

Recordkeeping

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

You will verify these requirements by reviewing the following:

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

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

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

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

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

There are seven different regulations that pertain to HACCP recordkeeping. Whether you are performing an 01 or 02 procedure, you should verify as many of these requirements as are applicable and possible. Below is a table summarizing the recordkeeping regulatory requirements and procedures used to verify compliance.

HACCP Recordkeeping Requirements and the Procedures Used to Verify Compliance

Regulatory Recordkeeping Requirement	HACCP Procedure Performed
Recordkeeping system 417.2(c)(6)	01 or 02
Supporting Documentation 417.5(a)(1) and (2) For canning establishments, also 318.300- 311/381.300-311	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

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

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

For canning establishments following §318/381.300 - .311, the 02 procedure will also include reviewing canning production records that apply to the specific production being verified.

Now let's go into more detail about each requirement as they relate HACCP plans.

Recordkeeping System

The regulatory requirement for recordkeeping is:

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

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

Gather information by asking questions

In performing the procedures, you should be seeking answers to the following questions.

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

Assess the information

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

- HACCP plan
- HACCP monitoring records

Reviewing the HACCP Plan for Recordkeeping Requirements

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

Reviewing HACCP Records for Recordkeeping Requirements

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

Recordkeeping Example 1: *You are performing the 03F01 procedure at an establishment which produces various types of jerky. You have randomly selected to verify the recordkeeping requirement. You review the HACCP plan to verify that it lists the records used to document monitoring of critical control points and you find the following records listed for the lethality CCP: time, temperature and humidity at smoking log; calibration log; and corrective action log. You also review the time, temperature and humidity at smoking log and observe that monitoring personnel have recorded that the critical limit was met, the actual time, temperature and humidity; actual time of*

monitoring; and monitors initials. Based upon your review, you determine that the establishment is in compliance with **this part** of the recordkeeping requirements of §417.2(c)(6) at this CCP.

Determine compliance

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

Noncompliance with the Recordkeeping System Requirement

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

- 1. You are reviewing the HACCP monitoring log for the drying CCP in a large pepperoni establishment and find that monitoring personnel are placing a checkmark on the drying log instead of the actual water activity reading as specified in the HACCP plan. **The monitoring personnel are not recording actual values as required in §417.2(c)(6).***
- 2. You are reviewing the HACCP plan for a very small establishment which makes dry sausage. You notice that there is a CCP for drying room temperature and humidity but the plan does not provide for any records for documenting the monitoring of humidity or temperatures. **The HACCP plan does not provide for a recordkeeping system that documents the monitoring of CCPs.***

Supporting Documentation Requirements

The regulatory requirements for supporting documentation are:

9 CFR 417.5(a)—The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation; (2) The written HACCP plan, including decision-making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

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

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

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

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

Note: As part of the requirement above, establishments will have documentation that address the requirement in §417.4(a). Section 417.4 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 the requirement of this regulation, by verifying that the establishment has the necessary documentation required in 9 CFR 417.5(a)(2). This verifies that the HACCP plan is theoretically sound.

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

Prerequisite Programs. Based on the regulatory requirements of 9 CFR 417.2(a)(1) and 9 CFR 417.5(a)(1), FSIS believes that the results of testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request, including records from a prerequisite program. These instructions were clarified in FSIS Directive 5000.2, 3/31/04.

A **prerequisite program** is defined as a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

You should be aware of all monitoring and of all food safety testing conducted by the establishment and should ask establishment management to make available for review the data that is generated by this monitoring and testing. You should review this data on at least a weekly basis.

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 criteria as they would when verifying the regulatory requirements of HACCP plans. For example, these records associated with monitoring and testing may include occasional instances of less than perfect control without resulting in threat to product safety. However, records generated from these programs must continue to support the decisions made in the establishment's hazard analysis.

You should determine whether the testing results suggest any food safety concerns that have not previously been recognized.

If you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures or prerequisite programs, you should contact the District Office. An EIAO may need to conduct a comprehensive food safety assessment in the establishment to verify that the design of the food safety systems in operation meet regulatory requirements.

If the establishment does not provide the CSI with records associated with a food safety concern when they are requested, the CSI should document this as noncompliance with the requirements specified in 9 CFR 417.5(a)(1).

