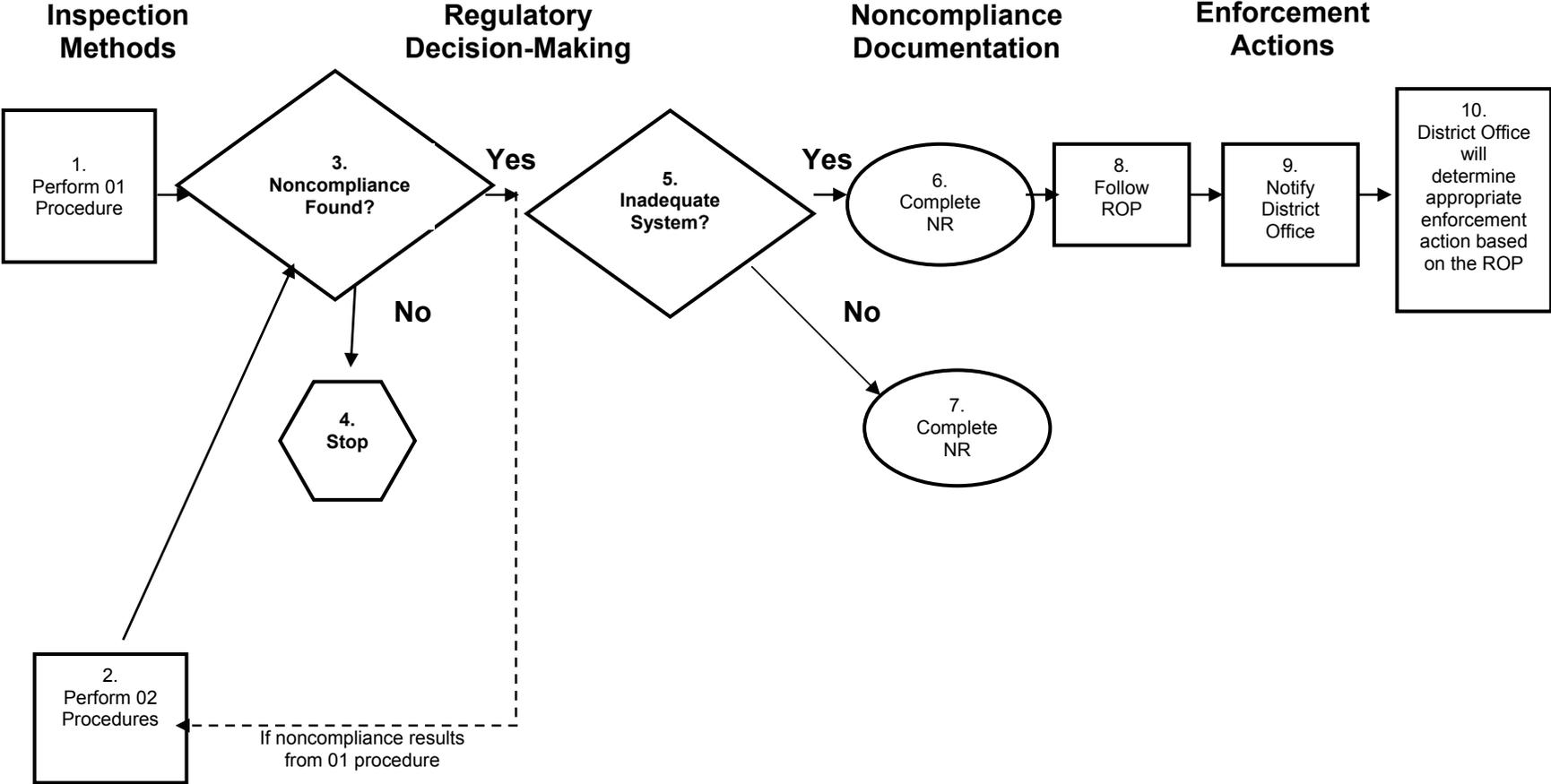


Regulatory Process for HACCP



Overview of the Regulatory Process

The diagram on the previous page shows the **Regulatory Process for HACCP**. It includes the following four steps: (1) inspection methods (HACCP 01 and 02 procedures), (2) regulatory decision-making, (3) compliance/noncompliance determinations, and (4) enforcement actions. As we cover in-plant inspection personnel's HACCP verification responsibilities, we'll explain the CSI responsibilities in the regulatory process.

FSIS Responsibilities

FSIS responsibilities are outlined in **FSIS Directive 5000.1, Revision 1**. The CSIs are responsible for understanding and properly performing the Agency's verification procedures as described in this Directive. The information in the Directive follows the regulatory process for HACCP. The Directive is the foundation for the remainder of this training. In this section, when the word "verification" is used it will refer to Agency, not establishment, verification procedures as defined in 9 CFR §417.8 unless specified.

Let's review what is covered in the Directive for HACCP verification. Turn to Chapter Two, and review the Table of Contents. Verification methodology is the first section. This includes 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 requirements. In Part IV, the Directive covers how to perform verification of the establishment's verification requirements. This is followed by how to verify the recordkeeping requirements, the corrective action requirements, and finally the reassessment requirement.

Now, take a few minutes to read Part I, HACCP Verification Methodology, of FSIS Directive 5000.1, Revision 1.

Verification Methodology/Inspection Methods

Let's review the information covered in Part I, HACCP Verification Methodology. The CSI uses two types of HACCP verification procedures – the 01 and 02 procedures – for verifying that an establishment complies with the requirements of 9 CFR Part 417. 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 the HACCP procedures has two components – a **recordkeeping** component and a **review and observation** component. The CSI can use either of these components, or a combination of these components to verify regulatory compliance.

To perform the **recordkeeping** component, the CSI reviews HACCP records to verify compliance. The CSI should select HACCP records and review them to verify that the records include all of the information necessary to meet the regulatory requirements.

To perform the **review and observation** component, the CSI might take measurements and compare the result with the company records to determine regulatory requirements or observe an establishment employee performing the activity listed in the HACCP plan and documenting the findings on the establishment records to make a determination on whether the establishment is following the plan and making accurate and timely record recordings.

The CSI can use one or both of these components to verify HACCP regulatory requirements. For example, the CSI can review records at one CCP, and/or take a measurement or observe the establishment take a measurement at another CCP along with a review of the records generated to verify that requirements are met.

If the CSI questions the content of the HACCP plan, while performing either the 01 or 02 procedure, he or she should review the hazard analysis and the decision-making documents supporting the hazard analysis to verify that the establishment can support the contents of its HACCP plan.

HACCP 01 Procedure

The HACCP 01 procedure is for randomly verifying one or more of the HACCP regulatory requirements. There are five regulatory requirements – monitoring, verification, recordkeeping, corrective actions, and reassessment. Because corrective actions and reassessment are triggered by a specific event, the majority of the time the CSI will be randomly verifying the requirements that are performed by the establishment on an ongoing basis – monitoring, verification, and recordkeeping. The CSI would verify that the corrective action requirements are met every time they are aware that a deviation or unforeseen hazard has occurred. Reassessment might be part of the corrective actions implemented by the establishment and would be verified in these situations as part of the corrective action verification.

HACCP 02 Procedure

The 02 procedure is used to verify **all** of the requirements (monitoring, verification, recordkeeping, corrective actions, and reassessment) at **all** CCPs in the HACCP plan for a specific production (defined by the establishment in terms of “lot” or shipment of product). The 02 procedure cannot be completed until the pre-shipment review is completed for the entire given lot/pallet, 1 hour of production, batch, smokehouse or shipment of product. When the CSI performs the HACCP 02 procedure, he or she should verify that the monitoring, verification, recordkeeping, corrective action, and reassessment requirements are met at all CCPs in the HACCP plan for a specific production.

In summary:

To perform the **01** procedure, the CSI will:

1. Review HACCP plan
2. Randomly select one or more of the HACCP requirements to verify (the CSI will not randomly verify the corrective action and reassessment requirements).
3. Select one or more of the CCPs from the HACCP plan where the verification will occur.
4. Determine which component (review and observation or recordkeeping) to perform.
5. Verify the requirement for that CCP.

Note: If the CSI determines noncompliance while performing the 01 procedure, the CSI must then perform the 02 procedure.

To perform the **02** procedure, the CSI will:

1. Review the HACCP plan.
2. Verify **all** of the HACCP requirements have been met at **all CCPs** in the HACCP plan for that **specific production**.
3. Also, verify that the **pre-shipment review** requirement for that specific production has been met.

Workshop 

Questions - 01 and 02 procedures

1. Which HACCP procedure is used to verify all five of the requirements in a HACCP plan for a specific production?
2. Which HACCP procedure is used to verify one or more of the requirements for one or more CCPs in a HACCP plan?
3. What are the five HACCP regulatory requirements that are verified when performing the HACCP 01 and 02 procedures?
4. An establishment has one HACCP plan with 2 CCPs (identified 1-2). Describe how you would perform the HACCP 01 procedure. Then, describe how you would perform the HACCP 02 procedure.
5. What are the two components of each HACCP procedure (01 and 02)?

Inspection Methods and Regulatory Decision-making

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. Let's start with the monitoring requirements. First, read Part III, Monitoring Requirement, of FSIS Directive 5000.1, Revision 1.

(1) *Monitoring*



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

- 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

CSIs verify the monitoring requirement by performing the HACCP 01 or 02 procedures. Use the following thought process and methodology when verifying the monitoring requirements. Verify the regulatory requirements for monitoring by reviewing the HACCP plan, reviewing HACCP records, observing establishment employees performing monitoring activities, and taking measurements at CCPs. When verifying the monitoring requirements, seek answers to the following questions.

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

Assessing Information

When assessing the information gathered, the CSI should do the following.

- Review the HACCP plan to determine whether the HACCP plan design contains monitoring procedures and frequencies for each CCP. Since the HACCP plan can be modified without the establishment notifying the CSI, the CSI should ensure that he or she is familiar with the monitoring procedures and frequencies in the HACCP plan each time he or she verifies the monitoring requirement. From the HACCP plan, the CSI should be able to visualize what the establishment employees do to monitor the CCP and how often this activity occurs. If the CSI cannot visualize what is occurring at the CCP, it could be an indication that the monitoring procedure is not adequately described.
- Observe an establishment employee performing the monitoring activities listed in the HACCP plan to determine whether the procedures are being carried out as written in the HACCP plan.
- Review monitoring records and/or observe the establishment performing the monitoring procedures to determine whether the monitoring procedures are being performed at the frequencies specified in the HACCP plan.

Determine compliance

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

Examples of monitoring noncompliance

There is noncompliance when:

- The establishment is not conducting the monitoring procedures as specified in the HACCP plan.
- The establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.
- The CSI takes a measurement at a CCP and finds that the critical limit is not met.

Note: We will discuss how to document noncompliance later during this training. Noncompliance with the monitoring requirements is documented using the monitoring trend indicator.

Workshop

Monitoring

Here are 2 examples of monitoring procedures and frequencies as stated in an establishment's HACCP plan and the CSI's findings when performing HACCP 01 or 02 procedures. Use the questions in 5000.1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider **just** the information presented in this workshop.

Key questions from FSIS Directive 5000.1, Revision 1.

- 1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the critical control points to ensure compliance with the critical limits?*
 - 2. Are the monitoring procedures being performed as described in the HACCP plan?*
 - 3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?*
 - 4. Are the critical limits met?*
-
1. The HACCP plan specifies that once each hour of operation monitoring personnel will take an internal product temperature measurement using a hand-held dial thermometer from a piece of product from the top and bottom tier of a rack moving through the continuous smokehouse. While performing the observation part of the review and observation component of a HACCP 01 procedure to verify the monitoring requirement, the CSI observes the monitoring procedure. The monitor took one temperature and recorded the result.

2. The HACCP plan specifies that the amount of sodium lactate (NaL) in each bologna batch produced during the day will be weighed and documented in the NaL log. While performing the recordkeeping component of the HACCP 02 procedure to verify all regulatory requirements were met, the CSO reviews the smokehouse recording chart records from yesterday and finds that four batches of bologna were produced. Next, the CSI reviews the NaL monitoring log and finds only three NaL amounts recorded on yesterday's log.

Scenario

Use the questions in FSIS Directive 5000.1, Revision 1 to explain what the CSI should do next in performing the following 01 or 02 procedures.

At Est. P-42, 03G01 is scheduled on the PS. The CSI randomly selects the monitoring requirement to verify while performing the review and observation component of the 03G01 procedure. The CSI reviews the HACCP plan and sees that the monitoring procedure for CCP 3 is to check the cooked internal temperature of turkey bologna. The plan states that the smokehouse operator will check the internal temperature using a hand-held digital thermometer of 1 piece of product from 3 locations on each rack of product (top, middle, bottom) in every smokehouse of product. The critical limit is 160°F or higher. The smokehouse operator will document all 3 readings on the Smokehouse Record. The CSI goes to the smokehouse area and discovers that the smokehouse operator is ready to conduct a monitoring check on the product the CSI planned to check. What does the CSI expect to see?

The CSI decided to also take a product temperature. What does the CSI do?

The CSI looks at the smokehouse record. What is the CSI looking for?

(2) Verification

This next section covers how to verify compliance with the verification requirements while performing your HACCP duties using the HACCP 01 and 02 procedures. Read Part IV, Verification Requirement, of FSIS Directive 5000.1, Revision 1.



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

- 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

CSIs verify the verification requirement by performing the HACCP 01 or 02 procedures. The CSI should use the following thought process and methodology verifying the regulatory requirements for verification. The CSI will verify the regulatory requirements for verification by reviewing the HACCP plan, reviewing HACCP records, and observing establishment employees performing verification activities. In verifying the verification requirement, the CSI should seek answers to the following questions.

1. Does the HACCP plan contain verification procedures and frequencies for the calibration of the process-monitoring instruments?
2. Does the HACCP plan contain verification procedures and frequencies for direct observations of monitoring activities and corrective actions?
3. Does the HACCP plan list verification procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

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

Assessing information

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

- Review the HACCP plan to determine whether the HACCP plan lists direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring instrument calibration procedures and frequencies. The CSI should review the HACCP plan each time the verification requirement is verified since the establishment can modify the plan without notifying inspection personnel.
- Observe an establishment employee perform the verification activities listed in the plan to determine if the procedures are being conducted as written in the HACCP plan.
- Review the HACCP records or observe the establishment performing the verification procedures to determine if the verification procedures are being performed at the frequency specified in the HACCP plan.
- If product sampling is included in the HACCP plan, the CSI should observe an establishment employee taking samples and review the results as part of the HACCP 01 or 02 procedures. If the establishment received positive results, the CSI should verify the corrective action requirements of 9 CFR 417.3(b) are met.

The CSI should use good judgment in recognizing that there are times when a HACCP plan might not include all three ongoing verification activities listed in 417.4(a)(2)(i)(ii)(iii). For example, if the establishment has a CCP where process-monitoring equipment is not used, there is no need for process monitoring equipment calibration to be listed as a verification activity. In a very small establishment, there may only be one individual working in the processing area performing both the monitoring and verification activities, this one individual cannot perform a monitoring activity **and** observe himself doing it as a direct observation verification activity. In this case, the HACCP plan would not need to list a direct observation of the monitoring activities.

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

Product sampling is often viewed as a verification activity *if* the establishment incorporates product sampling into the HACCP plan. It may be used to verify a CCP or it may be used as an overall verification of the HACCP system and not be associated with any one CCP. For example, some establishments may include their *Lm* testing programs in the HACCP plan. When that is the case, the CSI must verify the testing program is in compliance with the verification requirement (§417.4(a)(2)). The establishment may perform end-product sampling. If the establishment does end-product sampling, the verification is not necessarily associated with a single CCP, but it could be an overall verification of all the CCPs from the specific HACCP plan. 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, the CSI 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).

Each of the 3 on going verification activities are expected in the HACCP plan. It is not required that each be done for every CCP.

Determine compliance

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

Example: The CSI is scheduled to perform the 03101 procedure. The CSI randomly selects to verify the verification requirement at the finished product storage CCP. The CSI reviews the establishment's HACCP plan and finds one of the verification procedures specifies the HACCP Coordinator will observe maintenance personnel perform the monitoring check once per shift. The CSI reviews several recent room temperature logs and observes that the HACCP Coordinator has recorded results for the verification procedure for each shift. Therefore, the CSI determines that the direct observation requirement is met because the verification procedures are being performed as specified in the HACCP plan.

