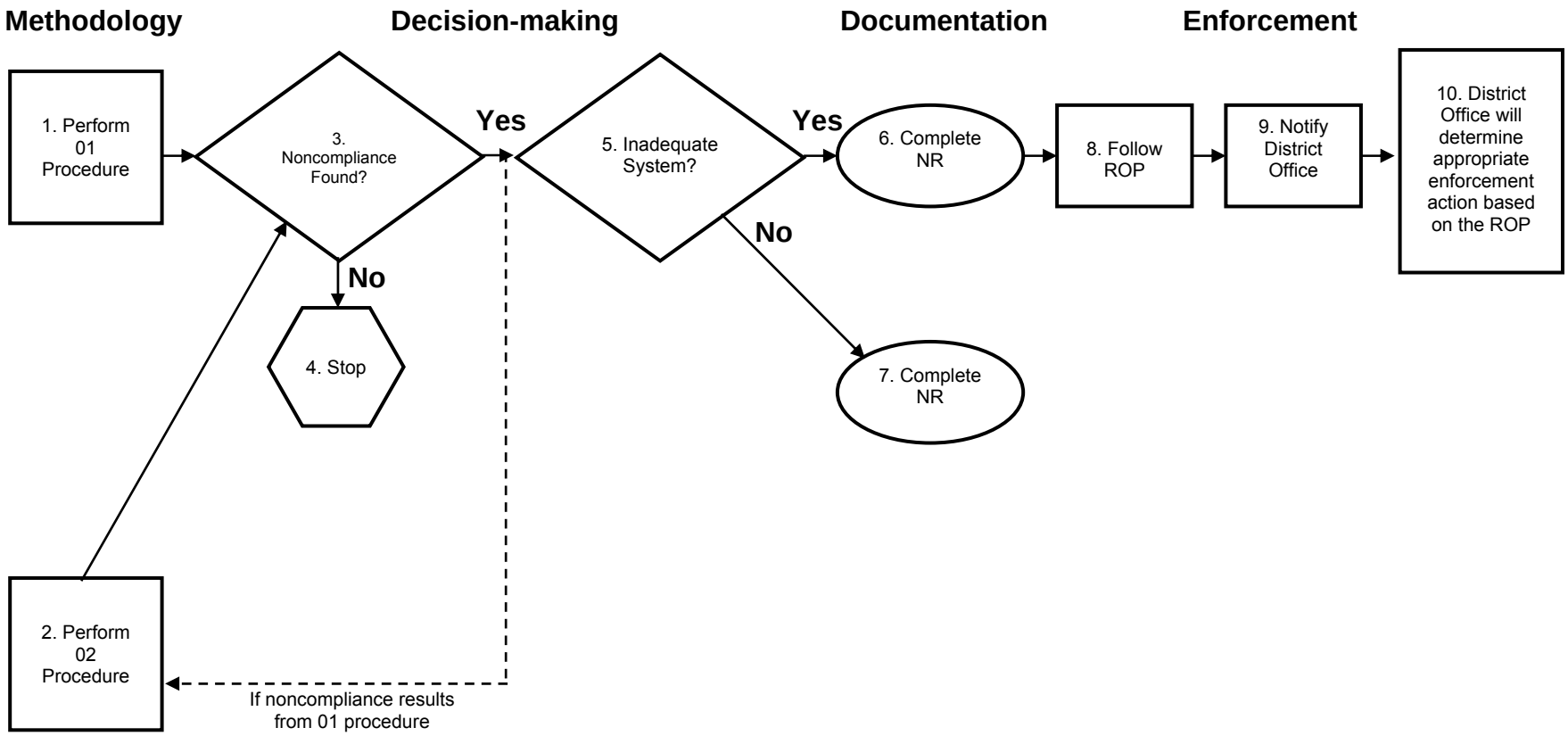
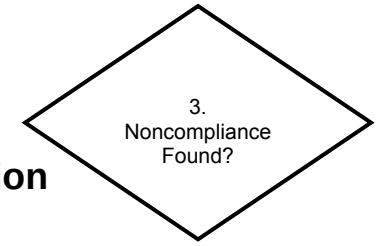
Decision-making (Blocks 3, 4, & 5)

Next in the regulatory process is decision-making. In the decision-making thought process you will determine whether or not the establishment is in compliance with the regulatory requirements. If noncompliance exists, then you will determine whether an inadequate system exists.