Canning Operations. In a canning establishment which does not address food safety hazards associated with microbiological contamination in the hazard analysis, you should verify that the establishment is meeting all of the regulatory requirements of the canning regulations. This will include observing the canning process and reviewing associated records. If your review shows that the establishment is not complying with the canning regulations, then the establishment will not be able to support the decision made in the hazard analysis that they did not need to address microbiological contamination in the HACCP plan. We will discuss this in more detail later in this training.

CCP and Prerequisite Programs. 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 you determine that a prerequisite program is used as a justification for not addressing a hazard with a CCP in the HACCP plan, you should notify the District Office. These programs must be evaluated by an employee trained in EIAO methodology.

Gather information by asking questions

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

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

2. Does the establishment have the decision-making documents associated with the selection of each CCP?
3. Do the documents explain why the establishment selected that location for the CCP?
4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?
5. Does the establishment have scientific, technical, or regulatory support for the critical limit?
6. Does the support appear credible?
7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?
8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?
9. If the establishment has supporting documents for these decisions, does the documentation support the decisions?

Assess the information

When assessing the information gathered you will review the following:

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

Reviewing supporting documentation

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 you are verifying the recordkeeping requirement, you 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 journal articles or other published scientific literature,
- FSIS regulations, or regulatory performance standards,
- FSIS compliance guidelines,
- FSIS directives,
- industry standards or surveys,
- trade association guidelines,
- pathogen modeling programs,
- processing authority documents, instructions or research,
- written information from industry experts or consultants,
- university extension publications,
- in-plant studies, research or historical data,
- written materials from equipment manufacturers.

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. The establishment must have supporting documentation to show that the critical limits established in its process adequately kill the pathogens of concern.

The establishment has the flexibility to determine its own CCPs. If you have questions about a CCP, you should request the supporting documentation associated with the selection of that CCP. If you have questions regarding the validity of the data, you should seek technical guidance from the TSC by providing the relevant information along with an explanation of the situation, and what your specific questions are.

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 documentation would not meet the recordkeeping requirement.

Supporting Monitoring Frequencies. 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.

Computer Modeling Programs. Some establishments may elect to use a microbial pathogen computer modeling program for supporting documentation. Since the models are only predictors, you would expect additional information to support any controls the establishment actually uses. Modeling programs must apply to the process and product produced.

Processing Authority. 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 supporting documentation that justifies the modified control parameters.

Regulations - Lethality and Stabilization. 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*.). FSIS has published several regulations for lethality and stabilization of RTE meat and poultry products. §318.17, *Requirements for the production of cooked beef, roast beef, and cooked corned beef products*, requires a lethality of 6.5-log reduction of *Salmonella*. This regulation also has a stabilization standard which requires establishments to prevent the multiplication of spore-forming pathogens, usually by proper cooling, to ensure there is no multiplication of *C. botulinum* and no more than 1-log growth of *C. perfringens* in the product. FSIS regulation §318.23 *Heat-processing and stabilization requirements for uncured meat patties* lists specific temperature and time combinations for lethality, and the same stabilization standard as §318.17. FSIS regulation §381.150 *Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips*, requires a lethality of 7.0-log reduction of *Salmonella*. This regulation also has a stabilization standard which requires establishments to prevent the multiplication of spore-forming pathogens, usually by proper cooling, to ensure there is no multiplication of *C. botulinum* and no more than 1-log growth of *C. perfringens* in the product.

FSIS has issued compliance guidelines that list specific temperature and time combinations that meet the FSIS performance standards for lethality and stabilization for RTE meat and poultry products. Processing establishments may use FSIS Directive 7111.1, 3/3/99, "Performance Standards for the Production of Certain Meat and Poultry Products" to support their processes. 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. Appendix A and Appendix B can be used also to support products not covered in the performance standard regulations.

FSIS Compliance Guidelines. FSIS has issued compliance guidelines for certain processes. The compliance guidelines are NOT regulatory, they are published to provide guidance to the industry, especially small and very small establishments. If the establishment uses an FSIS Compliance Guideline for setting its CCPs and critical limits, then the establishment should have a copy of that guideline 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. Compliance guidelines are not regulations and you should not mandate that the establishment use them as supporting documentation for the critical limits. The establishment has flexibility to develop the CCPs and establish critical limits as it determines appropriate, provided the CCP and CL can be supported. It is your responsibility to verify that the establishment can support those decisions. FSIS guidelines can be used for support, but establishments are not required to support the critical limits with these documents; establishments may provide other supporting documentation that supports the safety of their processes.