Example: Continuing with the 03I01 example, the CSI's review of the establishment's HACCP plan revealed that another verification procedure specified is that the HACCP Coordinator will check the accuracy of the finished product storage temperature monitoring equipment monthly, and calibrate as necessary. The CSI proceeds to the HACCP office, and reviews the thermometer calibration log. The thermometer calibration log has monthly entries demonstrating that the instruments were checked for accuracy as per procedures and frequencies in the HACCP plan. The CSI determines that this requirement is met because this verification procedure is being carried out as written in the HACCP plan. Is there any other type of verification activity the CSI may verify? Yes-records review.

Examples of noncompliance include the following.

1. 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 does not list the frequencies at which the calibration verification procedure will be performed.
3. The establishment is not performing the direct observation verification procedures as specified in the HACCP plan.
4. The establishment is not performing the records review verification procedures as specified in the HACCP plan.
5. The establishment is not performing the process-monitoring instrument calibration verification procedures as specified in the HACCP plan.
6. The establishment is not performing one or more of the verification procedures listed in the HACCP plan at the frequencies specified in the HACCP plan.

Noncompliance with the verification requirement is documented using the verification trend indicator.

Workshop Verification

Questions from FSIS Directive 5000.1, Revision 1.

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?*
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?*

Here are 6 examples of possible noncompliance. Use the questions in FSIS Directive 5000.1, Revision 1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider **just** the information presented in the example.

1. While performing a 03G01 procedure, the CSI reviews the HACCP plan and finds the verification activities listed in the HACCP plan state, “QC will observe the smokehouse operator monitor internal temperatures at least once per shift. QC will also take an internal temperature of product at the end of the cooking cycle at least 3 times per week. QC will review all Smokehouse Records at the end of each shift.” Using the questions from FSIS Directive 5000.1, Revision 1, do the activities listed in this plan meet the verification requirements?

2. The CSI is verifying the verification requirement while performing the recordkeeping component of the 03G01 procedure on the Friday afternoon shift in the previous example. The CSI reviews all of this week's records and notes that QC has recorded an internal temperature three times in the past week. The establishment's verification records indicate that QC reviewed the smokehouse records for the past four days (Monday – Thursday). These are all of the verification results available.
 - (a) Based on this information, is the establishment performing the direct observation verification frequencies as specified in the HACCP plan?
 - (b) Is the establishment performing the records review verification procedures as specified in the HACCP plan?

3. The CSI is assigned to a very small plant that only has one production employee. The CSI reviews the HACCP plan to ensure he/she is familiar with the current version and finds that the HACCP plan lists records review and thermometer calibration as the verification activities. Does this HACCP plan meet the requirements in 9 CFR 417.4(a)(2)(i)(ii)(iii)?

4. The CSI is performing the recordkeeping component to verify the verification requirement by reviewing the records for the past week. The CSI first reviews the HACCP plan to be familiar with the verification procedures and frequencies. The establishment's verification procedures state that direct observation of the monitor will be done weekly at each CCP and calibration of process-monitoring instruments will be done weekly. It also lists that the review of records will be conducted once daily. It lists the records that will be maintained for verification. The CSI sees the notation for observing the monitoring activities at each CCP. The CSI sees that a calibration of the process monitoring equipment was done this past week. The records review verification was appropriately documented every day. The same person performed all verifications. Using the questions from FSIS Directive 5000.1, Revision 1, is there any noncompliance?

5. The CSI is verifying the verification requirement while performing the 03G01 procedure and is looking at the HACCP plan to ensure he/she is familiar with the establishment verification procedures and frequencies in the plan. The HACCP plan lists product sampling *Listeria monocytogenes* as a verification activity. Two finished RTE product samples are to be collected and tested monthly. The CSI decides to use the recordkeeping component to verify the ongoing verification requirement. The CSI reviews the verification records for the past two months and finds that only one sample was taken and tested each month. Using the questions from FSIS Directive 5000.1, Revision 1, is there any noncompliance?

6. Scenario

As part of the 01 procedure, the CSI reviews the HACCP plan to verify that it contains on-going verification procedures and frequencies.

HACCP Plan for Cheesefurters			
CCP #1 - Biological	Critical Limit	Monitoring Procedures and Frequency	Verification Procedures and Frequency
Cooking	≥ 160°F internal temperature	Smokehouse operator will take an internal product temperature from each tree of product per batch and record it on the Smokehouse Record	QA will review monitoring records and observe the smokehouse operator taking and recording temperatures; QA will calibrate all thermometers used for monitoring the critical limits for this CCP

How does the CSI proceed with performing the 01 procedure? What questions will the CSI ask when verifying the verification requirement?

(3) Recordkeeping

This section covers how to perform your HACCP duties using the HACCP 01 and 02 procedures to verify compliance with the recordkeeping requirements. Read Part V, Recordkeeping Requirement, of FSIS Directive 5000.1, Revision 1.

The CSI verifies that the establishment is meeting the recordkeeping requirements by reviewing the following.

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

The CSI will verify some of the recordkeeping requirements when performing the HACCP 01 procedure. Other recordkeeping requirements are verified when performing the HACCP 02 procedure. In most instances, the CSI will only use the recordkeeping component of the HACCP procedures when the CSI is verifying the recordkeeping requirement. When entering on a new assignment, the CSI may want to use the review and observation component in order to become familiar with the method the establishment uses to meet the recordkeeping requirement for pre-shipment review. Review and observation should also be used to verify the authenticity of records. After this familiarization process it would not be necessary to perform the review and observation component again unless the establishment changed their method of performing this record review prior to shipment of the product. There are several regulations pertaining to HACCP recordkeeping and the CSI should verify as many of these requirements is possible.

HACCP Recordkeeping System Requirements



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

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

Gather information by asking questions

The CSI should review the HACCP plan to verify that it lists the records the establishment will use to document the monitoring of CCPs. The CSI should review HACCP records to verify that the establishment is recording actual values and observations that were obtained during the monitoring activities. The CSI should verify these requirements when performing the HACCP 01 or 02 procedures. In verifying the recordkeeping requirement, the CSI should ask 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?

Assessing the information

When assessing the information gathered the CSI should do the following:

- Review the HACCP plan to determine if the HACCP plan provides for a recordkeeping system that documents the monitoring of the CCPs.
- Review the HACCP records to determine if the records contain actual values and observations obtained during monitoring.

Determine compliance

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

Example: The CSI randomly selects the recordkeeping requirement to verify when performing the 03G01 procedure at an egg roll operation. The CSI reviews the HACCP plan to verify that it provides for a recordkeeping system that documents the monitoring of critical control points and the CSI finds the following records listed for the cooking CCP: Egg Roll Temperature Record, Oil Temperature Chart, Calibration and Maintenance Log, and Corrective Action Log. The CSI also reviews the Egg Roll Temperature Record and observes that monitoring personnel have recorded the time, product identification, temperatures, and initials. The record is dated to correspond with the day of the monitoring. Based upon the CSI's review, the CSI determines that the establishment is in compliance with the recordkeeping requirements of 417.2(c)(6) at this CCP.

Example: The CSI is performing the 03I01 procedure in a dry cured ham operation. He randomly selected the recordkeeping requirements to verify at the only CCP, product storage. The CSI reviews the establishment's HACCP plan and finds 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. The CSI also sees that the monitoring procedure specifies that maintenance personnel observe the product storage area thermometer every two hours, and records results on the room temperature log. The CSI reviews the room temperature logs for a specific date and observes that the maintenance personnel have recorded the temperatures and the times on the form, and initialed each result. Based upon the CSI's review, the CSI determine that the establishment is in compliance with the recordkeeping requirements of 417.2(c)(6) at this CCP.

Some examples of noncompliance are as follows.

1. The HACCP plan does not provide for a recordkeeping system that documents the monitoring of CCPs.
2. The monitoring personnel are recording results with a check mark rather than recording actual values and observations.

If noncompliance is determined, the CSI uses the recordkeeping trend indicator. The information gained during this verification can impact if the CSI documents the noncompliance and whether other enforcement action is necessary. For example, the CSI may need to discuss concerns with the establishment and issue a 30-day reassessment letter for a design flaw. Trend indicators and documentation are discussed in more detail in the Documentation and Enforcement section.

Workshop 
Recordkeeping system

Use the questions in FSIS Directive 5000.1, Revision 1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider **just** the information presented in the example

Questions from FSIS Directive 5000.1, Revision 1.

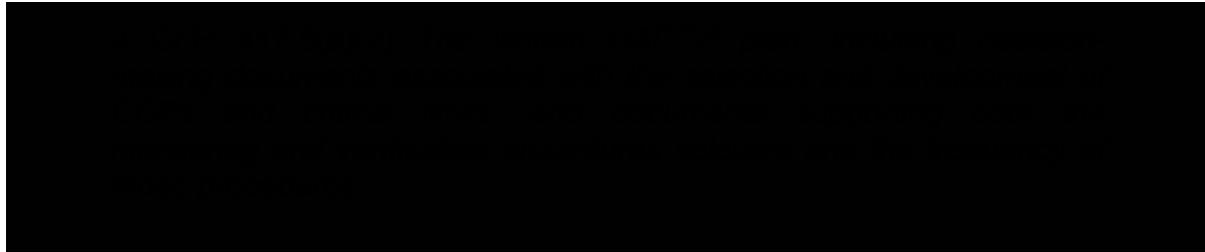
1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?
2. Do the records contain actual values and observations obtained during monitoring?

The CSI is reviewing the cooking CCP records. The CSI sees this record:

Product ID	Date	Time	160°F	Initials	Verification
Chicken B129910	3/15	8:24	Yes	GHI	1 BP
Turkey Ham CL99377	3/15	10:55	Yes	GHI	
Turkey Ham CL87221	3/15	2:18	Yes	GHI	
	3/15	3:20			2 BP
¹ Direct observation performed and monitoring performed as per the HACCP plan. ² Records review performed and records completed as per the HACCP plan					

Based on the questions from FSIS Directive 5000.1, Revision 1, is there noncompliance? Explain your answer.

Supporting Documentation Requirements



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

- 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.

Gathering information by asking questions

As part of the requirements noted above, establishments will have documentation that addresses the requirement in 9 CFR 417.4(a). 9 CFR 417.4(a) specifies that, “every establishment shall validate the HACCP plan’s adequacy in controlling the food safety hazards identified during the hazard analysis.” The CSI should determine compliance with this requirement 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.

To verify compliance with this requirement, perform the HACCP 01 procedure. Verify these requirements by reviewing the following.

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

The CSI should use sound judgment in requesting supporting documents and should not just arbitrarily ask for them. The CSI should request supporting documents when he or she questions whether a decision made by the establishment is the appropriate one. The supporting documentation is scientific, technical, or other references that support a decision made by the plant. Decision making documents are the record of the decisions made by the plant during the hazard analysis and why they made them.

In verifying these recordkeeping requirements, the CSI should seek answers to the following questions.

- a. Does the establishment have the supporting documentation for the decisions made in the hazard analysis?
- b. Does the establishment have the decision-making documents associated with the selection of each CCP?
- c. Do the documents explain why the establishment selected that location for the CCP?
- d. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?
- e. Does the establishment have scientific, technical or regulatory support for the critical limit?
- f. Does the support appear credible?
- g. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?
 - i. If the CSI questions the monitoring frequencies, he or she should perform a monitoring check between the scheduled performances of the establishment's monitoring procedure.
 - ii. If the CSI finds deviations and the establishment has not, he or she should verify that the establishment addresses this issue.
- h. Does the establishment have documents supporting the verification procedures and the frequencies listed in the HACCP plan? Do the documents support what the establishment has done?
- i. If the establishment has supporting documents for these decisions, does the documentation support the decisions?

Consider how the plant may be using prerequisite programs. A prerequisite program is a procedure designed to provide the basic environmental or operating conditions necessary for the production of safe, wholesome food. Some establishments may use **Good Manufacturing Practices (GMPs)** and/or **Standard Operating Procedures (SOPs)** to reduce the likelihood of certain hazards. GMPs are minimum sanitary and processing requirements and SOPs are step-by-step directions for completing important procedures. GMPs are fairly broad and general and can be used to help guide the development of Standard Operating Procedures (SOPs), which are very specific. GMPs are not designed to control specific hazards, but are intended to provide guidelines to help establishments produce safe and wholesome products. SOPs, on the other hand, are very specific instructions for performing a procedure and may address a specific hazard. Sanitation SOPs (SSOPs) may be considered by establishments to reduce the likelihood of occurrence of some food safety hazards. For example, the SSOP may address washing and sanitizing of the casing peeler at a certain frequency throughout the shift, to reduce potential contamination with pathogens.

Based on the regulatory requirements of 9 CFR 417.2(a) and 9 CFR 417.5(a)(1), FSIS believes that the results of such 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 prerequisite programs. The CSI 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. 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, CSIs should not apply the same verification criteria as they would when verifying the regulatory requirements of HACCP plans. The CSI should assess the overall effectiveness of the testing results and monitoring results to verify the overall effectiveness of the procedures or programs. The CSI should verify that if there is information in the records that requires the establishment to reevaluate the effectiveness of the Sanitation SOPs or 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 CSIs have concerns about the design or results from testing, procedures or programs, they can contact the Technical Service Center (TSC) or a CSO through supervisor channels. The CSO may 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 a hazard is judged reasonably likely to occur, the establishment must address the hazard with a CCP and **cannot** substitute a prerequisite program to control the hazard. Sometimes, however, an establishment determines that the hazard is not reasonably likely to occur, using the justification that a prerequisite program, properly implemented,

is preventing the hazard from occurring. If the Consumer Safety Inspector determines that a prerequisite program is used as a justification for not addressing a hazard with a CCP in the HACCP plan, the CSI should notify the District Office. These programs must be evaluated by a specially trained individual, such as a CSO.

Assessing the information

Review the hazard analysis and supporting documentation to determine if the documents support the decisions made in the hazard analysis. Review the HACCP plan and decision-making documents to determine if documents are available for the selection and development of CCPs and critical limits, and documents support both the monitoring and verification procedures and the frequency of those procedures.

When the CSI is verifying the recordkeeping requirement, he/she should be cognizant of the fact that there are many different kinds of supporting documents that an establishment might use to support the decisions it made in the hazard analysis and HACCP plan. The type of documentation necessary for support depends on the decisions made. Some examples of supporting documentation used by establishments include scientific journals, literature, or surveys; regulations, guidelines, directives, or performance standards; industry standards, trade association guidelines; university extension publications; in-plant studies or research; directions from processing authorities; written information from industry experts or consultants; and written materials from equipment manufacturers.

The establishment has the flexibility to determine its own CCPs. If the CSI has questions about a CCP, the CSI should request the supporting documentation associated with the selection of that CCP. If the CSI has questions regarding the validity of the data, the CSI should go through supervisory channels to seek technical guidance from the TSC by providing the relevant information along with the basis for the submission.

Keep in mind that even though the establishment may have documentation for its decisions, if that documentation does not support the decisions made in the hazard analysis and HACCP plan, that supporting documentation would not meet the recordkeeping requirement.

It is not a requirement that the establishment provide **statistical** data to support the monitoring frequencies. The documents supporting the monitoring frequency should demonstrate process control. The establishment may accomplish this by performing monitoring more frequently than stated in its HACCP plan. Over time, the establishment could show that actually monitoring less frequently satisfies process control and the more frequent monitoring records would serve as supporting documentation for the frequency.

Some establishments may elect to use a microbial pathogen computer modeling for supporting documentation. FSIS Notice 50-03 (Use of Microbial Pathogen Computer Modeling in HACCP Plans), 12/3/03, addresses this issue. Since the models are only predictors, the CSI would expect additional information to support any controls the establishment actually uses. Modeling programs must apply to the process and product produced.