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





Block 3—Noncompliance Determination

HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR Part 417: monitoring, verification, recordkeeping, corrective actions, and reassessment. If a HACCP noncompliance occurs, the establishment is expected to take immediate and further planned corrective actions.

Before you determine whether or not you should document the failure to meet the regulatory requirements as a noncompliance, you should consider the following questions:

1. Has the establishment already identified the failure to meet regulatory requirements or deviations from critical limits?

2. If product is involved, has the establishment ensured product safety?

3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken the 9 CFR 417.3 corrective and preventive measures to address the deviations?

4. Is a trend developing (i.e., has the establishment carried out the actions in 1 through 3 above for similar situations)?

NOTE: In answering these questions, it may be necessary to consider additional records.

If the answer is **yes** to questions **1, 2, and 3** and **no** to **question 4**, then there is **no noncompliance that you would document**, because the establishment has already identified and addressed the situation. You will document on the Procedure Schedule that the procedure was performed and no other action is necessary. Not writing an NR in this situation will not adversely affect your ability to track developing trends since the establishment's response to a deviation will provide the further planned actions and preventive actions. An establishment's failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant an NR in recurring situations.

If the answer is **no** to **questions 1, 2, or 3,** or **yes** to **question 4**, then there is a **noncompliance that you would document**. Issue an NR and perform the 02 procedure.

Examples of Noncompliance Determinations

The following are examples of situations that will require a determination of noncompliance.

Example 1: *While performing an 01 HACCP procedure records review, you find that an establishment employee missed a 9:00 a.m. monitoring check. You then find that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate measures for the noncompliance by re-training the employee. Also, you looked at previous NR and determined that the establishment had not missed a monitoring check in over three months. In this situation no NR is necessary even though there was a missed monitoring check, and the 01 procedure is marked as performed. However, if you find that adequate preventive measures were not in place, and that the missed monitoring check and correction had occurred several times within the month, you may determine that a trend for monitoring noncompliance has developed. In this case you will issue an NR and discuss this trend with establishment management during the weekly meeting.*

Example 2: *While performing an 01 HACCP procedure records review, you find that an establishment employee missed a 9:00 a.m. monitoring check and find no indication that the establishment identified the missed monitoring check. You write an NR for the 01 procedure. Then you perform an 02 procedure and find that the product was shipped without a pre-shipment review. In this situation you would write an NR that explains this noncompliance. Next you would determine whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, you would take action in accordance with the Rules of Practice, 9 CFR Part 500.*

Example 3: *While performing the 01 HACCP procedure records review, you observe that an establishment employee recorded a deviation from a critical limit on the monitoring record. You verify that the corrective actions taken by the establishment meet the requirements of 417.3(a). There is no regulatory noncompliance, and an NR is not necessary.*

Example 4: *While performing an 02 procedure records review for a single lot of product, you see in the records that an establishment employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. You continue to review the records and find that at pre-shipment review the establishment identified the deviation and took the proper 417.3 corrective and preventive measures but failed to address the monitoring error. In this situation you would write an NR for the monitoring error and determine whether the establishment can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the establishment cannot support product safety, you should take action in accordance with the Rules of Practice, 9 CFR Part 500.*

Noncompliance Determination for Residue Violations

9 CFR 417.2(a)(3)(v) makes it clear that violative residues present food safety hazards that may be reasonably likely to occur; therefore, slaughter establishments must consider the likelihood of their occurrence in developing HACCP plans.

If the establishment does not address residues in its HACCP plan, a violative carcass finding would be evidence that the HACCP plan may be inadequate and, therefore, should be reassessed.

Findings of violative levels of chemical residues in slaughtered carcasses by FSIS should result in the completion of a Noncompliance Record (NR) using the code **03J01** or **03J02** and the verification noncompliance classification indicator. FSIS will not treat violative residue findings that are followed by appropriate corrective actions [9 CFR 417.3(a)] as noncompliance under the following conditions:

1. If HACCP plans include residue controls that constitute the best available preventive practices for slaughter establishments;

2. If establishments implement those controls effectively; and

3. If establishments supply FSIS with information about violators.

Examples of **best available preventive practices** for control of violative residues include:

- Ensuring that all animals brought into an establishment for slaughter are identified so they can be traced back to their producers, with receiving as a CCP.