If the establishment uses an FSIS compliance guideline, 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 compliance guidelines, but is validating that it can meet the criteria in the guidelines.

Control of *E. coli* O157:H7 in dry fermented sausages. In 1994, an outbreak of illnesses due to *E. coli* O157:H7 was associated with dry-cured salami. At that time, a group called the Blue Ribbon Task Force of the National Cattlemen's Beef Association, consisting of scientists from FSIS, ARS, academia and industry developed several options that would ensure a 5-log reduction *E. coli* O157:H7 in dry fermented sausages. These processes involve various combinations of fermentation temperature, pH at the end of fermentation, holding times and temperatures, and drying and cooking. Many establishments continue to follow these recommendations and you may see this report used as supporting documentation. These options include:

1. Utilize a heating step as described in §318.17 or §318.23.
2. Apply a validated heat treatment of equal lethality.
3. Hold and test finished products using ICMSF lot acceptance criteria.
4. Apply a validated minimum 5-log reduction or process that results in less than 1 log *E. coli* O157:H7 per 100g.
5. Sample raw ingredients to demonstrate there is less than 1 *E. coli* O157:H7 organism per 100g and apply a 2-log lethality treatment.

Control of *Listeria monocytogenes*. FSIS requirements for control of *Lm* are found in part 430.4 of the regulations. An establishment producing RTE product which is exposed post-lethality must meet one of the alternatives prescribed by the regulations. FSIS Directive 10,240.4 (10/2/03) describes verification procedures for this regulation. FSIS has also published compliance guidelines and Q&As for this regulation.

There are **three possible outcomes** for verification of the supporting documentation requirements.

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

Use of the 30-Day Reassessment Letter. There are situations in which you need more information to determine whether the establishment is meeting the requirements of 9 CFR 417.2. For example, if the establishment is monitoring its critical limit every shift, and the only supporting documents that are available are the monitoring records for the past year, you might need more information to determine whether the HACCP plan complies with 9 CFR 417.2. You could issue a 30-day reassessment letter requesting that the establishment reassess its HACCP plan. (The 30-day reassessment letter will be discussed in a later section.) You have not been trained to assess the scientific and technical information that an establishment might have to support the HACCP system. You do have resources available to assist you in evaluating this information. You can contact the District Office or the TSC for assistance.

Reviewing the Hazard Analysis with Supporting Documentation

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

Recordkeeping Example 3: *While performing the 03E01 procedure for a pepperoni process to verify the recordkeeping requirements for supporting documentation, you review the records from product testing conducted outside the HACCP plan or Sanitation SOP. During this review, you find that the establishment received a positive E. coli O157:H7 result from pepperoni slices. You then review the establishment's corrective action records to verify the requirements of §417.3 were met. There was documentation on the corrective action record of a reassessment of the hazard analysis and HACCP plan. While reviewing the hazard analysis and HACCP plan, you request supporting documents for the decisions made in the hazard analysis and HACCP plan during the reassessment. The establishment provided supporting documentation when it was requested. You verify that the documents provided are adequate to support these decisions. You were able to determine that the supporting documentation supported the decisions made during the reassessment. You determine that there is compliance with these requirements.*

Reviewing the HACCP Plan and Supporting Documentation

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

Recordkeeping Example 4 *You are reviewing the hazard analysis and HACCP plan in a beef jerky operation. You review the establishment's hazard analysis documentation, and the process flow diagram. You find that all of the steps in the actual plant operations are described in the flow diagram, and each step is addressed in the hazard analysis. You find the hazard analysis considers potential biological, chemical, and physical food safety hazards at each step. Where potential food safety hazards are identified, the establishment has made a determination about whether they are reasonably likely to occur or not, and recorded the basis for that decision. You observe that at the receiving step the establishment has identified that there is a food safety hazard, "presence of E. coli O157:H7" and determined that it was reasonably likely to occur. A later step in the process, Heating/drying, is identified as a CCP "destruction of pathogens including E. coli O157:H7" and lists critical limits for cooking time-temperature combination, relative humidity during heating, and final water activity. You decide to request the supporting documentation for these critical limits. The establishment provides a copy of "Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants", December 2004, along with Appendix A "Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products". You review the guidelines and determine that the critical limits that the establishment has identified are supported by these guidelines. You determine that this requirement for the supporting*