Sometimes the establishment uses scientific and technical data developed and analyzed by a processing authority or other scientific expert as the basis for decision-making for the selection and development of CCPs and critical limits. If this is the case, that data must be part of the establishment's supporting documentation. If the establishment's basis for CCPs, critical limits, or other aspects of the HACCP plan are based on specific research, but do not use the exact control parameters used in the research, the establishment must have additional data that justifies the modified control parameters.

Certain RTE products have a higher public health risk because they have historically been associated with food borne illnesses caused by specific pathogenic bacteria or their toxins (*Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, *C. perfringens* or *C. botulinum*). For that reason, FSIS has set performance standards in the regulations (§318.17, §318.23, and §381.150) concerning the lethality and stabilization steps in the respective production processes.

If the establishment uses Table A of §318.23 for setting its CCPs and critical limits for cooking patties, then the establishment should have a copy of that regulation in its records as supporting documentation. That is sufficient supporting documentation. If the basis for a critical limit is recent scientific publications describing similar processing systems, then copies of those publications are required as supporting documentation for the critical limit.

There must be at least one critical limit for each CCP. Each critical limit must have supporting documentation to demonstrate that it is adequate to actually control the specific food safety hazard. For example, if the establishment intends to produce a fully cooked pork loin, and the CCP for cooking (lethality) has a critical limit of 160° F, the establishment must have supporting documentation to show that reaching a temperature of 160° F adequately kills the pathogens of concern for this product. Appendix A, Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products, updated June 1999, is one example of supporting documentation an establishment could use to support this decision.

When FSIS Directive 7111.1, 3/3/99, "Performance Standards for the Production of Certain Meat and Poultry Products" was issued, FSIS also published compliance guidelines for establishments to use to meet the Performance Standards described in §318.17 and §381.150. These guidelines are Appendix A for lethality and Appendix B

for stabilization. The establishments producing the products that are covered by §318.17 and §381.150 can use these appendices for supporting documentation to support the critical limits if they are following one of the time and temperature combinations in these appendices. Appendix A and Appendix B can be used also to support for products not covered in the performance standard regulations. Another directive plants may sometimes use for support is FSIS Directive 7110.3, 1/24/89, "Time/Temperature Guidelines for Cooling Heated Products." This directive contains cooling guidelines for heated products.

These compliance guidelines are not regulations and the CSI should not mandate that the establishment use them as supporting documentation for the critical limits. The establishment should have the flexibility to develop the CCPs and establish critical limits as they see fit. It is the CSI's responsibility to verify that the establishment can support those decisions. Appendix A and Appendix B are guidelines that can be used for support, but the establishments are not required to support the critical limits with these documents.

If the establishment uses the FSIS Compliance Guidelines, it is *still required* by §417.4(a) to validate the procedures and frequencies of its HACCP plan by repeatedly testing the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions. The establishment is not validating the performance standards, but is validating that it can meet the criteria in the guidelines.

Determine Compliance

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

1. Compliance
2. Noncompliance
3. Need more information to determine regulatory compliance

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

The HACCP 01 procedure is documented as "a" performed when the requirements are met. The CSI issues an NR when there is noncompliance with the requirements. A 30-day reassessment letter should be issued when there is not enough information available to determine whether the HACCP plan complies with 9 CFR §417.2. This provides the establishment with an opportunity to support the decisions made, or to reassess the hazard analysis and the HACCP plan and make decisions that it can support.

Note: There are situations in which the CSI needs 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, the CSI might need more information to determine whether the HACCP plan complies with 9 CFR §417.2. The CSI could issue a 30-day reassessment letter requesting the establishment to reassess its HACCP plan. The CSI has not been trained to assess the scientific and technical information that an establishment might have to support the HACCP system. The CSI does have resources available to assist in evaluating this information. The CSI can contact the District Office or the TSC for assistance.

Examples of recordkeeping noncompliance

1. 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. The establishment has no documentation supporting the verification procedure and frequency.
3. The establishment has no supporting documents associated with the decision-making process for the selection of the CCPs.
4. The establishment has no scientific, technical, or regulatory support for the critical limit.
5. The establishment has no documentation supporting the monitoring procedures and frequencies.
6. The establishment has documentation, but the documentation does not support the decisions made.

Example: The CSI reviews the hazard analysis in a cooked ground beef patty operation. The CSI reviews the establishment's hazard analysis and the flow chart. The CSI finds that all steps in the process are described in the flow chart, and each step is addressed in the hazard analysis. The CSI finds the hazard analysis considers 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 the hazards are reasonably likely to occur, and recorded the basis for that decision. The CSI observes that at the receiving step the establishment has identified that there is a physical food safety hazard (foreign material) but determined that it was not reasonably likely to occur on the basis that "establishment records show that there has been no incidence of foreign materials in products received in the establishment." The CSI decides to request the supporting documentation for this decision. The establishment provides receiving records from the last several months. These records contained entries of raw material inspections and findings. There were no significant foreign material findings documented on these records. The CSI determines that this requirement for the recordkeeping system is in compliance since 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.

Example: The CSI is scheduled to perform the 03G01 procedure. The CSI randomly selects the recordkeeping regulatory requirement to verify and knows to use the recordkeeping component for this requirement. The CSI selects the Salisbury steak (frozen dinner) HACCP plan. The CSI reviews the HACCP plan, hazard analysis, and supporting documentation for the freezing CCP to verify that it meets the requirement in §417.5(a). The CSI finds 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 of the CCP and the critical limits. Based upon the CSI's review, the CSI determines that the establishment is in compliance with §417.5(a)(1) and (2).

Workshop

Supporting documentation

Questions from FSIS Directive 5000.1, Revision 1.

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

3. The CSI is performing an 03G01 procedure. When reviewing the HACCP plan, the CSI sees that the establishment's HACCP plan for frankfurters lists a monitoring procedure for checking internal temperatures at CCP #1 once per shift. The CSI questions the monitoring frequency and asks for supporting documentation for the monitoring frequency. In response to this request, the establishment provides the smokehouse records for the last two months. What concerns might the CSI have?

4. The CSI is performing a HACCP 01 procedure to verify the verification requirement. The establishment does end product testing for *Listeria monocytogenes*. The verification procedure for the testing states, "The QC Manager will collect a sample according to the laboratory's guidelines once per shift. The lab results will be recorded on the Production Sheet along with the monitoring and verification results." The CSI ask for the guidelines to see how the sample will be collected. The establishment does not have a copy of the guidelines. What concerns might the CSI have?

5. The CSI is reviewing the HACCP plan for baked chicken. While reviewing the HACCP plan the CSI observes that there is no stabilization CCP. The CSI has concerns about this and decides to review the hazard analysis to determine how this decision was made. At this step in the hazard analysis, the establishment had considered *C. perfringens* as a potential hazard but not likely to occur. The justification for this not being likely to occur is that the product is rapidly chilled. The establishment had no prerequisite program covering the stabilization of this product. What concerns might the CSI have?

Scenarios

1. The establishment produces 20-lb cooked hams. While reviewing the HACCP plan, the CSI notices that the cooling critical limit for the hams does not meet the stabilization guideline in Appendix B. The CSI requests supporting documentation for the critical limit in the HACCP plan and the establishment provides a copy of FSIS Directive 7110.3, Rev. 1. What should the CSI do?

2. Review the following section of a hazard analysis. What questions might the CSI ask with regard to the supporting documentation for this hazard analysis?

Process Step	Hazard			Reasonably likely to occur?	Control measure to prevent, eliminate, or reduce hazard to acceptable level?
	Biological	Chemical	Physical		
Receiving-Raw Meat - Trim	Pathogens <i>Listeria monocytogenes</i> , <i>Escherichia coli</i> O157:H7, <i>Salmonella</i> , <i>Staphylococcus aureus</i> , <i>Trichina</i>	None	Foreign materials (such as metal, wood, glass, etc.)	B – Yes – pathogens are inherent in raw product P – No – establishment records show no incidence of foreign materials from suppliers	Lethality – cooking (later step)

HACCP Records Requirements



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

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

Gathering information by asking questions

CSIs should verify these requirements by reviewing HACCP records that document the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit, a deviation not covered by a critical limit, or an unforeseen hazard. These requirements can be verified by performing the HACCP 01 and 02 procedures. In verifying these requirements, the CSI should seek answers to the following questions.

1. Do the records document the monitoring of CCPs 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?

Assessing information

When assessing the information, the CSI should do the following:

- Review the HACCP plan to determine the records being used to record monitoring of the CCPs and their critical limits, the calibration of process-monitoring instruments, corrective actions, and verification procedures and results.
- Review the HACCP records to determine whether the records document the monitoring of CCPs and their critical limits, including actual times, temperatures, or other quantifiable values; the calibration of process-monitoring instruments; corrective actions; verification procedures and results; product codes, product name or identity, or slaughter production lot, and the date the record was made.

Determine compliance

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

Examples of noncompliance include the following.

1. The records do not have the monitoring results recorded.
2. The records do not include the actual times that monitoring is performed.
3. The records do not include the actual values as required.
4. The monitoring entries do not include the product identification or code.
5. The records do not include the date the record was completed.
6. The verification procedures and results are not being recorded.
7. The corrective actions taken in response to a deviation from a critical limit are not recorded.
8. The results of calibration of process monitoring instruments are not recorded.

If noncompliance is determined, the CSI uses the recordkeeping trend indicator. Trend indicators and documentation are discussed in more detail in the Documentation and Enforcement section.

Example: The CSI is performing the 03H01 procedure in a char-marked pattie operation. The CSI randomly selected to verify the recordkeeping requirement (for §417.5(a)(3)) for the cooling CCP. The critical limit listed in the HACCP plan states that the product will be chilled to 40 degrees or less within 30 minutes from the time it is removed from the char-marking step. The establishment has data to support that when the product is ready to package 25 minutes have lapsed since the char-marking step. The temperature is measured at the packaging step. The CSI reviews the HACCP records for this CCP and finds that the establishment personnel have made the following entries.

Char-marked Patties Cooling Log

Date	Lot No.	Time	Temp.	Corrective Actions	Monitored by	Verified by
4 - 29- 2003	1	0730	38	-	RH	* LM

*direct observation verification-results as per the HACCP plan

**records review verification-results as per the HACCP plan

Based upon the records review, the CSI determines that the establishment is in compliance with this part of the monitoring and verification recordkeeping requirements of §417.5(a)(3).

The CSI also verifies that monitoring, verification, and corrective action records include product codes, product name or identity, or production lot, and the date the record was made.

Example: The CSI is performing the 03G02 procedure in a lasagna operation. While conducting a HACCP 02 procedure, the CSI examines all HACCP records produced for a specific production. The CSI observed that each of the entry on the records includes the production code or the product name, where applicable, time, actual value or observation, initials, and that each record includes the date the product was produced. Based on the CSI's review, the CSI determines that the establishment is in compliance with this part of the recordkeeping requirement.

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

Example: The CSI is performing the 03H01 procedure in a bacon operation and randomly selects to verify the recordkeeping requirement for process-monitoring calibration. The CSI reviews the HACCP records for calibration and finds that the establishment personnel have made the following entries:

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

Date	Time	Area	Thermometer ID	Personal Thermometer Reading	Adjustment Required	Initials	Comments
5-1-2003	0800	Pickle Chilling	2A	32	No	TDM	

Based upon this information, the CSI determines that the establishment is in compliance with this part of the recordkeeping requirements for the pickle chilling CCP. The CSI would then proceed to verify other recordkeeping requirements.

Workshop 
Recordkeeping/HACCP Records Requirements

Questions from FSIS Directive 5000.1, Revision 1.

1. *Do the records document the monitoring of CCPs 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?*
8. *The results of calibration of process monitoring instruments are not recorded.*

Here are examples of possible noncompliance. Use the questions in FSIS Directive 5000.1, Revision 1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider **just** the information presented in the example.

1. While performing the 03G02 procedure, the CSI reviews the establishment's cooking record for ham. The critical limit for this product is 158 degrees or greater.

Date 4/29/03

Time	Monitoring Results	Monitor	Verification	Corrective Action
8:10 am	158	QVC		None
9:10 am	161	QVC	¹ TSP	None
10:32am	160	QVC		None
¹ Direct observation of the monitoring activity—monitoring being conducted as per HACCP plan				

What questions would the CSI ask?

What further information should the CSI seek?

Is there noncompliance? Explain your answer.

2. While performing the recordkeeping component of the 03G01 procedure, the CSI reviews a chiller record for hot dogs to verify the recordkeeping requirement. The critical limit is 40 degrees or less in one hour or less after cooking.

Product ID	Time	Temp °F	Initials	Verification	Corrective Action
8/1 lb	9:30 am	38	ABC	JQ	None
10/1 lb	12:20 pm	37	ABC		None
12 oz	1:22 pm	38	ABC	JQ	None

What questions would the CSI ask?

What further information should the CSI seek?

Is there noncompliance? Explain your answer.

3. While performing the recordkeeping component of the 03G01 procedure, the CSI reviews a cooking record for chicken nuggets to verify the recordkeeping requirement.

Date: 4/28/03		Chicken Nuggets			
Product ID	Time	Temperature of 160°F	Initials	Verification	Corrective Action
Lot 1	8:05 am	Met	QVC		None
Lot 1	8:45 am			1 - TSP	None
Lot 2	9:03 am	Met	QVC		None
Lot 3	10:10 am	Met	QVC	2 - TSP	None
1- record review- records completed as per the HACCP plan					
2- direct observation of monitoring - monitoring conducted as per HACCP plan					

What further information should the CSI seek?

Is there noncompliance?

4. While performing the recordkeeping component of the 03G02 procedure, the CSI reviews a stabilization record for lot 1323C lemon chicken. Prior to reviewing the records, the CSI reviews the HACCP plan. The critical limit for stabilization is 40 degrees or less at the time of packaging. The establishment has data to show that the packaging step is 58 minutes from the cooking step.

Date:	Stabilization Record		
Product ID	Temperature	Monitor Initials	Verifier Initials
Lemon Chicken lot 1323C	39	CC	1- EG
Lemon Chicken lot 1447A	38		
1- Direct observation of monitoring - monitoring as per the HACCP plan			

What further information should the CSI seek?

Is there noncompliance? Explain your answer.

5. When the CSI arrives at an establishment on a patrol assignment, establishment management tells the CSI that a deviation happened shortly before the CSI arrived. The CSI performs the HACCP 02 procedure to verify that the corrective actions the establishment took met regulatory requirements. The establishment manager tells the CSI what they did and the verbal explanation sounds as if the establishment met all 4 parts of the corrective actions required. The CSI looks for the documentation, but cannot find any. The establishment manager reminds the CSI that he already told the CSI what they did and that it met all parts of the corrective action requirement.

Is there noncompliance? Explain your answer.

6. While performing the recordkeeping component of the HACCP 01 procedure, the CSI reviews the thermometer calibration log to verify the recordkeeping requirement.

Date/Time	Thermometer	Findings	Initials	Comments
4/26 – 7:15a.m.	#1 Digital	34	WD	None
5/11 – 9:22 a.m.	#1 Digital	32	JR	None

What further information should the CSI seek?

Is there noncompliance? Explain your answer.

Record Authenticity Requirements



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

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

Gathering information by asking questions

CSIs should verify this regulatory requirement by reviewing HACCP records documenting the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit or a deviation not covered by a critical limit or an unforeseen hazard.

Verify this regulatory requirement by asking the following 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?

Note: *The recordkeeping requirement in 417.5(a)(3) requires that the record include the date the record was made. In 417.5(b) every entry on a record is required to include the date recorded. These two separate sections of the regulation in essence mean the same thing in terms of compliance. The intent of this recordkeeping regulation is not to require that the establishment write the same date multiple times on a record with each entry, but to have a date on the record to represent the data entries.*

Assessing information

When assessing the information, the CSI should do the following:

- Review the HACCP plan to determine the records used for recording monitoring, verification, and corrective actions.

- Review the HACCP records associated with monitoring, verification, and corrective actions to determine if each entry was made at the time the event occurred, the entry included the time and initials or signature of the person making the entry, and the records include the date.

Determine compliance

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

Examples of noncompliance include the following.

1. Some entries on the records do not contain the time the event occurred.
2. The records do not include the signature or initials of the person performing the activity.
3. There is no date on the records.
4. Results are not being recorded when the events occur.

If noncompliance is determined, the CSI uses the recordkeeping trend indicator.

