcasses, which you identified in your hazard analysis.

Adequate identification of hazards and of the CCP at which they are to be controlled is clearly at the heart of a valid HACCP system – doing so is necessary both to control the hazards and to facilitate documenting that control is being maintained. This is vital to protecting the public health. In addition, it is essential that establishments be able to support their decisions with documentation that is relevant to the control of any identified food safety hazards.

For the reasons stated above, FSIS is hereby notifying you that within 30 days you must reassess your HACCP plan to ensure that it meets the requirements of 9 CFR 417. This would include documentation suitable to support your decision to select room temperature as the critical limit of your CCP for controlling microbiological pathogens on carcasses. Information of this type can be obtained from numerous sources including, but not limited to, process authorities, published articles and scientific journals or through historical data that you have generated with your operation. If you believe that you do not have any reason to reassess your HACCP plan and to modify it, you need to be prepared to provide the scientific and technical data that support the plan as it is currently written. After 30 days, inspection program personnel will verify that your HACCP plan meets the regulatory requirements of all of 9 CFR 417.

If you would like to discuss this matter, I can be reached at "phone number".

Sincerely,

Jane Dough
Consumer Safety Inspector, "location"

Summary-Verifying the Five Regulatory Requirements

The following tables (**Table 1** and **Table 2**) provide a quick reference for the questions that you would seek answers to when verifying each of the requirements.

Table 1—Monitoring, Verification, and Recordkeeping Requirements

Monitoring	Verification	Recordkeeping
9CFR 417.2(c)(4) 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? 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 CCP listed in the HACCP plan? 4. Are the CL met?	**9CFR 417.2(c)(7) 417.4(a)(2)(i)(ii)(iii)** 1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments? 2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities & corrective actions? 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)? 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 direct observation 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?	**Recordkeeping Requirement – 9CFR 417.2(c)(6)** 1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP? 2. Do the records contain actual values & observations obtained during monitoring? **Supporting Documentation Requirement – 9CFR 417.5(a)** 1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis? 2. Does the establishment have the decision-making documents associated with the selection of each CCP? 3. Do documents explain why the establishment selected the location of the CCP? 4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards? 5. Does the establishment have scientific, technical, or regulatory support for the critical limit? 6. Does the support appear creditable? 7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan? 8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done? 9. If the establishment has supporting documents for these decisions, does the documentation support the decisions? **HACCP Records Requirement – 417.5(a)(3)** 1. Do the records document the monitoring of CCP and 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 verification procedures and results 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 process-monitoring calibration procedures & results recorded? **Records Authenticity Requirement – 417.5(b)** 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? **Computerized Records Requirement – 417.5(d)** Are appropriate controls provided to ensure integrity of electronic data and signatures? **Record Retention and Availability Requirement – 417.5(e)(1) and (2)** 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? 2. Are the records kept on-site for 6 months? 3. If the records are stored off-site, can they be retrieved in 24 hours? **Pre-shipment Review Requirement – 417.5(c)** 1. Has the establishment reviewed the records associated with the production of the product, prior to shipment? 2. Has the pre-shipment review been signed & dated by an establishment employee?

Table 2-Corrective Action and Reassessment Requirements

Corrective Actions	Reassessment
Corrective actions in response to a deviation from a critical limit – 9CFR 417.3(a) 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? **Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action or an Unforeseen Hazard – 9CFR 417.3(b)** 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?	**Annual reassessment requirement or changes in plant processes - 9CFR 417.4(a)(3)** 1. Did the establishment perform the annual reassessment of its plan or plans at some point during the previous calendar year? 2. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis? 3. Has any change occurred that could affect the hazard analysis or HACCP plan? 4. Did the establishment reassess? 5. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, was the HACCP plan modified immediately? 6. Did the establishment sign and date the HACCP plan or plans during the previous calendar year and upon any modification to the plan? 7. Has the individual who reassessed the HACCP plan, or who modified the plan, completed training or a course in the seven principles of HACCP including a segment on the development of a HACCP plan for specific product and review of records? **Reassessment of the Hazard Analysis – 9CFR 417.4(b)** 1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur? 2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists? 3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes. 4. Has the individual who reassessed the hazard analysis met the training requirement prescribed in §417.7?

Note: Corrective Action and Reassessment requirements are verified at **each occurrence**. For example, if you are performing the 01 or 02 procedure and you notice that the establishment had a deviation from a critical limit, you would verify that the corrective action requirements had been met.

Now let's summarize and review the methodology for verifying compliance with the five requirements by performing the 01 and 02 procedures.