documentation is in compliance in that the hazard analysis appears to have been conducted appropriately, and that the establishment has the documentation to support the hazard analysis and HACCP plan. Based upon your review, you determine that the establishment is in compliance with §417.5(a)(1)&(2).

Determine compliance

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

Noncompliance with the Supporting Documentation Requirement

The following are examples of noncompliance with this §417.5(a) (1) or (2).

- 1. You are reviewing the hazard analysis for a sliced pepperoni operation. You observe that the establishment has identified *Listeria monocytogenes* as reasonably likely to occur at the slicing and packaging steps. There are no preventive measures identified and there is no CCP established for control of this hazard. When you ask the establishment for support they tell you “everyone knows that *Lm* would not be able to survive on pepperoni slices” but they provide no documentation. **The establishment has no supporting documentation to support why it is not necessary to establish controls for food safety hazards identified in the hazard analysis.***
- 2. You observe that the establishment is using a water activity meter to measure A_w at the end of the drying time. You ask the establishment how it calibrates the accuracy of the meter. Establishment management are not able to provide any information regarding calibration procedures for this equipment, nor does the establishment have support for not needing to calibrate. **The establishment has no documentation supporting the verification procedure and frequency.***
- 3. An establishment producing beef jerky has one CCP, for lethality. You ask, but the establishment has no supporting documentation for this decision. **The establishment has no supporting documents associated with the decision-making process for the selection of the CCPs.***
- 4. An establishment produces a variety of dry beef sausages using one HACCP plan. The plan has a CCP for lethality with critical limits of 3 minutes at 136°F. You ask for supporting documentation. The establishment replies, “this is the way we have always made it” and does not provide any documentation. **The establishment has no scientific, technical, or regulatory support for the critical limit.***

5. *An establishment produces turkey jerky. The lethality CCP uses a critical limit of 145°F, with no associated time. You ask for support and they show you a pathogen modeling program printout showing a lethality curve for E. coli O157:H7. **The establishment has documentation, but the documentation does not support the decisions made.***

HACCP Records Requirement

The regulatory requirement for HACCP records is:

9 CFR 417.5(a)(3)—*The establishment shall maintain: Records documenting the monitoring of 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.*

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

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

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

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

Gather information by asking questions

When reviewing HACCP records for compliance with §417.5(a)(3), you should seek answers to the following questions.

1. Do the records document the monitoring of 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?

Assess the information

You will review:

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

Recordkeeping Example 5: You are reviewing the Fermentation Log at a Lebanon bologna establishment.

<i>Fermentation Log</i>						<i>Date 2-1-2005</i>
<i>Product code</i>	<i>Lot No.</i>	<i>Time</i>	<i>pH</i>	<i>Monitored by</i>	<i>Corrective Actions</i>	<i>Verification*</i>
176a	1	12:47pm	5.0	CL	--	*KL(good)
*=direct observation verification Good=The results are in accordance with HACCP plan (if not "good" then make note in CA and describe on back of this form).						

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

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

Recordkeeping Example 6: You are performing the 03E02 at a prosciutto ham operation. You review the following record:

<i>Drying log for: Prosciutto ham</i>				<i>CL: a_w .82 or less</i>		<i>Date: 4-1-05</i>
<i>Product code</i>	<i>Lot No.</i>	<i>Time</i>	<i>Water Activity</i>	<i>Monitor</i>	<i>Corrective Actions</i>	<i>Verified by*</i>
1999b	3	1:32pm	.82	SM	--	BH(DO)
*DO=direct observation verification-results are in accordance with HACCP plan (if not make note in CA)						

Based on your review, you decide that the plant is in compliance with this part of the recordkeeping requirement.