Example: The CSI is performing the 03G01 procedure in a smoked pork chop operation and has randomly selected to verify the recordkeeping requirements for the stabilization CCP. While reviewing the establishment's HACCP plan, the CSI sees that the verification procedure states that QC personnel will observe the monitor conduct the monitoring activities twice per shift. The CSI looks at the chilling record and QC has made one entry. The entry includes the time, that the direct observation was performed, the monitoring was being conducted as per the HACCP plan, and initials of the verifier. The monitoring entries on the form included product ID, time, actual temperatures, initials and form contain a date the form was made. The CSI determines that the establishment is in compliance for this part of the recordkeeping requirement.

Workshop 
Record Authenticity

Questions from FSIS Directive 5000.1, Revision 1.

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**?

Here is an example of possible noncompliance. Use the questions in FSIS Directive 5000.1, Revision 1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information.

1. While performing the HACCP 02 procedure, the CSI reviews the cooking log for the meatballs.

Mama's Meatballs

Date/Time	Temperature	Initials	Comments	Corrective Action
4/9/03				
3:45 p.m.	160	BB	None	None
6:25 p.m.	160		None	None

Computerized Records Requirements



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

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

Gathering information by asking questions

The CSI can verify this recordkeeping requirement by performing the HACCP 01 or 02 procedures. The CSI should verify this requirement by requesting the establishment to demonstrate the controls that it has in place to ensure the integrity of the records. When verifying this requirement, the CSI should seek the answer to the following question.

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

Assessing information

When assessing the information gathered, the CSI should do the following:

- Request the establishment to demonstrate the controls they have in place to ensure the integrity of the electronic records.
- Verify that they are following the controls that are in place to ensure the integrity of the electronic records.

Determine compliance

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

Examples of noncompliance are as follows.

1. The establishment does not have controls in place to ensure the integrity of the electronic records.
2. The establishment has controls to ensure the integrity of the electronic records but is not following those controls, e.g., passwords and electronic signatures are not kept secure.

Record Retention and Availability Requirements



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

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

Gathering information by asking questions

The CSI should verify that the records are being maintained for the required amount of time by reviewing the HACCP records. The CSI should not routinely request past records to verify that the HACCP records are being maintained for the appropriate time. If the CSI suspects that records are not being maintained for the required amount of time, he or she should contact the frontline supervisor for instructions. The CSI might request records stored off-site to verify this requirement. When verifying this

recordkeeping requirement, the CSI should seek answers to the following questions when performing the HACCP 01 or 02 procedures.

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?

Assessing the information

When assessing the information gathered, the CSI should review HACCP records to determine if HACCP records are being maintained on-site for six months, if records are being retained for the required time, if records stored off-site can be retrieved and provided on-site within 24 hours of the CSI's request. If the CSI is working a second or third shift and records are not available, he/she would communicate with establishment management in a professional manner that these regulations require records to be available to FSIS when the establishment is operating.

Determine compliance

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

Some examples of noncompliance are as follows.

1. The establishment is not maintaining records for the required length of time.
2. The records are not being maintained on-site for 6 months.
3. The establishment cannot retrieve the records within 24 hours when stored off-site.

Workshop 
Record Retention

Here are examples of possible noncompliance. Use the questions in 5000.1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider **just** the information presented in the example.

1. While performing the recordkeeping component of the 03G01 procedure at the fully cooked and smoked pork chop establishment, the CSI decides to verify the record retention requirement. The establishment has been producing this product for only two years. The QC Manager gives the CSI a thick file and says that it contains all the HACCP records that the establishment has for these products. The CSI looks at yesterday's record (March 29, 2003), which is on top. The CSI looks through the records in the folder and notes that the oldest date is for June 30, 2002.

2. While performing the recordkeeping component of the 03I01 procedure, the CSI randomly selected the recordkeeping requirement to verify. The CSI decided to look at the HACCP records for last month to verify the records are available. The establishment informs the CSI that it will take at least 48 hours for them to get the records from the off-site storage facility where they are kept for security reasons because the establishment is running short-handed this week.

Pre-shipment Review Requirements



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

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

Gathering information by asking questions

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 inspection program personnel to know whether the company has taken full and final responsibility for applying its HACCP controls to the product it has produced. The CSI 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 of the HACCP 02 procedure. The CSI should understand that the pre-shipment review can be accomplished if the product is at a location other than the producing establishment as long as the review of appropriate documents and compliance with 9 CFR §417.5(c) occurs before the product leaves the control of the producing establishment.

When verifying an establishment’s pre-shipment review of its records by performing the HACCP 02 procedure, the CSI 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?

Assessing the information

When assessing the information gathered, the CSI should do the following:

- Communicate with the establishment to ensure that he/she is familiar with the pre-shipment review procedures used in the establishment.
- Review pre-shipment review records to determine if records are being signed and dated prior to the shipment of the product.

Determine compliance

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

Some examples of noncompliance are as follows.

1. The establishment shipped the product without conducting a pre-shipment review.
2. The establishment performs pre-shipment review but does not sign and date the records.

Records Misrepresentation

In cases when the CSI suspects deliberate misrepresentation of records, do not discuss the situation with an establishment employee. Notify the IIC and document the findings in a memorandum to the files—not on a NR. The IIC will use a secure phone (off-premises if necessary) to call the District Office. FSIS does not consider the telephone in the government office or cellular phones to be secure. The District Manager will provide instructions for further action. If the IIC is not available, the CSI should use a secure phone to notify the District Office and follow the District Manager's instructions.

Workshop 

Pre-shipment review

1. What key questions would the CSI want answered when verifying compliance with the pre-shipment review requirement?

Here are examples of possible noncompliance. Use the questions in 5000.1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider **just** the information presented in the example.

2. The CSI is waiting to send a product sample to the lab. The CSI cannot send it until the pre-shipment review has been completed. The CSI checks the records and the pre-shipment review has not been performed on the specific production for which the CSI has taken a sample. The CSI asks the shipping foreman when he expects that product to be shipped, and after the foreman checks his records he tells the CSI the product has been shipped.

3. The CSI is performing the HACCP 02 procedure because while performing the HACCP 01 procedure monitoring noncompliance was documented. The CSI checks the records for the pre-shipment review, which is made at the bottom of the chilling record and observes the following documentation.

Pre-shipment Review Signature: _____

Date: 3/9/03

Summary of Recordkeeping Requirements and HACCP Procedures

Following is a summary of the HACCP recordkeeping requirements and the procedures that are used to verify each of the requirements.

**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)(2)	01 or 02
Pre-shipment Review 417.5(c)	02

Corrective Actions

This next section covers how to perform your HACCP duties using the HACCP 01 and 02 procedures to verify compliance with the corrective action requirements. First, read Part VI, Corrective Actions, of FSIS Directive 5000.1, Revision 1.



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

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

Gathering information by asking questions

When there is a deviation from a critical limit, the CSI verifies that the requirements of 9 CFR §417.3(a) are met by comparing the corrective actions taken by the establishment to the requirements of the regulation. The CSI should verify the corrective action requirements as part of the HACCP 01 and 02 procedures. The CSI can verify these requirements by using the recordkeeping component or the review and observation component of the procedures. The corrective action requirements should be verified **every time** a deviation occurs. To verify compliance with the corrective action requirements, the CSI seeks 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?

Assessing the information

When assessing the information gathered, the CSI should do the following:

- Review the corrective action records associated with the deviation from the critical limit 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(a) to determine whether the corrective actions taken in response to the deviation from the critical limit meets all of these requirements.
- Observe the establishment executing the corrective actions to verify that the establishment has identified the appropriate affected product.
- Observe the establishment executing the corrective actions to verify that the establishment has identified and eliminated the cause of the deviation.
- Observe the establishment executing the corrective actions to determine if the CCP is under control after the actions were taken.
- Observe the establishment executing the corrective action to verify that preventive measures are established.
- Observe the establishment executing the 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.

Determine compliance

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

Some examples of noncompliance are as follows.

1. The establishment did not identify the cause of the deviation from a critical limit.
2. The establishment identified the cause of the deviation from the critical limit, but did not take appropriate actions to eliminate that cause.
3. The establishment did not implement appropriate measures to ensure that the CCP is under control after the actions were taken.

4. The establishment did not implement measures to prevent the recurrence of the deviation.
5. The establishment did not take appropriate measures to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce.

The CSI will document any noncompliance using the corrective action trend indicator. The CSI may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

Note:

This requirement cannot be randomly verified because corrective action occurs when it is triggered by a deviation from a critical limit or an unforeseen hazard occurs. Anytime there is a deviation from a critical limit the CSI will verify that the corrective actions taken by the establishment meet the requirements of the regulation.

Example Part 1: The CSI arrives at an establishment which produces roast beef and is notified that a deviation of the cooling CCP has occurred. The CSI begins the corrective action verification by reviewing the HACCP plan.

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

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

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

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

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

Example Part 5 - verifying §417.3(a)(4): Continuing, the plant has held and segregated the affected product, and provided a processing authority with its cooling data points (time/temperature combinations) for the deviation. The processing authority has plotted the data into a pathogen modeling program and used other scientific literature to determine that there would be no outgrowth of *Clostridium botulinum* and no more than one log increase in *Clostridium perfringens*, based on the cooling curve that the product experienced. The report from the processing authority which indicates that the product is safe for distribution is attached to the corrective action log. The CSI determines that the establishment has prevented product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce. The CSI determines that the requirements for 417.3(a) have been met, and records 03G01 as an unscheduled procedure, marking it "a" performed.

Workshop

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-Deviation from Critical Limit

1. The HACCP plan has a monitoring procedure for the temperature of the brine chilling medium for wieners. The CSI performs a HACCP 01 procedure and reviews the chill medium temperature log and observes a deviation recorded. The CSI reviews the associated corrective action log and finds that the establishment recorded the cause of the deviation, eliminated the cause, and ensured that the CCP was in control after the corrective action was taken. The CSI's review also reveals that the establishment implemented a preventive measure of "will increase monitoring frequency." The corrective action log does not contain any record of what was done with the product that was produced while the critical limit was out of control. The CSI reviews shipping records and observes that the product has been distributed. The establishment cannot produce any further records to demonstrate the safety of this product. Does this meet §417.3(a)?

2. You review a corrective action log.

Date: 5/10 Product: Ham with Natural Juices, lot 556677-2W

The cooking temperature was not reached. All product in the lot was in the same smokehouse and all product of lot 556677-2W is on hold. The product will be recooked and QA will monitor the product temperatures to ensure that product reaches the required 160°F internally. QA will then check 6 pieces of product in each smokehouse at random locations at the end of the cooking cycle for the next 4 days.

J.J. Turner 10:30 am

What do you conclude from this entry?

Unforeseen Hazard



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

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

Gathering information by asking questions

If an unforeseen hazard occurs, the CSI is to verify that the regulatory requirements of 9 CFR §417.3(b) are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR §417.3(b). The CSI should verify that these requirements are met each time there is a deviation not covered by specific corrective actions, or an unforeseen hazard occurs. These requirements should be verified as part of the HACCP 01 or 02 procedures. The CSI should ask 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?

Assessing the information

When assessing the information gathered, the CSI should do the following:

- Review the corrective action records associated with the deviation or unforeseen hazard and observe the establishment executing corrective actions.
- Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR §417.3(b)(1)(2)(3)(4) to determine whether the corrective actions taken meet all of these requirements.
- Observe the establishment segregating and holding all of the affected product to verify that the establishment segregated and held all affected product.
- Observe the establishment evaluating the affected product so that only acceptable product is released.

Determine compliance

Sometimes a hazard may occur that the establishment had not anticipated in its hazard analysis, or if it did, it did not determine that the hazard was reasonably likely to occur. For example, the establishment did not identify *Listeria monocytogenes* as a hazard. An FSIS sample of the establishment's chicken salad (intact sample) had a positive result for *Listeria monocytogenes*. The establishment may not have considered this situation, but it is required to take corrective action to ensure food safety. If an unforeseen hazard occurs, the CSI should verify that the establishment meets the regulatory requirements (§417.3(b)). The CSI must verify that the corrective actions the establishment implements meet all required parts of the corrective action regulation. Verify that these requirements are met **each time** there is a deviation not covered by specific corrective action, or an unforeseen hazard by performing the HACCP 01 or 02 procedures.

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

Some examples of noncompliance include the following.

1. The establishment did not hold all affected product.
2. The establishment held product, but it was not the product that was affected.

3. The establishment did not evaluate the product to determine whether it was acceptable for distribution.
4. The establishment evaluated the product and found it to be unacceptable for distribution, but did not take the necessary action to ensure that no product injurious to health or otherwise adulterated, as a result of this deviation or unforeseen hazard enters commerce.
5. A reassessment was not conducted to determine whether the newly identified deviation or unforeseen hazard should be incorporated into the HACCP plan.

Example (Part 1): The CSI is performing the 03G02 procedure in a poultry parts cooking operation to follow-up on an event that occurred earlier in the shift in which the establishment monitoring personnel found metal shavings on the parts after the batter and breading operation. The establishment decided that the metal would constitute a food safety hazard. The establishment has no CCP for metal contaminants. The CSI reviews the corrective action log dated 5-4-2003 and finds the following entry for this incident:

All parts exiting the batter and breading system held by QA on trays and placed in the cooler. Parts were visually examined by production personnel for the presence of metal. Pieces with metal shavings were placed in inedible containers. After deciding that too much product was affected, all parts on the trays and all parts in the batter and breading system were condemned. All product from the shift (exiting the blast freezer) will be held and run through a metal detector on 5-5-03. Such product will be held in freezer under QA tag. HACCP plan will be reassessed by 5-5-03.

Based upon the CSI's review of the records, the CSI determines that the recorded actions meet the requirements of §417.3(b).

The CSI observes the establishment executing corrective actions to verify that all affected product is segregated and held.

Example (Part 2): Continuing from the previous example, the CSI verifies that the establishment segregates and holds the affected product by going to the batter and breading system. The CSI finds no product exiting the system. The CSI finds no product on any trays in the cooler, but the CSI does see an inedible barrel over half filled with various denatured battered and breaded chicken parts. The CSI goes to the freezer and sees 5 skids of boxed product under a QA tag stating the product was to be run through a metal detector. Based upon the CSI's observations, the CSI determines that the establishment has adequately held and segregated affected product.

Workshop 
Unforeseen Hazard

1. What questions would the CSI want answered when verifying compliance with the corrective action requirements of §417.3(b)?

Here are examples of possible noncompliance. Use the questions in FSIS Directive 5000.1, Revision 1 to determine compliance/noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider **just** the information presented in the example.

2. While performing a HACCP 02 procedure, the CSI sees in the corrective action log that the establishment listed the cause of an unforeseen hazard and eliminated it, brought the CCP under control, made sure that no product injurious to health or otherwise adulterated entered commerce. Does this meet regulatory compliance per §417.3(b)?

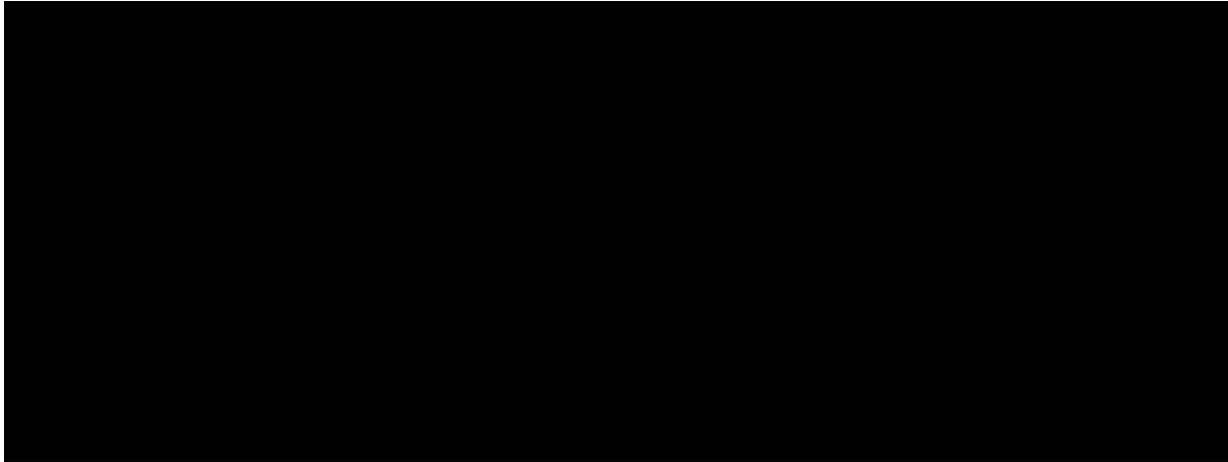
3. The results of a sample the establishment sent in for analysis of its turkey ham, sliced, was positive for *Salmonella*. The establishment had held the sampled lot of product pending laboratory analysis. The establishment evaluated the product for acceptability and determined to condemn. It performed a reassessment of the HACCP plan. That is the information the CSI reviewed in the corrective action log as an unscheduled 03G01 the CSI performed as a result of learning about the deviation. Does this meet the requirements of §417.3(b)? Explain your answer.