Performing the 01 Procedure

Remember that the 01 procedure is for verifying compliance with a random sample of the regulatory requirements. To perform the 01 procedure, you will do the following:

1. Randomly select one (or more) of the three HACCP requirements to verify.

2. Select a HACCP plan.

3. Select one (or more) of the CCP from the HACCP plan to verify.

4. Determine which component to perform (Rk or R&O).

5. Read the pertinent part of the HACCP plan.

6. Perform the verification for that requirement for that CCP.

Corrective Actions and Reassessment will be verified as part of the 01 procedure at each occurrence but cannot be randomly selected.

Remember, the thought process you should use when verifying regulatory requirements includes:

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

Note: You may wish to use **Table 1** and **Table 2** as an aid in performing the 01 procedure.

01 Example 1: *An 03J01 procedure is on the Procedure Schedule for this date. You randomly select to verify the monitoring requirement. You decide to verify this requirement at CCP-2, the Carcass Chiller CCP, using the review and observation component. Your selection from among the possible requirements to verify is shown in the diagram below.*

CCP-1 Fecal	**CCP-2 Carcass Chiller**	**CCP-3 Reprocessing**
Monitoring Verification Recordkeeping Corrective Action* Reassessment *	**Monitoring** √ **R&O** Verification Recordkeeping Corrective Action * Reassessment *	Monitoring Verification Recordkeeping Corrective Action * Reassessment *

** verified at each occurrence*

*You gather information by seeking answers to the questions from **Table 1** for monitoring by:*

- *Reviewing the HACCP plan*

- *Reviewing the chiller temperature recording chart.*

- *Taking an independent measurement of the chiller medium temperature.*

- *Comparing your findings to the chiller temperature recording chart.*

You assess the information that you have gathered and you determine regulatory compliance.

01 Example 2: *An 03B01 procedure is on the Procedure Schedule for this date. The HACCP plan has two CCP: CCP- 1 Receiving and CCP- 2 Finished Product Storage. You randomly select to verify the recordkeeping requirement. You elect to verify the requirement at CCP 2-Finished Product Storage using the recordkeeping (Rk) component. Your selection from among the possible requirements to verify is shown in the diagram below.*

CCP-1 Receiving	**CCP-2 Finished Product Storage**
Monitoring Verification Recordkeeping Corrective Action * Reassessment *	Monitoring Verification **Recordkeeping** √ **Rk** Corrective Action * Reassessment *

** verified at each occurrence*

You gather information by seeking answers to the questions from ***Table 1*** *for recordkeeping. You proceed to the QA office where you request to look at the records from the previous day for the finished storage CCP. You examine the records and assess the information.*

After you have gathered and assessed all available information pertaining to the recordkeeping requirement, you determine regulatory compliance. You should verify as many as possible (for records, check the date, initials, if the CL was met, the time, monitoring and/or verification results, corrective actions, etc., and in the plan, check the recordkeeping system).

Performing the 02 Procedure

The 02 procedure is performed by verifying **all requirements at all CCP for a specific production** including the pre-shipment review. The 02 procedure verifies implementation of the HACCP plan as it is applied to a specific production. You may use either, or both, components in performing the 02 procedure. To perform the 02 procedure, you will do the following:

1. Read the HACCP plan.

2. Verify all of the HACCP requirements have been met for all CCP in the HACCP plan for that specific production.

3. Verify the pre-shipment review requirement is met for that specific production.

Corrective Actions and Reassessment will be verified as part of the 02 procedure at each occurrence.

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

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

Note: As with the 01 procedure, you may wish to use **Table 1** and **Table 2** as an aid in performing the 02 procedure.

02 Example 1: *You are performing the 03B02 procedure and proceed to verify all the requirements at all the CCP for the first lot of ground beef patties produced on the shift. The establishment has two CCP: receiving and storage temperature. You would seek to answer the questions in* ***Table 1*** *for all of the requirements at both of the CCP. You decide to use the recordkeeping component at the receiving CCP. For the storage temperature CCP you decide to use the review and observation component since there have been some inconsistencies in the cooler temperatures lately. The CCP and the associated requirements, along with the components you selected to use in performing the procedure, are shown in the diagram below.*

CCP-1 Receiving	**CCP-2 Finished Product Storage**
Monitoring √ **Rk** **Verification** √ **Rk** **Recordkeeping** √ **Rk** Corrective Action * Reassessment *	**Monitoring** √ **R&O** **Verification** √ **R&O** **Recordkeeping** √ **R&O** Corrective Action * Reassessment *

**verified at each occurrence*

You proceed to check the records at the receiving CCP to see if all requirements have been met, and then you go to the storage area to take a temperature measurement

using the wall thermometer and compare it to the continuous recording thermometer. You also check the records at this CCP to verify it meets the regulatory requirements. There has been no corrective actions nor reassessment associated with this lot of product so you would not verify these requirements. Later in the shift you go to the QA office to check records to determine that the establishment has carried out the ***pre-shipment review*** *for that particular lot.*

Note: You will **always** perform the 02 procedure when noncompliance is found as a result of performing the 01 procedure.