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

Recordkeeping Example 7: You are performing the 03F01 procedure in a dry sausage operation and randomly select to verify the recordkeeping requirement as part of the recordkeeping verification, you look at the records to see if they comply with §417.5(a)(3). You review the HACCP records for this verification activity and find that the verification personnel have made the following entries:

Thermometer Calibration Log							Date: 2-1-2003
Time	Area	Thermometer ID	Standard temperature reading	Personal Thermometer Reading	Adjustment Required	Initials	Comments
0800	fermentation	2A	90	90	No	OT	

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

Determine compliance

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

Noncompliance with the HACCP Records Requirement

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

1.

Fermentation Log Date 3-1-2005

Product code	Lot No.	Time	pH	Corrective Actions	Monitored by	Verified by *
176a	1	12:47pm	ok	--	CL	*KL
179	2	1:09pm	ok	--	CL	

*=direct observation verification-results are in accordance with HACCP plan

The records do not have the monitoring actual values recorded.

2.

Fermentation Log Date 4-4-2005

Product code	Lot No.	Time	pH	Corrective Actions	Monitored by	Verified by *
123a	3		5.0	--	BL	
125	6		5.0	--	BL	*KL

*=direct observation verification-results are in accordance with HACCP plan

The records do not include the actual times that monitoring is performed.

3. You are reviewing the monitoring records for the heat treatment CCP in a pepperoni establishment and you find that the temperature results are recorded simply as “meets” instead of the actual temperature as described in the HACCP plan. **The records do not include the actual values as required.**
4. You are reviewing the HACCP records for the fermentation time/temperature CCP in a thuringer operation and notice that the fermentation log does not contain the lot number or product ID as is specified in the regulations. **The monitoring entries do not include the product identification or code.**
5. From the above example, you notice that the fermentation log from the previous shift does not have the date on it. **The records do not include the date the record was completed.**
6. You observe QC as they perform the daily calibration of the pH meter. You do not observe them write anything on the record. The next morning you review the records and observe that there are no results for pH meter calibration yesterday. **The verification procedures and results are not being recorded.**
7. You are notified by the QC technician that they are dealing with a deviation from a critical limit at the cooking temperature. You observe that the establishment takes all required parts of §417.3(a). Later, you ask for the corrective action records and are told “we notified you verbally, we assumed that was enough and we didn’t write anything down.” **The corrective actions taken in response to a deviation from a critical limit are not recorded.**
8. You are reviewing the records for the acetic acid dip CCP prior to heating in a turkey jerky operation and you find that the calibration for the pH meter had not been documented for the shift. The HACCP plan specifies that the calibration will be performed and recorded prior to every shift startup. You request more information and the establishment provides you with evidence that the calibration was performed. **The results of calibration of process monitoring instruments are not recorded.**

Records Authenticity

The regulatory requirement for record authenticity is:

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

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

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

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

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

Gather information by asking questions

In verifying that the establishment is in compliance with this requirement, you will seek answers to these questions.

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

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.

Assess the information

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

When reviewing the HACCP records for compliance with §417.5(b), you should verify that each record entry is made at the time the event occurred and includes the time as part of the entry. In addition, verify that each entry was signed and initialed by the establishment employee making the entry.

Recordkeeping Example 8: You are performing procedure 03F01 at an establishment that produces snack sticks. You have randomly selected to verify the recordkeeping requirements for the formulation CCP (addition of antimicrobial agent – lactic acid). You review the establishment’s HACCP plan and see that the monitoring procedure is that QC will check the pH of each batch of product prior to transportation to the stuffing room, and the associated record is the Formulation log. You look at today’s Formulation log, which includes today’s date at the top. You observe that for each batch there is an entry which includes the product ID, time, the actual value of the pH, and the monitor’s initials. You observe the monitor perform a pH check, and immediately record the results. Based on your observations, you conclude that the establishment is in compliance with §417.5(b).

Determine compliance

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

Noncompliance with HACCP Record Authenticity

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

The Lethality CCP for the meat snack sticks HACCP plan reads “Temperature at thermometer gauge A and B are checked and recorded, and the number of tiers passing the checkpoint is counted for one minute and recorded, once per hour.” You proceed to the smokehouse area at about 2:20 am. You observe this record:

Date: 6-19-05		Lethality log			Product: teriyaki turkey		
Critical Limits		Temperature: 350		Speed, no more than: 22/minute			
Time	Monitor	Temp A	Temp B	Speed	Comments	Verification	Verifier
12:22 am	ER	350	350	22			
1:15 am		350	350	22			

The records do not include the signature or initials of the person performing the activity.