4. The establishment had an unforeseen hazard. It performed a review to determine acceptability of the affected product for distribution, segregated all affected product, made sure that no product that was injurious to health or otherwise adulterated as a result of the hazard entered commerce, and held the segregated product. Does this meet the requirements of §417.3(b)? Explain your answer.

(5) Reassessment

This next section covers how to perform your HACCP duties to verify compliance with the reassessment requirements. First, read Part VII, Reassessment Requirement, of FSIS Directive 5000.1, Revision 1.

Reassessment Requirement



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

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

Gathering information by asking questions

The establishment is not required to document reassessments that are conducted as a result of changes in the process, unless the reassessment reveals that modification of the HACCP plan is necessary. If the reassessment reveals that modification of the HACCP plan is necessary, the HACCP plan must be modified immediately, and then signed and dated. The establishment is also required to sign and date the HACCP plan to demonstrate that the annual reassessment was conducted. The CSI should review reassessment records, if available, and the HACCP plan to verify these requirements. When verifying compliance with 9 CFR §417.4(a)(3), the CSI should consider the following questions.

1. Has a reassessment been conducted to meet the annual reassessment requirement?

2. Did the establishment consider any significant developments that have occurred in the plant or have occurred with respect to the types of products produced by the plant in its analysis?
3. Has 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 meets regulatory requirements, was the HACCP plan modified immediately?

Assessing the information

When assessing the information gathered, the CSI should do the following:

- Review the HACCP plan to determine if the establishment signed and dated the HACCP plan to demonstrate it was reassessed annually.
- Evaluate the process to determine if changes have occurred in the establishment that could affect the hazard analysis or HACCP plan. Such changes may include 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.
- Review any reassessment documentation available to determine that if the reassessment revealed that the HACCP plan no longer meets regulatory requirements, the HACCP plan was modified immediately.

Keep in mind that there is no recordkeeping requirement for reassessment other than to meet the annual reassessment requirement **and** as part of the corrective actions. Reassessment does not always result in modification to the HACCP plan.

Determine compliance

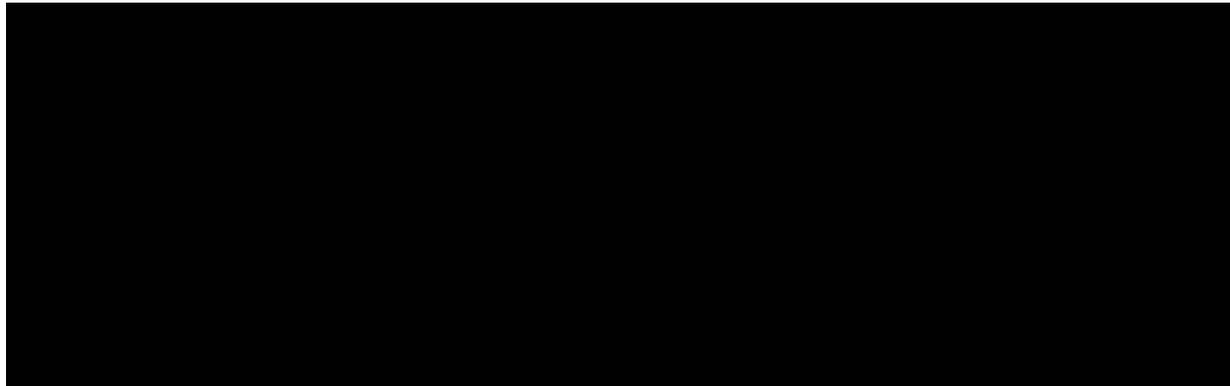
After the CSI has gathered and assessed all available information pertaining to the reassessment requirement, he/she must determine regulatory compliance. If the CSI finds that the establishment has met all these regulatory requirements, there is no noncompliance. If the CSI finds that the establishment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

Some examples of noncompliance include the following.

- The annual reassessment was not conducted.
- Reassessment revealed that the HACCP plan no longer meets the requirements of 9 CFR §417.2(c), and the plan was not immediately modified.

Note: "Annually" does not mean that if the establishment initiated the plan on January 25, every year on or very near January 25 it must reassess the plan. What it does mean is that if the plan was initiated in 1999, it should have been reassessed in 2000, 2001, 2002, and sometime in 2003. The actual month and day is immaterial to the meaning of "annually." This is based on the calendar year. FSIS verifies this regulatory requirement near the anniversary date of the HACCP plan for uniformity associated with the verification of this reassessment requirement.

Reassessment of the Hazard Analysis



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

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

Gathering information by asking questions

The CSI must rely on his or her knowledge of the operation and the changes that occur within that operation. When verifying compliance with §417.4(b), the CSI should answer the following questions.

- 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?
- Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?
- If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

Assessing the information

When assessing the information gathered, the CSI should do the following:

- Evaluate the process to determine if changes have occurred that could affect whether there is a food safety hazard reasonably likely to occur. Such changes might be 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.
- Review the hazard analysis to determine if a reassessment has been conducted as a result of any changes that might have occurred. If during the reassessment of the hazard analysis a food safety hazard was determined to be reasonably likely to occur, verify that the establishment developed a HACCP plan.

Determine compliance

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

Some examples of noncompliance include the following.

- 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.
- 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.

The CSI may need to discuss concerns with the establishment and issue a 30-day reassessment letter. The CSI will document any noncompliance.

Workshop 
Reassessment

Here are examples of possible noncompliance. Determine if these findings indicate noncompliance. If there is noncompliance, cite the regulatory reference and state why this is noncompliance in the space below the information. For each example, consider just the information presented here.

1. An establishment had a process without a HACCP plan and decided to add another step in its process. It reassessed its hazard analysis and determined that a CCP was now needed in the process. It documented this need, but the HACCP plan was not developed.
2. The establishment had an unforeseen hazard, but did not perform a reassessment.
3. The HACCP plan in use was last reassessed in 1999.
4. While performing the annual reassessment, the establishment determined that the HACCP plan no longer met the requirements of §417.2(c). It decided to contract a group to redo the HACCP plan, but the group won't be available for about 2 – 3 months.
5. An establishment's hazard analysis showed that it did not need a HACCP plan for its products. The establishment has recently installed some additional equipment and plans to expand its processing capabilities. Under §417.4(b), how does the CSI determine if the establishment reassessed the hazard analysis?

(6) Hazard Analysis

This next section covers how to perform your HACCP duties to verify that an establishment has performed a hazard analysis. First, read Part II, Hazard Analysis, of FSIS Directive 5000.1, Revision 1. The hazard analysis is a key element in the HACCP system. The hazard analysis is used to create the list of hazards identified to meet the first principle of HACCP and is used for the basis of the HACCP plan. The hazard analysis and HACCP plan are the building blocks of the HACCP system.

The CSI should use the thought process and methodology described below when verifying the hazard analysis. CSIs will verify compliance by reviewing the flow charts the hazard analysis, the HACCP plan, and HACCP records.

Before reviewing the hazard analysis, the CSI should understand that a food safety hazard is defined in 9 CFR §417.1 as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. The CSI must review hazard analysis records to determine if the analysis 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 plant) does not mean that the hazard analysis must address that hazard. If the CSI has a concern about whether relevant hazards have been considered, he or she may decide to discuss issues with the establishment or may seek guidance through the TSC.

The Basic Compliance Checklist (FSIS Form 5000-1) can be used by the CSI to assist in assessing compliance with Part 417 in a new establishment, with the addition of a new product or new process, or when the CSI becomes aware that a modification has been made to the 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 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: Section 417.4(a)(1) provides more details 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 CCPs, 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 CCPs 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?

If noncompliance exists with the hazard analysis, the CSI will document it appropriately. For example, **noncompliance** results if the establishment is not maintaining supporting documentation if the flow chart is missing a step, if the plant failed to consider a step in the hazard analysis, etc. If noncompliance is determined when the CSI verifies §417.5(a), the CSI uses the recordkeeping trend indicator. The information gained during this verification can impact if the CSI documents the noncompliance and whether other enforcement action is necessary. If the CSI makes the determination that more information is needed or that questions still remain regarding the hazard analysis the CSI may issue a 30-day reassessment letter. Trend indicators and documentation are discussed in more detail in the Documentation and Enforcement section.

30-Day Reassessment Letter

The CSI should issue a 30-day reassessment letter when the CSI needs 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. Do **not** use a 30-day letter when there is noncompliance.

Examples of when the CSI might write a 30-day reassessment letter are when the establishment has supporting documentation which still raises questions with the CSI:

- ✓ that the only CCP is at receiving and is determined to be adequate to control the food safety hazards identified in the hazard analysis throughout the process.
- ✓ for monitoring procedures and frequencies.
- ✓ for the verification procedures and frequencies in the HACCP plan.
- ✓ for the decisions made in the hazard analysis.

The CSI must use good judgment in assessing these situations. If the CSI determines that any of the situations result in imminent food safety issues, follow the Rules of Practice. For example, if the establishment has a critical limit for lethality of an internal product temperature of 140° F with no holding time, and it has no support for this critical limit, then the 30-day reassessment letter is **not** appropriate.

The CSI should discuss his or her concerns with establishment management, and contact the Technical Service Center if technical guidance is needed.

30-Day Reassessment Letter Example

Example Only For Use In Training

June 3, 2002
Mr. Establishment Manager
Manager, Est. 00038 M
The Pork Co.
Omaha, NE

Dear Mr. Establishment Manager,

The HACCP plan is required to adequately address the food safety hazards that are reasonably likely to occur with the 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 (CCPs). 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 the HACCP plan and the hazard analysis, the establishment has

made the selection of room temperature as the critical limit of the CCP for controlling microbiological pathogens in product. The documentation, both historical data and other scientific or technical information, available in the HACCP plan, or in other establishment documents provided, does not indicate a relationship between the temperature of the cooler and the control of microbiological pathogens in product.

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 the CCPs. This would also include supporting documentation to demonstrate that the preventive measures stated in the HACCP plan are adequate to control microbiological pathogens in product, which is identified in the hazard analysis.

Adequate identification of hazards and of the CCPs 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 the HACCP plan to ensure that it meets the requirements of 9 CFR §417. This would include documentation suitable to support the decision to select room temperature as the critical limit of the CCP for controlling microbiological pathogens in product. 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 the operation. If you believe that there is not a reason to reassess the HACCP plan and to modify it, 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 the HACCP plan meets the regulatory requirements of all of 9 CFR Part 417.

If you would like to discuss this matter, I will be happy to meet with you.

Sincerely,

Jane Dough
Consumer Safety Inspector
Omaha, NE

Summary

Now let's summarize and review the inspection 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, the CSI will

1. Review the HACCP plan.
2. Randomly select one (or more) of the three (monitoring, verification and recordkeeping) HACCP requirements to verify
3. Select one (or more) of the CCPs from the HACCP plan to verify
4. Determine which component to perform (recordkeeping or review and observation)
5. Perform the verification for that requirement for that CCP

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

Note: The CSI may wish to use **Table 1** and **Table 2** on the following pages as an aid in performing the 01 procedure.

Summary of Verifying the Five Regulatory Requirements

Table 1 and Table 2 provide a quick reference for the questions that the CSI would seek answers to when verifying each of the requirements.

Table 1—Monitoring, Verification, and Recordkeeping Requirements

Monitoring	Verification	Recordkeeping
<p>9CFR 417.2(c)(4)</p> <p>1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?</p> <p>2. Are the monitoring procedures being performed as described in the HACCP plan?</p> <p>3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?</p>	<p>9CFR 417.2(c)(7) 417.4(a)(2)</p> <p>1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?</p> <p>2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities & corrective actions?</p> <p>3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?</p> <p>4. Does the HACCP plan list product sampling as a verification activity?</p> <p>5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?</p> <p>6. Are direct observation verification activities conducted as per the HACCP plan?</p> <p>7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?</p>	<p>Recordkeeping Requirement – 9CFR 417.2(c)(6)</p> <p>1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?</p> <p>2. Do the records contain actual values & observations obtained during monitoring?</p> <p>Supporting Documentation Requirement – 9CFR 417.5(a)(1)(2)</p> <p>1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis?</p> <p>2. Does the establishment have the decision-making documents associated with the selection of each CCP?</p> <p>3. Do documents explain why the establishment selected the location of the CCP?</p> <p>4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?</p> <p>5. Does the establishment have scientific, technical, or regulatory support for the critical limit?</p> <p>6. Does the support appear creditable?</p> <p>7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?</p> <p>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?</p> <p>9. If the establishment has supporting documents for these decisions, does the documentation support the decisions?</p> <p>HACCP Records Requirement – 417.5(a)(3)</p> <p>1. Do the records document the monitoring of CCPs and critical limits?</p> <p>2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?</p> <p>3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date each record was made?</p> <p>4. Are verification procedures and results documented?</p> <p>5. Is the time recorded when the verification activity was performed?</p> <p>6. Does the record contain the date the record was made?</p> <p>7. Are process-monitoring calibration procedures & results recorded?</p> <p>Records Authenticity Requirement – 417.5(b)</p> <p>1. Was each entry on the record made at the time the event occurred?</p> <p>2. Does each entry include the time?</p> <p>3. Was each entry on the record signed or initialed by the establishment employee making the entry?</p> <p>Computerized Records Requirement – 417.5(d)</p> <p>Are appropriate controls provided to ensure integrity of electronic data and signatures?</p> <p>Record Retention and Availability Requirement – 417.5(e)(1)(2)</p> <p>1. Are the records being maintained for the required amount of time, i.e., one year for slaughter and refrigerated products and two years for frozen, preserved, or shelf-stable products?</p> <p>2. Are the records kept on-site for 6 months?</p> <p>3. If the records are stored off-site, can they be retrieved in 24 hours?</p> <p>Pre-shipment Review Requirement – 417.5(c)</p> <p>1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?</p> <p>2. Has the pre-shipment review been signed & dated by an establishment employee?</p>

Table 2-Corrective Action and Reassessment Requirements

Corrective Actions	Reassessment
<p><u>Corrective actions in response to a deviation from a critical limit – 9CFR 417.3(a)</u></p> <ol style="list-style-type: none"> 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? <p><u>Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action or an Unforeseen Hazard – 9CFR 417.3(b)</u></p> <ol style="list-style-type: none"> 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? 	<p><u>Annual reassessment requirement or changes in establishment processes - 9CFR 417.4(a)(3)</u></p> <ol style="list-style-type: none"> 1. Has a reassessment been conducted to meet the annual reassessment requirement? 2. Did the establishment consider any significant developments that have occurred in the establishment or that have occurred with respect to the types of products produced by the establishment, 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? <p><u>Reassessment of the Hazard Analysis – 9CFR 417.4(b)</u></p> <ol style="list-style-type: none"> 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.

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

Example: A 03G01 procedure is on the Procedure Schedule for this date. The CSI randomly selects to verify the monitoring requirement. The CSI decide to use both parts of the review and observation component to verify this requirement at the brine chiller CCP. In **Table 1** under the monitoring requirement the CSI finds that the questions to seek answers to are:

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

The CSI proceeds to seek answers to these questions by:

- Reviewing the HACCP plan.
- Observing the brine chiller temperature recording chart (a process monitoring instrument).
- Taking an independent measurement of the brine chiller medium temperature.
- Comparing the CSI findings to the establishment records.

