

Recordkeeping

This section covers how to perform your HACCP duties using the HACCP 01 and 02 procedures to verify compliance with the recordkeeping requirements.

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:

- **G**athering information by asking questions
- **A**ssessing the information
- **D**etermining 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.

Example 1: 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 2: The CSI is performing the 03101 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:

- Room temperature log
- Calibration log, and
- 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.

Supporting Documentation Requirements

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

- **G**athering information by asking questions
- **A**ssessing the information
- **D**etermining 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. botulinium*). 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 1: 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 2: 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).

HACCP Records Requirements

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

- **G**athering information by asking questions
- **A**ssessing the information
- **D**etermining 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 1: 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 Time

Date	Lot No.	Time	Temp.	Corrective Actions	Monitored by	Verified by
4-29-03	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 2: 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 3: 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
5-1-03	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.

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.

Gather 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 1: 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.

Computerized Records Requirements

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

- **G**athering information by asking questions;

- Assessing the information; and
- Determining regulatory compliance.

Gather 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

Gather 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.

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.

Gather 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.

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.

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