You observe the monitor perform a monitoring check. He checks both temperature gauges, then opens the door on the chain speed checkpoint and checks the wallclock and watches the chain moving for one minute. You observe that he goes about other duties for some time, without writing this down on the log. You return later in the shift, and observe that there is a notation for the 2:20 am check recorded.

Results are not being recorded when the events occur.

Computerized Records

The regulatory requirement for computerized records is:

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

Electronic signatures are different from the digitized signature you might make when you sign for a credit card purchase. An electronic signature, or digital signature, uses computer technology to ensure the security of records or messages. The person making the record or message uses an electronic “code” to identify him/herself. The computer, using an electronic “key,” decodes the record or message. This endorses the identity of the user.

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

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

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

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

Gather information by asking questions

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

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

Assess the information

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

Recordkeeping Example 9: *An establishment enters all HACCP activity results into hand-held computer devices. Network access is for QA employees only. Each employee has a unique log-in name and password that is kept secure. Passwords are changed periodically. Once an entry is made, it is saved as read-only, and cannot be changed.*

Determine compliance

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

noncompliance. You will receive more information about making compliance determinations in a later section.

Noncompliance with the Computerized HACCP Records Requirement

The following is an example of noncompliance with §417.5(d).

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

Record Retention and Availability

The regulatory requirement for record retention and availability is:

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

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

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

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

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

Gather information by asking questions

You should seek answers to the following questions.

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

Assess the information

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

- HACCP records.

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

Note: If you determine that records are not available, you would communicate with establishment management in a professional manner that the HACCP regulations require records to be available to FSIS when the establishment is operating (§417.5(f)).

Determine compliance

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

Noncompliance with Records Retention and Availability

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

- 1. In September, you ask the establishment to provide a sample of the pepperoni fermentation pH CCP monitoring log records from last January. They give you a folder that contains February through September records. You ask the establishment about January's records and they tell you the records cannot be located and have probably been discarded. The establishment cannot produce January's records. **The establishment is not maintaining records for the required length of time.***
- 2. In January, you rotate into a new assignment and are reviewing the HACCP records for the sampling component of the lethality CCP in a large beef snack-sticks plant. You suspect the establishment is not maintaining records on site. You discuss this with your frontline supervisor and then you ask the establishment for the records from September. They tell you that they can give you the records for the past month but they will have to retrieve any other month's records from a record storage facility in another state. **The records are not being maintained on-site for 6 months.***
- 3. You are new to an assignment at a canning plant (metal detection CCP) and are performing records maintenance verification as part of a 03D01. You wonder about whether the establishment is able to retrieve records stored offsite and discuss this with your supervisor. You decide to ask the establishment to provide a sample of records from 8 months in the past. They tell you that after 6 months they store them at corporate headquarters. You request they retrieve the records from corporate headquarters. You receive the records 3 days later. **The establishment cannot retrieve the records within 24 hours when stored off-site.***

Pre-Shipment Review Requirement

The regulatory requirement for pre-shipment review is:

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

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

Verify an establishment's pre-shipment review of its records by performing the 02 procedure. Although you will normally verify this recordkeeping requirement using the recordkeeping component, you should occasionally perform a verification check by observing the establishment employee perform the pre-shipment review.

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

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

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

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

Gather information by asking questions

You should seek answers to the following questions.

1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?
2. Has the pre-shipment review been signed and dated by an establishment employee?

Assess the information

You should review the pre-shipment review records.

Determine compliance

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

Noncompliance with Pre-Shipment Review Requirement

The following is an example of noncompliance with §417.5(c).

*Your procedure schedule for today calls for performing the 02 procedure. You observe a specific production of the product being loaded onto trucks for distribution, and record the production codes. You proceed to the HACCP office and request the production records for that specific production. You observe that the pre-shipment records review form is not included, and upon further request the establishment is not able to provide the records. You verify that the product has left the control of the establishment. **The establishment shipped the product without conducting a pre-shipment review.***

Records Misrepresentation

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