- Notifying animal producers in writing of residue findings, with such notification including: a discussion of the issues involved; the company's future expectations; an indication that repeat violators will not be future suppliers.

- Explore possibilities for the establishment of state-certified voluntary residue avoidance programs comparable to those developed by major producer trade organizations and require suppliers to participate in such programs and supply certifications to that effect.

- Explore the possibilities of live-animal testing so slaughter establishments could have a rapid, convenient verification tool.

Noncompliance Determination for Positive *E. coli* O157:H7 Directed Sampling Results

At the present time, the only directed sampling program is for *E. coli* O157:H7 in raw beef products. To obtain the results for direct sampling, you access LEARN. If the sample is positive and the plant **did not** find same lot positive, document it on your PS under the appropriate HACCP procedure (03B01 or 03C01) and select the "verification" noncompliance classification (trend) indicator. Document the positive sample result on an NR. In block 10, document:

- Sample collection date
- Product name
- Production or lot code
- Organism or toxin found
- Sample request form number
- Whether the plant shipped product from the sampled lot

When a sample is positive for *E. coli* O157:H7, you will also perform the following:

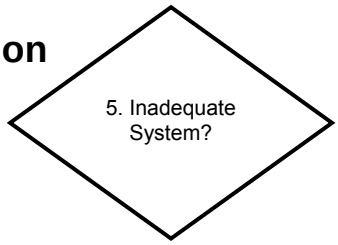
- Notify the DO if product was shipped (DO will determine if recall is needed and will coordinate that effort),
- Assist DO with information needed for the recall, if applicable,
- Perform an 02 procedure on product records for the specific production represented by the sample,
- Perform the 01B01 and 01C01 procedures on the plant's SSOP covering the timeframe for when the sampled product was produced,
- Verify plant's corrective actions (§417.3(a) or (b)),
- If plant's actions to identify all affected product are not sufficient, then retain such product (be sure this is included on the NR),
- Collect follow-up samples as directed by the District Office and OPHS,
- As needed, verify the adequacy of the HACCP plan, and
- As needed, review records generated as part of a prerequisite program

Do not issue an NR when FSIS finds the sample positive and the plant finds the same lot positive, maintains control of the affected product, and performs corrective actions on the affected product that meets the requirements in §417.3.

Block 4—Stop

If the establishment is found in compliance with the regulatory requirements, you would stop and mark “performed” on the Procedure Schedule.

Block 5—Inadequate System Determination

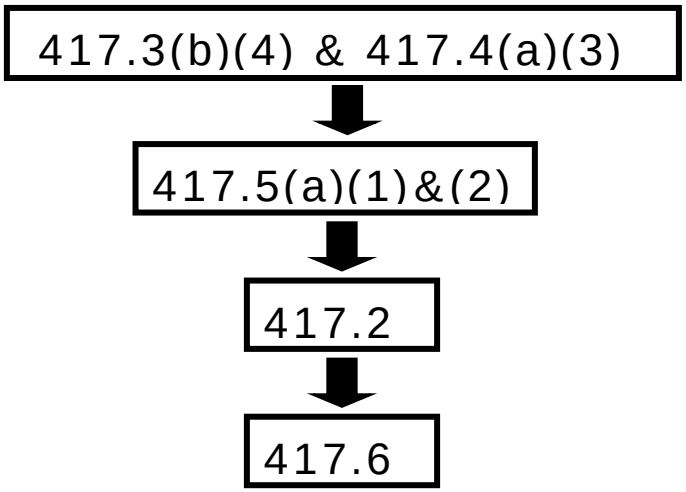


If noncompliance is found, you need to determine if it indicates an **inadequate system**.

Sec. 417.6 Inadequate HACCP Systems.
A HACCP system may be found to be inadequate if:
(a) The HACCP plan in operation does not meet the requirements set forth in this part;
(b) Establishment personnel are not performing tasks specified in the HACCP plan;
(c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;
(d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or
(e) Adulterated product is produced or shipped.