Example: An 03H01 procedure is on the Procedure Schedule for this date. The CSI randomly selects to verify the recordkeeping requirement. The CSI knows that the supporting documentation requirement, reassessment requirements, and computerized records were verified recently so the CSI decides to verify the HACCP records and records authenticity requirements for the finished product storage CCP. The CSI looks at **Table 1** under those requirements and find the questions to seek answers to the following questions.

HACCP Records Requirement

1. *Do the records document the monitoring of CCPs 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, slaughter production lot, and the date the 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 and results recorded?*

Records Authenticity Requirement

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?*

The CSI proceeds to the QA office where the CSI requests to look at the records from the previous day for the finished storage CCP. The CSI examines the records seeking answers to the questions listed above.

Performing the 02 Procedure

The CSI performs the 02 procedure by verifying **all** requirements **at all CCPs for a specific production**, including the preshipment review. The CSI may use either or both components in performing the 02 procedure. To perform the 02 procedure, the CSI will:

1. Verify that all of the HACCP requirements have been met for all CCPs in the HACCP plan for that specific production. The CSI must understand what the establishment has defined as their specific production which will be shipped. The CSI must observe at least once how the establishment meets the requirements in §417.5(c) prior to being able to properly perform the 02 procedure.
2. Verify the pre-shipment review requirement for that specific production is met.
3. Observe the records reviewed by the establishment during its defined pre-shipment review process to determine if all the relevant records reviewed associated with that specific production.

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

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

Example: The CSI is performing the 03I02 procedure and proceeds to verify all the requirements at all the CCPs for a lot of Westphalian hams. The establishment has two CCPs, one at receiving and one at storage. The CSI seeks to answer the questions in **Table 1** for all of the requirements at both of the CCPs. The CSI decides to use the recordkeeping component at the receiving CCP. For the storage temperature CCP the CSI decides to use the review and observation component since there has been some inconsistency in the cooler temperatures lately. The CSI proceeds to check the records at the receiving CCP to see if all requirements have been met, and then the CSI goes to the storage area to take a temperature measurement and compare it to the continuous recording thermometer (process monitoring instrument). The CSI also checks the records at this CCP to verify that the results meet the regulatory requirements. There have been no corrective actions nor reassessment associated with this lot of product so the CSI cannot verify these requirements. Later in the shift the CSI goes to the QA office to check records to determine that the establishment has carried out the preshipment review for that particular lot.

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

SUMMARY WORKSHOP

It is March 3, 2003, and the CSI has a 03G01 procedure scheduled at Establishment P-42. The CSI decides to verify the monitoring, verification, and recordkeeping requirements by using the recordkeeping component of the 01 procedure. The CSI decides to use the records from the previous day to perform this procedure.

The CSI looks at the HACCP plan to ensure it has not been modified and that he/she is familiar with all the procedures and frequencies listed in the plan. Look at the HACCP plan, hazard analysis and records provided and determine compliance with the monitoring, verification, and recordkeeping requirements. You should gather information, assess the information, and determine regulatory compliance. There are three possible outcomes: compliance, noncompliance, or more information needed. Determine one of these outcomes for each requirement verified. If more information is needed, list the type of information needed and the concerns you are wanting addressed with this information.

1. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **monitoring** requirements specified in 9CFR 417.2(c)(4) are:

- a) Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?
- b) Are the monitoring procedures being performed as described the HACCP plan?
- c) Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?
- d) Are the CLs met?

When you have gathered the information asking these questions, you should assess the information you gathered and make a supportable regulatory decision.

- e) Is the monitoring requirement met?
- f) Is there regulatory noncompliance with the monitoring requirement? If so, what is the noncompliance?
- g) Do you need more information to determine monitoring compliance? If so, what type of information is needed and what concerns do you have?

2. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **verification** requirements specified in 9CFR 417.2(c)(7) and 9CFR 417.4(a)(2)(i)(ii)(iii) are:

- a) Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?
- b) Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?
- c) Does the HACCP plan list procedures and frequencies for the reviews of records generated and maintained in accordance with 9CFR 417.5(a)(3)?
- d) Does the HACCP plan list product sampling as a verification activity?
- e) Are process-monitoring instrument calibration activities conducted as per the HACCP plan?
- f) Are direct observation activities conducted as per the HACCP plan?
- g) Are records generated in accordance with 9CFR 417.5(a)(3) being reviewed by the establishment?

When you have gathered the information asking these questions, you should assess the information you gathered and make a supportable regulatory decision.

- h) From what we have considered so far, is the verification requirement met?
- i) Do you need more information to determine verification compliance? If so, what type of information is needed and what concerns do you have?

3. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **recordkeeping** requirements specified in 9CFR 417.2(c)(6)?

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

4. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **recordkeeping** requirements specified in 9CFR 417.5(a)(1), 417.5(a)(2) are:

- a) Does the establishment have the supporting documentation for the decisions made in the hazard analysis?
- b) Does the establishment have the decision-making documents associated with the selection of each CCP?
- c) Do the documents explain why the establishment selected that location for the CCP?
- d) Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?
- e) Does the establishment have scientific, technical, or regulatory support for the critical limit?
- f) Does the support appear credible?
- g) Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?
- h) 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?
- i) If the establishment has supporting documents for these decisions, does the documentation support the decisions?

5. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **recordkeeping** requirements specified in 9CFR 417.5(a)(3) are?

- a) Do the records document the monitoring of CCPs and their critical limits?
- b) Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?
- c) Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date the record was made?
- d) Are the verification procedures and results of those procedures documented?
- e) Is the time recorded when the verification activity was performed?
- f) Does the record contain the date the record was made?
- g) Are the process-monitoring calibration procedures and results being recorded?

When you have gathered the information asking these questions, you should assess the information you gathered and make a supportable regulatory decision.

- h) Is the recordkeeping requirement met?

- i) Is there regulatory noncompliance with the recordkeeping requirement? If so, what is the noncompliance?

- j) Do you need more information to determine recordkeeping compliance? If so, what type of information is needed and what concerns do you have?

HACCP PLAN

CCP DESCRIPTION, CRITICAL LIMITS, MONITORING PROCEDURES, CORRECTIVE ACTION(S)

PROCESSING CATEGORY: FULLY COOKED, NOT SHELF STABLE					
PRODUCT: Oven Roasted/Smoked Turkey Breasts					
CCP # and Location	Critical Limits	Monitoring Procedures and Frequencies	HACCP Records	Verification Procedures and Frequencies	Corrective Action(s)
Cooking CCP # 1	Internal cooked product temperature will be $\geq 160^{\circ}$ F	The smokehouse operator will measure the internal temperature of two pieces of product in each oven of product cooked in the cold spots of the oven using a probe thermometer.	Cooking log Equipment calibration log Corrective action log	Once per shift the smokehouse supervisor will measure the internal temperature of 2 breasts at the conclusion of the cooking process. Smokehouse supervisor will review cooking logs daily.	If a deviation from a critical limit occurs, the smokehouse supervisor will retain the product involved in the deviation and notify the QA Manager. The QA Manager will be responsible for the corrective actions meeting the requirements of 417.3(a).

Signature: Blaine Logan Date: 1-1-03

HACCP PLAN

CCP DESCRIPTION, CRITICAL LIMITS, MONITORING PROCEDURES, CORRECTIVE ACTION(S)

PROCESSING CATEGORY: FULLY COOKED, NOT SHELF STABLE					
PRODUCT: Oven Roasted/Smoked Turkey Breasts					
CCP # and Location	Critical Limits	Monitoring Procedures and Frequencies	HACCP Records	Verification Procedures and Frequencies	Corrective Action(s)
Chilling CCP # 2	Product will be chilled from 130 ⁰ F to 80 ⁰ F in 90 minutes and from 80 ⁰ to 40 ⁰ or less in 5 hours or less.	Oven operator will measure the internal temperature of 2 breasts when they are removed from the smokehouse. The temperature of the breasts and the time they are placed into the cooler will be recorded on the chilling log. Hourly the QA technician will measure the internal temperature of 2 breasts from each oven of product in the cooler to ensure limit is met.	Chilling log Equipment calibration log Corrective Action log	Daily, before operation, QA will check the hand-held thermometers used for measuring product temperatures and calibrate them within 2 ⁰ F of an instrument of known accuracy. QA Manager will review chilling records daily. Once per shift the packaging supervisor will observe the QA technician perform the monitoring activity.	If a deviation from a critical limit occurs the QA technician will retain the product involved in the deviation and notify the QA Manager. The QA Manager will be responsible for the corrective actions meeting the requirements of 417.3(a).

Cooking Log

Date: 3-2-03

Critical limit: Product will be cooked to $\geq 160^{\circ}$ F

Product ID	Lot Number	Oven	Time	Temperature	Comments	Monitor's Initials	Verification Initials
ORBR	1-62	1	8:47 am	162°, 166°		JE	
ORBR	2-62	2	10:23 am	164°, 168°		JE	GG
		3-2-03	4:30 pm		Reviewed cooking log- all critical limits were met.		MG

Chilling Log

Date: 3-2-03 Critical limit: Product will be chilled from 130° F to 80° F in ≤ 90 minutes and from 80° F to 40° F in ≤ 5 hours

Product ID	Lot Number	Time entered cooler	Temperature	Time	Comments	Monitor's Initials	Verification Initials
ORBR	1-62	10:05am	98°, 99°			JE	
ORBR	1-62		77°, 78°	10:59 am		QA	
ORBR	1-62		67°, 65°	12:01 pm		QA	
ORBR	1-62		56°, 54°	12:56 pm		QA	
ORBR	1-62		44°, 46°	1:59 pm		QA	
ORBR	1-62		39°, 38°	2:50 pm	Observed monitoring activity	QA	PS
ORBR	2-62	11:28 am	100°, 98°			DF	
ORBR	2-62		80°, 78°	12:25 pm		SA	
ORBR	2-62		66°, 64°	1:23 pm		SA	
ORBR	2-62		54°, 52°	2:15 pm		SA	
ORBR	2-62		40°, 38°	3:18 pm	Observed monitoring activity	SA	SS
			3-2-03	3:45 pm	Reviewed chilling log- all critical limits were met.		PG

Pre-shipment Review Log

Product ID: 1-62-2-62

Were monitoring records for CCP #1 complete? Yes

Were scheduled verification activities completed? Yes

Were there any deviations to the critical limit? No

If there were deviations, was appropriate corrective action taken? _____

Were monitoring records for CCP #2 complete? Yes

Were scheduled verification activities completed? Yes

Were there any deviations to the critical limit? No

If there were deviations, was appropriate corrective action taken? _____

Comments:

Reviewed by: Larry Wagner

Date: 3-3-03

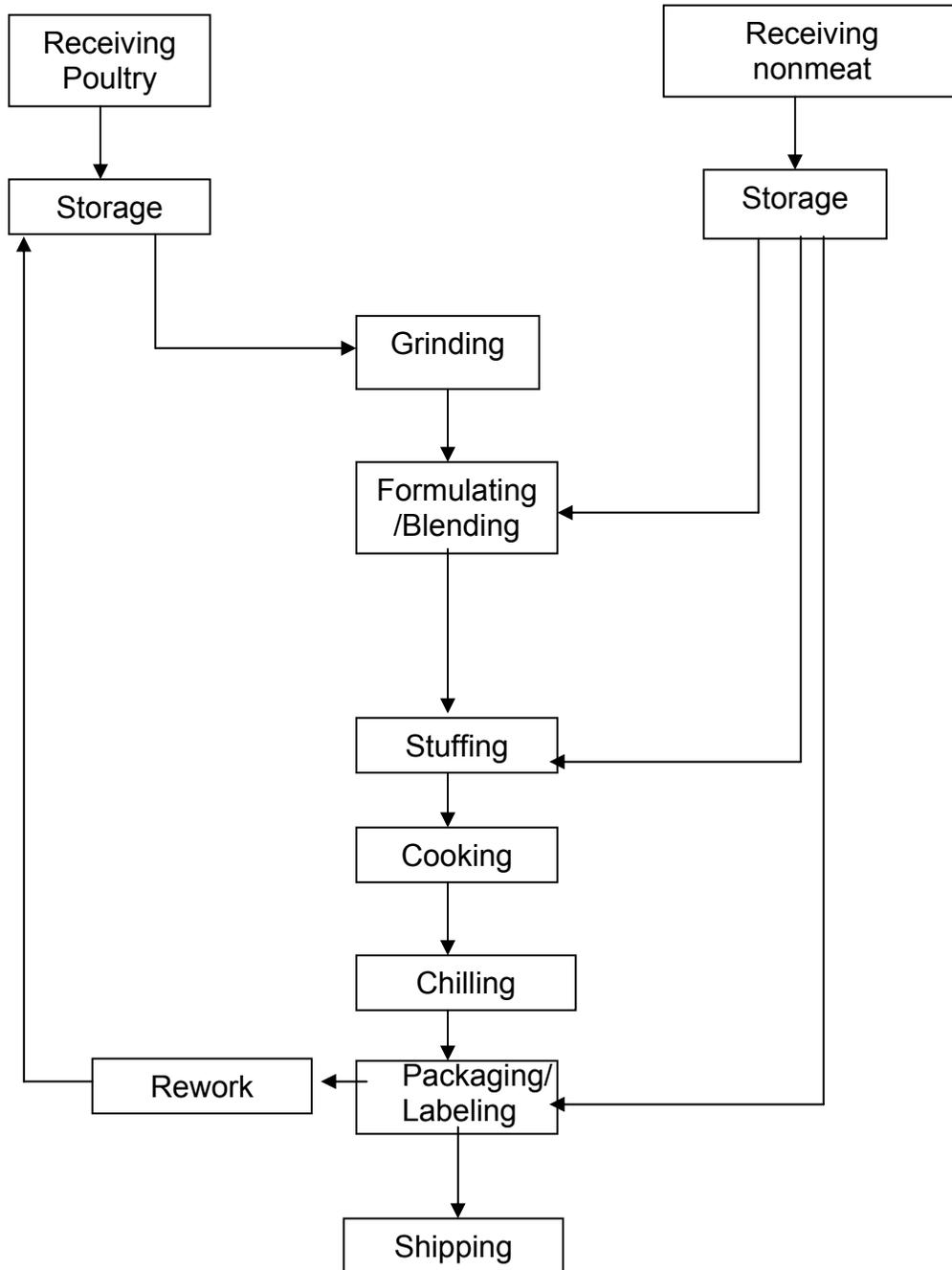
THERMOMETER CALIBRATION LOG								
Criteria Within ±2° F of Control Thermometer								
Date	Time	Department or Area	Thermometer ID#	Control Thermometer Reading	Personal Thermometer Reading	Adjustment Required (Yes or No)	Initials	Comments
3-2-03	6:00 am	Cooking	T-1	140°	140°	No	KM	
3-2-03	6:05 am	QA	T-2	40°	40°	No	KM	
3-2-03	6:07 am	Packaging	T-4	40°	39°	No	KM	
3-2-03	6:10 am	Formulation	T-3	40°	40°	No	KM	
3-2-03	6:15 am	Smokehouse Supervisor	T-5	140°	137°	Yes	KM	

If a thermometer is broken or taken out of service, document this in the comment column.

Reviewed by: _____

Date: _____

**PROCESSING CATEGORY: Fully Cooked, Not Shelf Stable
Flow Diagram for Oven Roasted/Smoked Turkey Breasts**



HACCP PLAN MUST BE PLANT SPECIFIC. THESE MATERIALS ARE TO BE USED FOR FACILITATION PURPOSES ONLY.

EST. P-42: PROCESS DESCRIPTION

PROCESS CATEGORY: FULLY COOKED, NOT SHELF STABLE

PRODUCT: OVEN ROASTED/SMOKED TURKEY BREASTS

1. COMMON NAME?	OVEN ROASTED/SMOKED FABRICATED TURKEY BREASTS
2. HOW IS IT TO BE USED?	READY TO EAT
3. TYPE OF PACKAGE?	VACUUM PACKED
4. LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?	45 DAYS AT 40°
5. CONSUMERS OR INTENDED USE?	HRI (Hotel, Restaurant, Institution)
6. LABELING INSTRUCTIONS?	KEEP REFRIGERATED
7. DISTRIBUTION?	REFRIGERATED TRUCKS

HACCP PLAN MUST BE PLANT SPECIFIC. THESE MATERIALS ARE TO BE USED FOR FACILITATION PURPOSES ONLY.