02 Example 2: *You performed a poultry fecal slaughter food safety standard check as part of a 03J01 procedure and found one noncompliance in the sample set of 10 birds. You notified the establishment and they executed the appropriate corrective actions according to 417.3(a). You proceed to perform a 03J02 procedure on the specific production to verify that all regulatory requirements are met. You decide to use the recordkeeping component to seek answers to all of the questions in* ***Table 1*** *and* ***Table 2*** *for this specific production. In addition, you perform a 10 bird fecal check as part of the 02 procedure to verify the CCP is in control. Lastly, you go to the pre-shipment review location and verify that the establishment has carried out the pre-shipment review.*

Summary Workshop

1. You are assigned to a small pork slaughter establishment. There is one HACCP plan with two CCP. Your PS for today lists 03J01. Please describe how you would go about performing this procedure, including the thought process you would use.

2. Continuing with the above example, you determine noncompliance during the performance of the 03J01 procedure. Remember, that the 02 procedure must be done every time an 01 procedure results in a noncompliance determination. Describe how you would go about performing the 02 procedure, including the thought process you would use.

Slaughter Food Safety Standard

As we mentioned in the hazard analysis section, the establishment must have controls in place to prevent the contamination of carcasses with certain contaminants, such as fecal material. Now let's discuss the food safety standard for livestock and poultry postmortem and how they are verified.

Enforcing Food Safety Standard for Livestock Postmortem

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

FSIS enforces food safety standards for fecal, ingesta, and milk contamination on livestock carcasses and on head meat, cheek meat, and weasand meat through postmortem inspection activities at establishments that slaughter livestock. The establishment must meet the food safety standard for visible fecal, milk, and ingesta contamination on livestock carcasses at or after the **postmortem rail inspection station,** regardless of the location of the CCP. The CCP for pathogen contamination or visible contaminants may be at other locations as supported by the hazard analysis.

- For example, the establishment may locate the critical control point after the postmortem rail inspection station.

- In other cases, the establishment may have a CCP prior to the postmortem rail inspection station.

Note: Regardless of the location of the CCP, FSIS off-line inspectors will verify compliance with the food safety standard at the rail inspection station.

When the on-line inspectors at the rail station find feces, ingesta, or milk on livestock carcasses, the establishment reexamines and reconditions the entire carcass (trimming all contamination). **On-line** inspectors are to **stop the slaughter line** for carcass reexamination and reconditioned by the establishment **unless**:

- The establishment has elected to provide a rail-out loop to rail contaminated carcasses off-line for reexamination, trimming, and positioning back on the line for final inspection, **and**

- The IIC has not determined that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses.

Additionally, on-line inspection program personnel are to notify the IIC or, if unavailable, other off-line inspection program personnel when they believe that:

- An establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses, or

- An establishment's slaughter or dressing processes are not under control (for example, when repeated presentation of carcasses contaminated with fecal

material, ingesta, or milk for postmortem inspection at the rail inspection station indicates failure to control dressing processes).

Establishments must also meet the food safety standard for no visible fecal, milk, or ingesta contamination on head meat, cheek meat, and weasand meat at the end of the harvesting process after all of the establishment controls and interventions have been implemented. This verification may take place at the time of packaging or when product is placed in a container for storage.

When verifying the food safety standard, inspection personnel should verify that the establishment is meeting all of the requirements, including no fecal, milk, or ingesta contamination on carcasses, and the head meat, cheek meat, and weasand meat.

If the on-line head inspector finds fecal, milk, or ingesta contamination, the contamination must be removed by the establishment before the head can be passed. Also, if the on-line inspector finds fecal, milk, or ingesta contamination on weasand meat during the harvesting step, the establishment must remove the contamination before the weasand meat can be passed. If fecal, milk, or ingesta contamination is repeatedly found, on-line inspection personnel are to notify the off-line inspection personnel. The off-line inspection personnel will perform verification activities to determine if the establishment's process and sanitary dressing procedures are controlling fecal, milk, and ingesta contamination during the head meat or weasand meat production process.