To determine the plant's HACCP system adequacy, you must consider more than the HACCP plan. All available evidence and supporting documentation must be taken into account. You should evaluate other systems within the plant (SSOP, in-plant testing programs, etc.). Depending on the problems identified, the establishment may need to reassess the HACCP plan. For example, if an establishment has not identified E. coli O157:H7 as a food safety hazard likely to occur in its process and is testing outside the HACCP plan or SSOP and gets a positive result, a reassessment of its HACCP plan and hazard analysis is required in 9 CFR 417.4(a)(3). The establishment is required to support the decisions made during the reassessment as specified in 417.5(a)(1)&(2).

It is your responsibility to verify that the establishment is meeting these requirements. If the establishment did not reassess its HACCP plan and hazard analysis as required by 417.3(b)(4) and 417.4(a)(3) or does not have supporting documentation required by 417.5(a)(1)&(2), you cannot determine that the HACCP plan is meeting the requirements of 417.2, therefore the HACCP system may be determined to be inadequate as described in 417.6.



To determine if there is an inadequate system you need to answer the following:

1. Does the HACCP plan meet the regulatory requirements of Part 417?

If the establishment is not implementing all or some of its program, it has not met regulatory requirements. For example, if an establishment is not maintaining **any** records associated with its HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify its HACCP plan when it no longer met the requirements---then the establishment has not met the regulatory requirements. Therefore, you are unable to determine whether or not the establishment is producing adulterated product, and, therefore the HACCP system is inadequate. In these cases, the HACCP system would be considered inadequate because it did not meet the regulatory requirements of Part 417.

If the answer is **no** to question 1, this may be indicative of an **inadequate system**.

2. Was adulterated product produced or shipped?

If the HACCP system did not prevent the production and distribution of adulterated product, it is an inadequate system. If you determine that the establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per Section 417.3 of the Federal regulations, and the establishment has performed its pre-shipment review, the HACCP system is inadequate.

If the answer is **yes** to question 2, this may be indicative of an **inadequate system**.

3. Is there a trend in establishment noncompliance?

You should observe trends in the noncompliance classification indicators marked on NR when determining whether an establishment's HACCP system is inadequate. If two or more NR have the same noncompliance classification indicators marked and if descriptions of noncompliance indicate that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate.

There is no specific number of incidents which determine a trend. Because there will be a variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily supports an inadequate system. Therefore, you must thoroughly analyze and document noncompliance trends that may support a determination. When reviewing a possible trend in incidents of noncompliance, you must closely review the descriptions of noncompliance contained in Block 10 of the NR form. You should not solely rely on the number of marked noncompliance classification indicators. Only through careful analysis of written descriptions of noncompliance can you determine whether there is a trend indicating that a HACCP system may be inadequate.

If the answer is **yes** to question 3, this may be indicative of an **inadequate system**.

Action to Take If an Inadequate System Exists

If you determine that an **inadequate system** exists, then you must take action.

- You would notify the District Office, which is covered in step 3A in the diagram.
- If you determine that adulterated product has been produced and shipped, you would take an immediate withholding action, according to the Rules of Practice.

The main point to remember is to contact the District Office if you believe an inadequate system exists. We will cover these enforcement actions in more detail in later sections.

Documentation (Blocks 6 & 7)

Blocks 6 & 7—Completing a Noncompliance Record (NR)

When documenting noncompliance on a Noncompliance Record (NR), do the following.

- Identify each noncompliance.
- Be specific and thorough, including time and location.
- Explain that plant management has received notification.
- State any regulatory control actions you took.

If you need further information about completing the NR, please consult FSIS Directive 5400.5.

When you determine that a HACCP noncompliance has occurred, you will complete a Noncompliance Record (NR), which will include marking the appropriate noncompliance classification (trend) indicator.

HACCP Noncompliance Classification Indicators

There are four noncompliance classification (trend) indicators for HACCP noncompliance: **monitoring, verification, recordkeeping,** and **corrective action.**

1. Monitoring

You will use the monitoring noncompliance classification indicator when there is noncompliance with the monitoring requirement. The monitoring noncompliance classification indicator would be marked if:

a. The establishment is not monitoring the critical limit at the frequency stated in the HACCP plan.

b. The establishment is not monitoring the critical limit using the prescribed procedures in the HACCP plan.

c. A deviation from a critical limit exists that the establishment has no way of detecting.