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

Process step	Food safety hazard	Reasonably likely to occur?	Basis	If Yes in column 3, what measures could be applied to prevent, eliminate or reduce the hazard to an acceptable level?
Receiving – Poultry	Biological – <i>Salmonella</i> <i>L. monocytogenes</i> <i>C. perfringens</i>	Yes	It is known that these pathogens are reasonably likely to occur in the poultry received.	Product will be stored at a temperature to preclude proliferation of these pathogens. These pathogens will be eliminated or reduced to an acceptable level during the cooking step.
Receiving – Nonmeat Ingredients	Chemical – None			
	Physical – None			
	Biological – None			
	Chemical – Not acceptable for intended use	No	Letters of guaranty are received from all suppliers of nonmeat ingredients.	
	Physical – Foreign material	No	Historical data demonstrates that no foreign material in nonmeat ingredients received.	

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

Process step	Food safety hazard	Reasonably likely to occur?	Basis	If Yes in column 3, what measures could be applied to prevent, eliminate or reduce the hazard to an acceptable level?
Storage – Poultry Storage - Nonmeat Grinding	Biological – Pathogens Chemical – none Physical – None Biological – None Chemical – None Physical – None Biological – None Chemical – None Physical – None	Yes	Pathogen proliferation is likely to occur in this product if temperature is not maintained at or below a level sufficient to preclude the proliferation.	Maintain product temperature at or below a level sufficient to preclude pathogen proliferation. Pathogens will be eliminated or reduced to an acceptable level at the cooking step.

Figure 3

HAZARD ANALYSIS – FULLY COOKED, NOT SHELF STABLE

Process step	Food safety hazard	Reasonably likely to occur?	Basis	If Yes in column 3, what measures could be applied to prevent, eliminate or reduce the hazard to an acceptable level?
Chilling Rework	Biological – <i>C. Perfringens</i> Chemical – None Physical None Biological – None Chemical – None Physical – None	Yes	Insufficient chilling would result in proliferation of <i>C. perfringens</i> .	Apply chilling procedures to reduce internal product temperature as quickly as possible.

Figure 3

Supporting Data for Meeting Stabilization Performance Standard

Establishment P42 normally showers the cooked product for an hour after the product has completed the cook cycle. The establishment gathered data by using data tracers in the product during the shower cycle in order to gather the information necessary to determine how they could meet the stabilization critical limit in their HACCP plan for fully cooked, not shelf stable products. The company has records showing that 45 minutes of showering will drop the internal temperature of the product to 130 degrees. The temperature recorded on the chilling record in the "time entered cooler" column represents the temperature of the product after the completion of the one-hour shower. Therefore, 15 minutes of the shower time must be included as part of the stabilization step in reducing the product temperature from 130 to 80 degrees.

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Appendix A

Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products

Introduction

Establishments producing ready-to-eat roast beef, cooked beef and corned beef products and certain ready-to-eat poultry products are required by FSIS to meet the lethality performance standards for the reduction of Salmonella contained in §§ 318.17(a)(1) and 381.150(a)(1) of the meat and poultry inspection regulations. Further, FSIS requires meat and poultry establishments, if they are not operating under a HACCP plan, to demonstrate how their processes meet these lethality performance standards within a written process schedule validated for efficacy by a process authority (§§ 318.17(2)(b) and (c) and 381.150 (2)(c) and (d)).

To assist establishments in meeting the lethality requirements, FSIS is issuing these compliance guidelines, which are based upon the time/temperature requirements contained in previous regulations. Establishments may choose to employ these guidelines as their process schedules. FSIS considers these guidelines, if followed precisely, to be validated process schedules, since they contain processing methods already accepted by the Agency as effective.

Also within these guidelines, FSIS has provided discussion regarding disposition of product following heating deviations and advice for the development of customized procedures for meeting the lethality performance standards.

Guidelines for Cooked Beef, Roast Beef, and Cooked Corned Beef

1. Cooked beef and roast beef, including sectioned and formed roasts, chunked and formed roasts, and cooked corned beef can be prepared using one of the following time and temperature combinations to meet either a 6.5- \log_{10} or 7- \log_{10} reduction of Salmonella. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for a least the stated time:

Minimum Internal Temperature		Minimum processing time in minutes or seconds after minimum temperature is reached	
Degrees Fahrenheit	Degrees Centigrade	6.5-log ₁₀ Lethality	7-log ₁₀ Lethality
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.
145	62.8	4 min.*	4 min.*
146	63.3	169 sec.	182 sec.
147	63.9	134 sec.	144 sec.
148	64.4	107 sec.	115 sec.
149	65.0	85 sec.	91 sec.
150	65.6	67 sec.	72 sec.
151	66.1	54 sec.	58 sec.
152	66.7	43 sec.	46 sec.
153	67.2	34 sec.	37 sec.
154	67.8	27 sec.	29 sec.
155	68.3	22 sec.	23 sec.
156	68.9	17 sec.	19 sec.
157	69.4	14 sec.	15 sec.
158	70.0	0 sec.**	0 sec.**
159	70.6	0 sec.**	0 sec.**
160	71.1	0 sec.**	0 sec.**

* Past regulations have listed the minimum processing time for roast beef cooked to 145°F as "Instantly." However, due to their large size, most of these roasts dwell at 145°F, or even at higher temperatures, for at least 4 minutes after the minimum internal temperature is reached. FSIS has revised this time/temperature table to reflect this and emphasizes that, to better ensure compliance with the performance standard, establishments should ensure a dwell time of at least 4 minutes if 145°F is the minimum internal temperature employed.

**The required lethalties are achieved instantly when the internal temperature of a cooked meat product reaches 158°F or above.

2. Cooked beef, including sectioned and formed roasts and chunked and formed roasts, and cooked corned beef should be moist cooked throughout the process or, in the case of roast beef or corned beef to be roasted, cooked as in paragraph (3) of this compliance guide. The moist cooking may be accomplished by placing the meat in a sealed, moisture impermeable bag, removing the excess air, and cooking; by completely immersing the meat, unbagged in water throughout the entire cooking process; or by using a sealed oven or steam injection to raise the relative humidity above 90 percent throughout the cooking process.

3. Roast beef or corned beef to be roasted can be cooked by one of the following methods:

- Heating roasts of 10 pounds or more in an oven maintained at 250 °F (121 °C) or higher throughout a process achieving one of the time/temperature combinations in (1) above;
- Heating roasts of any size to a minimum internal temperature of 145 °F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour; or
- Heating roasts of any size in an oven maintained at any temperature that will satisfy the internal temperature and time combinations of the above chart of this compliance guide if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour. The relative humidity may be achieved by use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity.

4. Establishments producing cooked beef, roast beef, or cooked corned beef should have sufficient monitoring equipment, including recording devices, to assure that the time (accuracy assured within 1 minute), the temperature (accuracy assured within 1 °F), and relative humidity (accuracy assured within 5 percent) limits of these processes are being met. Data from the recording devices should be made available to FSIS program employees upon request.

Guidelines for Cooked Poultry Rolls and Other Cooked Poultry Products

1. Cooked poultry rolls and other cooked poultry products should reach an internal temperature of at least 160 °F prior to being removed from the cooking medium, except that cured and smoked poultry rolls and other cured and smoked poultry should reach an internal temperature of at least 155 °F prior to being removed from the cooking medium. Cooked ready-to-eat product to which heat will be applied incidental to a subsequent processing procedure may be removed from the media for such processing provided that it is immediately fully cooked to the 160 °F internal temperature.

2. Establishments producing cooked poultry rolls and other cooked poultry products should have sufficient monitoring equipment, including recording devices, to assure that the temperature (accuracy assured within 1 °F) limits of these processes are being met. Data from the recording devices should be made available to FSIS program employees upon request.

Discussion

Heating Deviations and Slow Come Up Time

Determining the appropriate disposition of products following heating deviations can be even more difficult than determining the disposition of product after a cooling deviation. Heating deviations, which most often involve slow come-up time or an inordinate dwell time within the optimum temperature range for microorganism growth, can foster the multiplication of many pathogens. This multiplication sometimes can be so prodigious that even re-cooking may be ineffective in rendering the product safe. Also, certain toxigenic bacteria can release toxins into the product. Some of these toxins, such as those of Staphylococcus aureus, are extremely heat stable and are not inactivated by normal re-cooking temperatures.

Further, the sampling of product following a heating deviation may not yield sufficient information to determine the safety of the product in question. Heating deviations can favor the multiplication of many types of bacteria. It would be difficult and expensive to sample for all of them.

Depending on the circumstances, establishments may want to use computer modeling to estimate the relative multiplication of bacteria. For example, in a past incident involving an extreme heating deviation, product was put in an oven in which the temperature was inadvertently set to 95°F for about 12 hours. Computer modeling was easily applied in this case because much of the dwell time was at one temperature. The Agency determined that within a 6 hour time frame (with other growth conditions assumed to be favorable), the relative multiplication of many pathogens of concern could have exceeded five logs. Clearly the product could not be salvaged by reprocessing and was therefore destroyed.

Under changing conditions of temperature, however, computer modeling becomes more difficult. One approach is to average lag/log times over small increments such as 5° and add these times to get an approximation of possible total relative growth over a larger increment of time. Establishments must keep in mind that the population of bacteria before processing is generally unknown and that assumptions in the high range often are used as input parameters in the modeling.

Establishments should ultimately rely upon the expertise of a processing authority to determine the severity of heating deviations and subsequent appropriate disposition of the product in question. Dwell times of greater than 6 hours in the 50°F to 130°F range should be viewed as especially hazardous, as this temperature range can foster substantial growth of many pathogens of concern. And, a knowledge of the specific product and factors that would favor or inhibit the growth of various bacteria is essential.

Computer Modeling Program Availability

The Microbial Food Safety Research Unit of the Eastern Regional Research Center, USDA Agriculture Research Service, has developed a bacterial pathogen modeling program. Entitled "Pathogen Modeling Program-Version 5.1 for Windows," it is available on the Internet from <http://www.arserrc.gov>. Other programs may be available commercially.

Customized Processes

Although compliance with these guidelines will yield product that meets the lethality performance standards, some establishments may want to develop customized processing procedures that meet the codified lethality performance standards: 6.5₁₀ logs of Salmonella in ready-to-eat beef products and 7 log₁₀ in ready-to-eat poultry products. Establishments also may want to develop and implement processes using alternative lethality standards. Keep in mind, however, that all processes also must achieve, throughout the product, an appropriate reduction of other pathogens of concern and their toxins or toxic metabolites.

Establishments or their process authorities may develop customized procedures or alternative lethality standards that meet the performance standards by using information obtained from the literature and/or by comparing their methods with established processes. However, statistical calculations on results obtained from sampling alone are not sufficient to demonstrate that product satisfies reduced initial product conditions or that product meets the performance standards. Rather, the demonstration should be based on scientific rationale, supported by experimental data.

One of the most definitive tools at the disposal of an establishment or processing authority is the challenge study. Although challenge studies must be conducted in the laboratory rather than the establishment, they should be designed and conducted to accurately simulate the commercial process. Challenge studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in salmonellae research. A cocktail of various serotypes of Salmonella should be used in an inoculated pack study to demonstrate that the lethality performance standard is met. Relatively heat resistant pathogenic strains should be included in the cocktail to develop a worst case. The serotypes/strains selected should be among those that have been historically implicated in an appreciable number of outbreaks.

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Appendix B

Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)

Introduction

Establishments producing ready-to-eat roast beef, cooked beef and corned beef products, fully cooked, partially cooked, and char-marked meat patties, and certain partially cooked and ready-to-eat poultry products are required by FSIS to meet the stabilization performance standards for preventing the growth of spore-forming bacteria (9 CFR §§ 318.17(a)(2), 318.23(d)(1), and 381.150(a)(2), respectively). Further, FSIS requires meat and poultry establishments, if they are not operating under a HACCP plan, to demonstrate how their processes meet these stabilization performance standards within a written process schedule validated for efficacy by a process authority (§§ 318.17(b) and (c); 318.23(d)(2) and (3); and 381.150(c) and (d)).

To assist establishments in meeting the stabilization requirements, FSIS is issuing these compliance guidelines, which are based upon FSIS Directives and the product cooling requirements contained in previous regulations. Establishments may choose to employ these guidelines as their process schedules. FSIS considers these guidelines, if followed precisely, to be validated process schedules, since they contain processing methods already accepted by the Agency as effective.

Also within these guidelines, FSIS has provided discussion regarding disposition of product following cooling deviations and advice for the development of customized procedures for meeting the stabilization performance standards.

Stabilization Guidelines

It is very important that cooling be continuous through the given time/temperature control points. Excessive dwell time in the range of 130° to 80°F is especially hazardous, as this is the range of most rapid growth for the clostridia. Therefore cooling between these temperature control points should be as rapid as possible.

1. During cooling, the product's maximum internal temperature should not remain between 130°F and 80°F for more than 1.5 hours nor between 80°F and 40°F for more than 5 hours. This cooling rate can be applied universally to cooked products (e.g., partially cooked or fully cooked, intact or non-intact, meat or poultry) and is preferable to (2) below.

2. Over the past several years, FSIS has allowed product to be cooled according to the following procedures, which are based upon older, less precise data: chilling should begin within 90 minutes after the cooking cycle is completed. All product should be chilled from 120°F (48°C) to 55°F (12.7°C) in no more than 6 hours. Chilling should then continue until the product reaches 40°F (4.4°C); the product should not be shipped until it reaches 40°F (4.4°C).

This second cooling guideline is taken from the former ("Requirements for the production of cooked beef, roast beef, and cooked corned beef", 9 CFR 318.17(h)(10)). It yields a significantly smaller margin of safety than the first cooling guideline above, especially if the product cooled is non-intact product. If an establishment uses this older cooling guideline, it should ensure that cooling is as rapid as possible, especially between 120 °F and 80°F, and monitor the cooling closely to prevent deviation. If product remains between 120 °F and 80 °F more than one hour, compliance with the performance standard is less certain.

3. The following process may be used for the slow cooling of ready-to-eat meat and poultry cured with nitrite. Products cured with a minimum of 100 ppm ingoing sodium nitrite may be cooled so that the maximum internal temperature is reduced from 130 to 80 °F in 5 hours and from 80 to 45 °F in 10 hours (15 hours total cooling time).

This cooling process provides a narrow margin of safety. If a cooling deviation occurs, an establishment should assume that their process has exceeded the performance standard for controlling the growth of *Clostridium perfringens* and take corrective action. The presence of the nitrite, however, should ensure compliance with the performance standard for *Clostridium botulinum*.

Establishments that incorporate a "pasteurization" treatment after lethality and stabilization treatments (e.g., applying heat to the surface of a cooled ready-to-eat product after slicing) and then re-stabilize (cool) the product should assess the cumulative growth of *C. perfringens* in their HACCP plans. That is, the entire process should allow no more than 1-log₁₀ total growth of *C. perfringens* in the finished product. When employing a post-processing "pasteurization," establishments may want to keep in mind that at temperatures of 130 °F or greater, *C. perfringens* will not grow.

Support documentation for this process was filed by the National Food Processors Association on April 14, 1999. It is available for review in the FSIS Docket Room, Room 102, Cotton Annex, 300 12th St., SW, Washington, DC 20250-3700.

Discussion

Cooling Deviations

In spite of the best efforts of an establishment to maintain process control, cooling deviations will occasionally occur. Power failures or breakdowns of refrigeration equipment cause situations that cannot always be anticipated. However, it is important that the establishment plan how to cope with such eventualities before they occur.

The recommended time/temperature combinations in these guidelines incorporate a small safety margin. Therefore, an occasional small lapse in and of itself may not cause a problem in every instance. If the cause of a small cooling deviation is not traced and corrected when first noticed, however, the problem will likely recur and possibly become more frequent and more severe. The processor should consider an occasional small deviation an opportunity to find and correct a control problem. Of course, a large deviation or continual small ones will always constitute unacceptable risk.