IIC and other off-line inspection program personnel will verify the adequacy of establishment procedures to ensure compliance with the food safety standard for fecal, ingesta, or milk contamination, **when notified by on-line inspection program personnel of an apparent problem or when scheduled by PBIS.**

Follow these steps when verifying establishment procedures for livestock carcasses:

1. **Off-line** inspection program personnel are to randomly select carcass units at the **postmortem rail inspection station** for examination on-line, at or after the postmortem rail inspection station, **regardless of the location of the CCP**. (This inspection should occur before the final wash. In situations where this is difficult, such as those related to worker safety, the IIC should develop appropriate procedures with plant management in order for this inspection to be properly conducted).

2. Based on the expected slaughter volume for that day (number of animals), determine the number of carcass units to be examined, using the following table. If carcasses are split, each half carcass is ½ of a carcass unit. (Select two times as many half-carcasses.)

Slaughter Volume (# of animals per day)	**# of Carcass Units (Unit = whole carcass)**
100 or less	2
101 to 250	4
251 to 500	7
More than 500	11

Note: It is not necessary to examine all of these units at the same time.

3. Examine the selected carcass units using the same technique that inspection program personnel use at the postmortem rail inspection station.

Follow these steps in livestock slaughter establishments when verifying establishment procedures for head meat, cheek meat, and weasand meat:

1. Review the HACCP plan.
2. Examine the same amount of product as the establishment has listed in the HACCP plan for monitoring procedures. (Note: If the establishment does not have documents supporting the monitoring procedures and frequency, there is noncompliance with 9 CFR 417.5(a)(2).)
3. Select product after all of the establishment controls and interventions have been applied. Verification may occur at the time of packaging or when product is placed in a container for storage.

03J01

If the 03J01 is scheduled, perform the 01 procedure as per the methodology (randomly select 1 or more of the 3 regulatory requirements, pick a plan, select 1 or more CCP, determine which component to perform, read the pertinent part of the plan and use the GAD thought process) ***and*** perform the slaughter food safety performance standard check for carcasses and head/cheek/weasand meat.

If there is a need to perform an unscheduled slaughter food safety performance standard check, you only perform the check on the carcasses and head/cheek/weasand meat. When it is unscheduled, you can follow the 01 methodology, but it is not required.

Off-line inspection program personnel who find feces, ingesta, or milk on carcasses in livestock slaughter establishments, and the head meat, cheek meat, and weasand meat in livestock slaughter establishments as part of an **03J01** procedure will:

a. Notify establishment of the contamination

b. Verify that the corrective action requirements of 9 CFR 417.3 are met.

b. Issue an NR using the "monitoring" noncompliance classification indicator.

c. Perform procedure 03J02. Focus on the specific production thereafter, in which one or more contaminated carcasses or carcass parts were found.

03J02

Whether or not the 03J02 is scheduled, **anytime** you perform the 03J02, you must follow the 02 methodology.

Off-line inspection program personnel who find feces, ingesta, or milk on carcasses in livestock slaughter establishments, and the head meat, cheek meat, and weasand meat in livestock slaughter establishments as part of an **03J02** procedure will:

a. Notify establishment of the contamination finding.

b. Complete the 03J02 procedure for that product, including verification of the corrective action requirement.

c. Document all noncompliances on an NR using the most appropriate noncompliance classification indicator. If the only noncompliance was the fecal material, milk, or ingesta contamination, the monitoring noncompliance classification indicator would be documented.

Enforcing the Food Safety Standard for Poultry Postmortem

References: FSIS Directive 6420.2, 381.65(e), and part 417.

FSIS enforces a food safety standard for visible fecal material on poultry carcasses and poultry carcass parts through postmortem inspection and reinspection activities at poultry slaughter establishments. This food safety standard also is reflected in the regulations. FSIS views preventing carcasses with visible fecal contamination from entering the chilling tank as critical to preventing the cross-contamination of other carcasses.

In each establishment slaughtering poultry, in conjunction with other postmortem inspection and reinspection activities, **off-line** inspection personnel are to perform fecal contamination checks.

These checks are performed at either the same location as pre-chill testing in establishments inspected under the finished products standards (FPS), or the inspection station where Acceptable Quality Level (AQL) testing is conducted in a plant under traditional inspection, regardless of the location of the plant's CCP. To perform a fecal contamination check, inspectors are to:

- Select 10 carcasses randomly (using an established FSIS method), and
- Examine the selected carcasses off line using the following inspection procedure:

- For the outside back – While holding the carcass, with the back of the carcass toward the observer, start at the hock area and observe the hocks, back part of the legs, tail area, back of the carcass and top side of the wings.
- For the outside front – Turn the carcass and observe the bottom side of the wings, breast, and front part of the legs.
- For the inside – Observe the inside surfaces of the carcass and the abdominal flaps and fat.
- For the neck flap area – Observe the neck flap and the thoracic inlet area.