Monitoring Noncompliance Classification Indicator Example 1: *You are verifying monitoring at the establishment's fecal CCP in a poultry slaughter operation. The establishment has a CCP for feces in the reprocessing area and the carcasses are*

dumped directly into the chill system after leaving this area. Monitoring personnel have already completed their observation of the carcasses and found no deviations; however, in your reinspection you find a carcass with feces on the leg. The establishment would be notified and an NR would be completed using procedure code 03J01 and the monitoring noncompliance classification indicator. You would also perform an 03J02 procedure on that specific production. This would be a deviation that the establishment has no way of detecting since the deviation has gone undetected by the establishment controls.

Monitoring Noncompliance Classification Indicator Example 2: *You are performing an 03J01 procedure at a beef slaughter operation and observe establishment personnel perform a monitoring procedure by observing two consecutive carcasses at the final rail station for contaminants. From your review of the HACCP plan, you know that the HACCP plan specifies that the monitoring procedure will consist of ten consecutive carcasses observed for contaminants. You check the records and find no explanation why only two carcasses are being observed. You would notify the establishment, complete an NR for 03J01, and mark the monitoring noncompliance classification indicator. You would also perform an 03J02 procedure on that specific production. The establishment is not monitoring the critical limit using the prescribed procedures in the HACCP plan.*

Monitoring Noncompliance Classification Indicator Example 3: *You are performing an 03J01 procedure at a pork slaughter operation and have selected to verify the monitoring requirement. You review the HACCP monitoring records for the antimicrobial rinse CCP. It is four hours into the shift, and you note that QA personnel have not yet recorded a procedure for monitoring the pressure and concentration of the rinse. From reviewing the HACCP plan, you know it specifies that monitoring will be performed every two hours for pressure and concentration of the rinse at this CCP. You request any further information available about the apparent missed monitoring, which the establishment cannot provide. You would notify the establishment, write an NR for 03J01, and mark the monitoring noncompliance classification indicator. You would also perform an 03J02 procedure on that specific production. The establishment is not monitoring the critical limit at the frequency stated in the HACCP plan.*

2. Verification

The verification noncompliance classification indicator should be used when:

1. The establishment is not conducting the verification activities as described in the HACCP plan.

2. The establishment is not conducting the verification activities at the frequencies prescribed in the HACCP plan.

3. The establishment has a positive FSIS *E. coli* O157:H7 sampling result and did not find the same product lot positive.

Verification Noncompliance Classification Indicator Example 1: *You are performing the 03C01 procedure in a multi-shift mechanically deboned chicken operation and have randomly selected to verify the establishment verification requirements. You review the establishment's HACCP plan and find one of the verification procedures specifies that the HACCP Coordinator will observe QC personnel perform the monitoring check for product exiting the deboning machine once per shift. You review several recent temperature logs and observe that the HACCP Coordinator has recorded results for the verification procedure for each day rather than each shift. You ask the HACCP Coordinator about the apparent missed verification procedures, but no further information can be provided by the establishment. You determine that this requirement is not in compliance because the verification procedures are not being performed at the frequency specified in the HACCP plan. You would document this finding on an NR and mark the verification noncompliance classification indicator.*

Verification Noncompliance Classification Indicator Example 2: *Continuing with the above example, you decide to observe the next verification procedure and accompany the HACCP Coordinator to the deboning machine. You observe the HACCP Coordinator perform a temperature check of the product. The QC personnel are not present in the cooler. You observe the HACCP Coordinator record this on the temperature log as a direct observation verification procedure. You determine that this requirement is not in compliance because the verification procedure is not being conducted as described in the HACCP plan. You recall that a plant verifier conducting the same activity as the monitor does not meet the regulatory requirement for the direct observation verification activity described in 9 CFR 417.4(a)(2)(ii). You would document this finding on an NR and mark the verification noncompliance classification indicator.*

3. Corrective Action

The corrective action noncompliance classification indicator should be used when corrective actions taken by the establishment in response to a deviation from a critical limit, or unforeseen hazard, did not meet the requirements of 417.3 because they did not:

1. Adequately address identifying and eliminating the cause of the deviation.
2. Include measures to ensure that the CCP is under control.
3. Include measures to prevent the deviation or unforeseen hazard from recurring.
4. Include appropriate disposition of the product.
5. Conduct a reassessment, if an unforeseen hazard was identified.