After it is determined that a cooling deviation has occurred, the processor should:

1. Notify the inspector, the QC unit, and other concerned units, such as refrigeration maintenance and production.
2. Hold the involved product and determine the potential adulteration by bacteria, particularly clostridial pathogens. If adulteration is confirmed or appears to be likely, inform the inspector.
3. Postpone further product manufacturing using that chill facility until the processor has:
 - a. determined the cause of the deviation;
 - b. completed adjustments to assure that the deviation will not recur; and
 - c. informed the inspector and the production units of the determinations and adjustments and make any needed amendments in the written processing procedures.

Computer modeling and sampling

In the event that a cooling deviation does occur, the product may often be salvaged if the results of computer modeling and/or sampling can ensure product safety. Because of a lack of information concerning the distribution of *C. perfringens* in product, sampling may not be the best recourse for determining the disposition of product following cooling deviations. However, computer modeling can be a useful tool in assessing the severity of a cooling deviation. While computer modeling cannot provide an exact determination of the possible amount clostridial growth, it can provide a useful estimate.

A technical document (available from the FSIS Docket Room) provides description of the calculations that are used to estimate relative growth.

With careful continuous monitoring of the heating and cooling time/temperature profile of each lot, there will always be many available data points, enhancing the accuracy of computer modeling. Conversely, when there are few documented time/temperature data points, the accuracy of the modeling decreases markedly. If time/temperature monitoring has not been conducted through the end point internal product temperatures of 40° F or less, sampling is not an option and the product should be destroyed.

Options after computer determination of cooling deviation severity.

If computer modeling suggests that the cooling deviation would likely result in more than one log increase in *C. perfringens*, without any multiplication (remains in lag phase) of *C. botulinum*, then the establishment can choose to recook or sample the product.

Recook only when:

- All product was either immediately refrigerated after the deviation or can be immediately recooked after the deviation; and

- The re-cooking procedure can achieve a final internal product temperature of at least 149°F (65°C) for two minutes. Subsequent to re-cooking, the product must be cooled in strict conformance to existing guidelines. When the product is to be reworked with another raw product, the re-cooking procedure for the combined product must achieve a minimum internal temperature of 149°F, to address the cooling deviation, and further to an increased time/temperature if necessary to be in accord with any other requirement relative to microbiological safety for the intended final product. Subsequent to re-cooking, the product must be cooled in strict conformance to existing guidelines.

Custom Stabilization Processes

While compliance with the guidelines above will yield product that meets the cooling performance standards, some establishments may want to develop customized stabilization procedures. Because customized process schedules must be validated by process authorities for efficacy, most establishments will probably rely upon processing authorities to develop such procedures, demonstrate their efficacy, and attest to their safety. Process authorities may obtain information from the literature, or likely compare peer reviewed methods in determining safe procedures that meet the performance standards.

Probably one of the most definitive tools at the disposal of the processing authority is the inoculated pack study. Such studies should, of course, be conducted only in the laboratory, not in the plant. Further, such studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in clostridial research. *C. perfringens* can be used alone in an inoculated pack study to demonstrate that the cooling performance standard is met for both microorganisms, *C. perfringens*, and *C. botulinum*. This is because conditions of time/temperature that would limit the growth of *C. perfringens* to one log or less would also prevent multiplication of *C. botulinum*, which is much slower. A cocktail of various strains of *C. perfringens* spores is often used for this purpose. Relatively "fast" toxigenic strains should be used to develop a worst case. However, the strains selected should be among those that have been historically implicated in an appreciable number of outbreaks, especially in products similar to those being prepared in the establishment.

Appendix 1

Random Number Generator

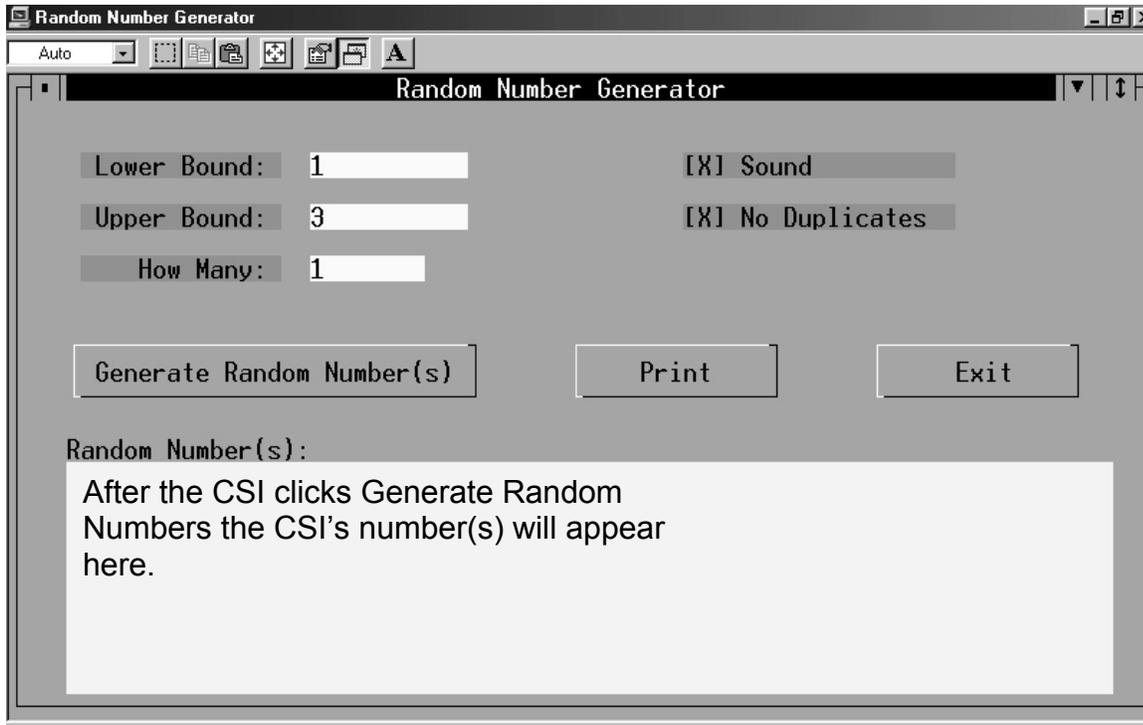
The CSI can use a computer with the FSIS FAIM load to select a random number. This is one way to randomly select the regulatory requirements to verify during the 01 procedure. Remember that the first item, which the CSI will always need to randomly select, is a number between one and three to represent which of the three regulatory requirements the CSI are going to verify. Remember that the CSI may also choose to verify more than one regulatory requirement.

- 1-Monitoring
- 2-Verification
- 3-Recordkeeping

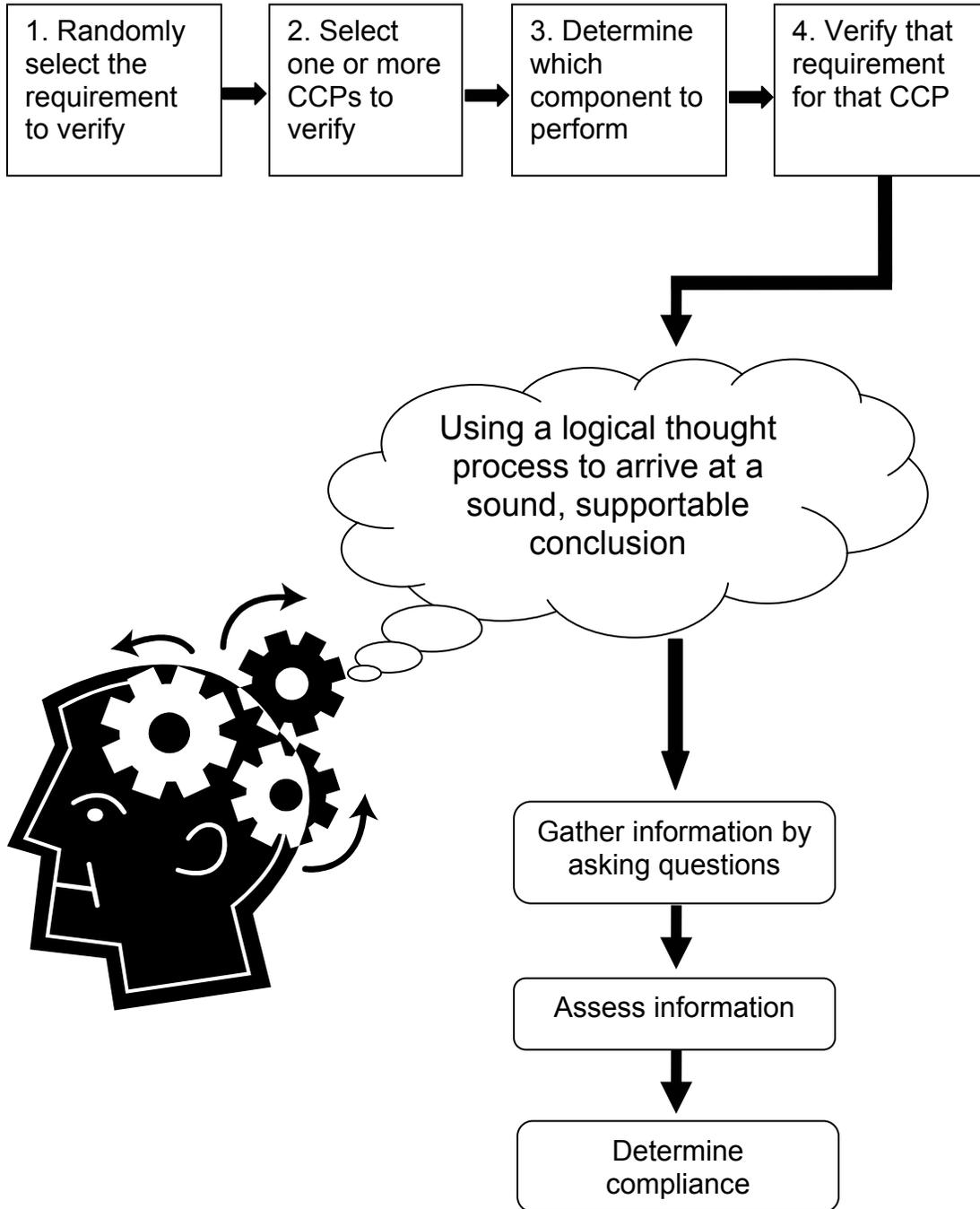
Here are some instructions on how to do this on the CSI's computer.

Go to Start, select FSIS Applications, select Other Tools, and select Random Number Generator. In Lower Bound enter the lowest number in the group of numbers the CSI are randomly selecting from. In Upper Bound enter the highest number in the group of numbers the CSI are randomly selecting from. In How Many enter the number of random numbers the CSI want to generate. Click on Generate Random Numbers.

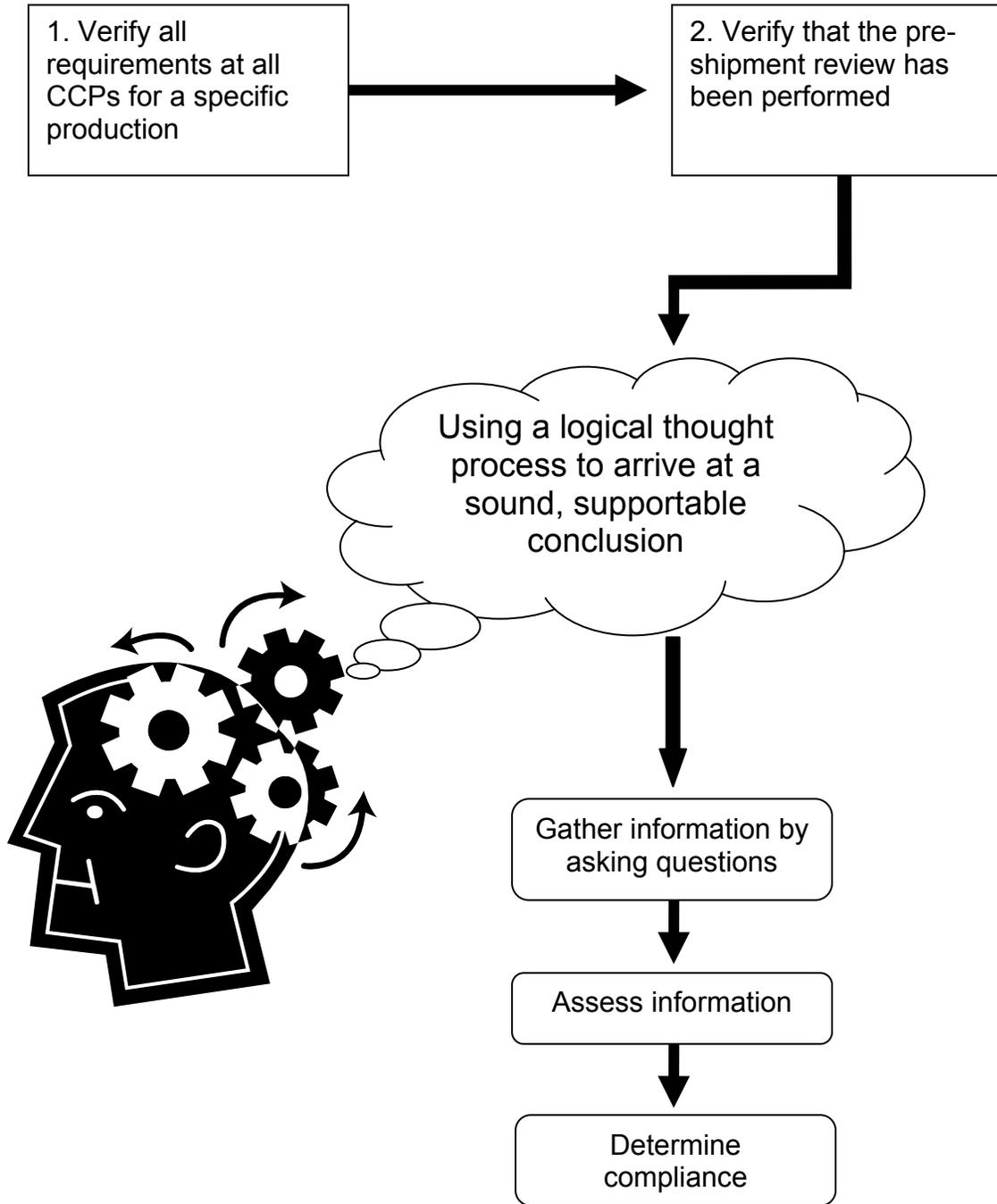
Example: To select one out of the three regulatory requirements, enter “1” in Lower Bound, enter “3” in Upper Bound, and enter “1” in How Many, then click Generate Random Numbers. To select two of the three regulatory requirements, repeat the same instructions, but enter “2” in How Many.



01 HACCP Procedure Methodology



02 HACCP Procedure Methodology



Verifying the Five HACCP Requirements

Requirement	Regulatory References	Procedure	Component
Monitoring	417.2(c)(4) <u>Monitoring Requirement</u>	01 or 02	Rk R&O
Verification	417.2(c)(7) <u>Verification Requirement</u> 417.4(a)(2)(i)(ii)(iii) <u>Verification Activities</u>	01 or 02	Rk R&O
Recordkeeping	417.2(c)(6) <u>Recordkeeping System</u>	01 or 02	Rk
	417.5(a)(1)(2) <u>Supporting Documentation</u>	01 (02 ²)	Rk
	417.5(a)(3) <u>HACCP Records</u>	01 or 02	Rk
	417.5(b) <u>Records Authenticity</u>	01 or 02	Rk R&O
	417.5(d) <u>Computerized Records</u>	01 or 02	Rk
	417.5(e)(1)(2) <u>Record Retention and Availability</u>	01 or 02	Rk
	417.5(c) <u>Pre-shipment Review</u>	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 ³ or 02	Rk R&O
Reassessment	417.4(a)(3) Annual Reassessment ⁴ or Changes in Establishment Processes 417.4(b) Hazard Analysis Reassessment	01 or 02	Rk

² Product acceptability or disposition could be verified using the 02 procedure.

³ Corrective actions and reassessment can be verified through 01 but not randomly.

⁴ 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)(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 CCPs 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 CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

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)(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) Preshipment 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

417.4(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.