At least two fecal checks will be performed for each line on each shift.

Using procedure code 03J01 or 03J02, record the results for every ten bird check performed. If inspection program personnel are only conducting the 10-bird check to verify that the establishment's process is producing carcasses free of visible fecal material, they are performing procedure 03J01. If inspection program personnel are verifying other HACCP regulatory requirements in conjunction with the 10-bird check, inspection program personnel can be performing the 03J01 or 03J02 procedure.

If the 03J01 is scheduled, perform the 01 procedure as per the methodology (randomly select 1 or more of the 3 regulatory requirements, pick a plan, select 1 or more CCP, determine which component to perform, read the pertinent part of the plan and use the GAD thought process) ***and*** perform the slaughter food safety performance standard check.

For example, if you were in a plant with 2 poultry lines, you would need to perform a minimum of 4 slaughter food safety performance standard checks. If the 03J01 were scheduled for the day, you would mark the appropriate result code on the procedure schedule for the scheduled 03J01 and the other 3 are documented as unscheduled 03J01 based on the result of the checks. Therefore, you have 4 separate 03J01 entries in PBIS.

If no visible fecal material is found on a check, the Procedure Schedule will be marked as performed to indicate compliance.

If fecal material is found, the inspector will:

- Notify the establishment of the contamination.
- Verify that the corrective action requirements of 9 CFR 417.3 are met.
- Complete a Noncompliance Record (NR) and mark the monitoring noncompliance classification indicator.
- If the noncompliance was found when performing an 03J01 procedure, perform 03J02 to ensure the adequacy of the HACCP system for the specific lot of product.

If ingesta is observed during the fecal contamination check, the establishment should be notified of this finding. The ingesta should be removed from the bird. There would be no noncompliance for this finding.

Workshop: Food Safety Standard in Slaughter

Refer to the module to complete the following questions.

1. What contaminants are covered by the food safety standard in livestock slaughter?

2. What parts must be free of these contaminants?

3. At what location will FSIS verify the food safety standards for livestock carcasses?

4. Where will FSIS verify the food safety standard for head meat, cheek meat, and weasand meat in livestock slaughter operations?

5. If a livestock slaughter establishment has a CCP for visible contaminants for livestock carcasses at the final washer, where would FSIS verify compliance with the food safety standard?

6. You are a GS-7 inspector working the rail inspection station in a large beef slaughter establishment. You notice a fecal smear on the hindquarter of a carcass. The establishment has a rail-out procedure.

   a. What action would you take?

   b. What action would you take if the establishment had no rail-out procedure?

   c. What is expected of the establishment?

   d. Would a Noncompliance Record (NR) be completed by the on-line inspector? By the off-line inspector?

   e. If you had repeated instances of contaminated carcasses during your time at the rail inspection station, what would you do?

7. You are a GS-8 off-line slaughter inspector in a large beef slaughter establishment that kills 2000 head per shift. You are performing an 03J01 procedure to verify compliance with the food safety standard.

   a. How many **sides** would be selected for examination?

   b. Where, and with what technique, would the sample sides be examined?

   c. If no feces, ingesta, or milk is found on the samples, what action would you take?

   d. If ingesta were found on one carcass side, what action would you take?

8. What contaminants are covered by the food safety standard in poultry slaughter?

9. At what location will FSIS verify the food safety standard for poultry slaughter?

10. If the establishment has a CCP at the antimicrobial rinse after the pre-chill FPS inspection location and just prior to the chiller, where would FSIS verify compliance with the food safety standard?

11. You are a new GS-8 off-line slaughter inspector at a large poultry slaughter operation that has 4 lines and slaughters 160,000 per shift. The establishment has two shifts.

    a. How many fecal contamination checks would need to be performed for one shift including all lines?

    b. How many birds are examined at each check?

    c. What procedure code is used for the checks?

d. How are the birds selected at the pre-chill inspection station?

e. If you find a fecal noncompliance, what actions would you take?

f. If you do not find a fecal noncompliance in any of the checks, what actions would you take?

12. The plant sets “specific production” as all product from one line for a shift. While performing a food safety standard check on line 2, you found feces on a chicken carcass. About two hours later, you notice feces on a carcass on this same line after the washer and prior to the chiller. The establishment tells you that since you were not performing a procedure, the second finding was not a food safety standard failure. Is this correct? Why or why not?

13. How do you determine the amount of product to inspect when performing the off-line procedure in a livestock slaughter establishment to verify that the meat from heads, cheeks, and weasands are not contaminated with fecal material, ingesta, or milk?