Corrective Action Noncompliance Classification Indicator Example: *You are performing the 03B01 procedure in a ground turkey operation. You realize that you should verify the corrective actions whenever a deviation occurs. You also realize that the plant does not have to notify you of the deviation when it occurs. Therefore, you*

regularly review the corrective action logs, and ask QC personnel about any current corrective actions that are taking place. When you arrived and walked through the plant today, you observed that the QC department has put a production hold on a particular lot of product and you decide to investigate. You observe that yesterday's monitoring log for chilling recorded a deviation; product was not within the critical limit for temperature. You review today's monitoring log, observe the chilling equipment, and take a measurement. You conclude that the equipment appears to be working properly. You review the corrective action log and find that it includes documentation of the deviation found at monitoring and the measures taken to ensure that the CCP is under control. You find a notation that the product is being held pending microbiological tests to be reviewed by a processing expert. You ask for further information but this is all that the establishment has available. You determine that there is a noncompliance; corrective actions did not include adequately identifying and eliminating the cause of the deviation, and there are no measures to prevent the deviation from recurring. You would document this finding on an NR and mark the corrective action noncompliance classification indicator.

4. Recordkeeping

The recordkeeping noncompliance classification indicator should be used when:

1. The monitoring records do not include the actual times, temperatures, or other quantifiable values, the calibration of process monitoring instruments, corrective actions, verification procedures and results, product identity, signature or initials of the person making the entry, or the date the record is made.

2. The establishment does not have the decision-making documents associated with the selection and development of the CCP and critical limits, and documents supporting both the monitoring and verification procedures and frequencies.

3. The establishment did not conduct the pre-shipment review.

4. The establishment is not retaining HACCP records for the required length of time.

Recordkeeping Noncompliance Classification Indicator Example 1: *You are performing the 03B01 procedure in a raw ground beef patty operation and have randomly selected to verify the establishment recordkeeping requirements for the product storage CCP. You review the establishment's HACCP plan and find that the monitoring procedure is that QC personnel will check the product storage area temperature every two hours, and record results on the room temperature log. The critical limit at this CCP is room temperature not to exceed 45º F. You review the current room temperature log.*

Temperature Log		Date: 5-11-04
Time	Temperature	Monitor initials
1:00 pm	✓	JP
3:00 pm	✓	JP

Based on your observations, you determine that this part of the recordkeeping requirement is not in compliance because check marks rather than the actual temperature results are being recorded. You would document this finding on an NR and mark the recordkeeping noncompliance classification indicator.

Recordkeeping Noncompliance Classification Indicator Example 2: *Continuing with the above example, you request supporting documentation from the establishment. Specifically, you ask the establishment how it has validated that the room temperature correlates with the product temperature, how it has determined the critical limit is adequate to control the hazard, and how it has determined that the monitoring frequency is adequate. The plant manager responds with "we have plenty of historical data," provides you with all of the past room temperature logs, and notifies you that they have never had a deviation from the critical limit at this CCP. You determine that the establishment has not met the requirements of 9 CFR 417.5(a) because it does not have decision-making documents associated with the selection and development of CCP and critical limits, and documents supporting the monitoring procedures and the frequency of those procedures. You issue the NR because there is no support, especially you are concerned about the critical limit. You decide to contact the District Office to inform them that you have concerns about the design of this HACCP plan. (In some cases, a 30-day letter is appropriate, but not when there is no support, such as for a critical limit.)*

Workshop: Noncompliance

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

In questions 1-5, read each scenario and state the most appropriate noncompliance classification indicator and cite the regulatory reference.

1. Establishment P-42 is a poultry processing plant that manufactures mechanically deboned chicken. The plant has a HACCP plan covering raw product—not ground that identified a biological hazard at the deboning step. The critical limit is that the temperature of the product will be maintained at 40º F or less. The monitoring procedure is that every hour the deboning room supervisor will measure the temperature of the product after it exits the deboner, using a digital thermometer, and record the product temperature on the temperature log. The HACCP plan also states that the QC technician will perform verification by observing the monitoring check, reviewing the monitoring record, verifying that the temperature gauge on the deboner equipment reads 30º F or below, and recording the temperature once per shift; and that calibration of the thermometers is verified and adjusted daily, if needed. On 3-2-03, you randomly chose to verify the monitoring and verification regulatory requirements at the deboning step. Consider these different situations:

a. You review the deboning temperature log for 3-1-03. You observe that there is no verification recorded. The establishment cannot provide further information.

b. You review the deboning temperature log for 3-1-03. You observe that there is no verification recorded. The QC supervisor tells you that the QC technician went home sick, and that he performed the verification before he left but neglected to write it down.

2. Establishment 38 has a HACCP plan for beef slaughter that has a critical control point at the cooler for controlling a biological hazard. The critical limit is that the carcasses will reach a surface temperature of 50º F within 12 hours of slaughter. The monitoring procedure is that the cooler employee will measure the surface temperature in five locations throughout the cooler and record them on the cooler temperature log each morning. On 4-4-03 you randomly choose to verify the monitoring regulatory requirements at this CCP. Consider these different situations:

a. You observe the employee take three temperatures and write them down. They are within the critical limit.

b. You observe the employee take five temperatures that are within the critical limit, but he does not immediately record them. Later, you review the temperature log and note that there are no temperatures recorded for 4-4-03.

c. You review the temperature log in the cooler for 4-4-03 and note that there are already five temperatures recorded, and that they are within critical limits. You take a temperature yourself from one of the carcasses in that specific production. You get a temperature of 56º F.

d. You review the temperature log for 4-4-03 and note that 1 of the 5 temperatures is not within critical limits. You observe that some of the carcasses in that specific production have already been removed from the cooler. You ask the monitor for any information about the apparent deviation, but the monitor does not appear to understand. You ask the HACCP coordinator for any corrective action report, but there is none available.

3. Establishment P-42 has a HACCP plan for poultry slaughter. The HACCP plan lists a CCP for slaughter food safety standard after the final washers and before the chillers. The critical limit is no visible fecal contamination entering the chillers. You perform a slaughter food safety standard check as part of the 03J01 procedure and you observe that the establishment had found a deviation from a critical limit at the slaughter food safety standard CCP. You observe establishment actions to verify that the regulatory requirements of 417.3(a) are met. You found that all four requirements of 417.3(a) are met. However, you did not see anyone recording the corrective actions taken in response to the deviation from the critical limit. You decide to come back later and check the records. Later you look at the records and find there is no record of the corrective action taken.

4. Establishment 38 has a HACCP plan for fresh turkey bratwurst. The HACCP plan lists a temperature control CCP for control of a biological hazard, with a critical limit of product temperature 40º F or less in the cooler. The monitoring procedure is that the packaging supervisor will check the cooler room temperature at the beginning of each shift and record it on the temperature log. On 4-4-03 you randomly choose to verify the monitoring regulatory requirements at this CCP. You review the temperature log and find all temperatures recorded and within the critical limit.

a. You check the product temperature at two places in the cooler and find temperatures of 42 and 43º F.

b. Continuing with the above, you notify plant management, and decide to verify whether the plant takes any action to verify the safety of the product in the cooler. You investigate, but can find no indication that anything is done with this product.

c. Continuing with the above, you decide to ask for supporting documentation for the monitoring procedure and frequency. The establishment provides one year's past records, showing that all monitoring procedures were performed and that there was no deviation recorded.

5. You are performing the 03B01 procedure in a raw ground beef operation and have randomly selected to verify the establishment recordkeeping requirements for all CCP. You review a recent corrective action log that documents a large fecal smear observed on the boneless bull meat chucks as they were being prepared for grinding. Currently the plant does not have a CCP for visual observation of raw materials. Under preventive measures on the corrective action log is recorded "none needed." You ask whether they considered this an unforeseen hazard, and whether they performed a reassessment of the hazard analysis and HACCP plan. The QC manager replies "No, because this was the only time we've observed this."

6. You are performing the 03J01 procedure at a young turkey slaughter operation. You review the hazard analysis and HACCP plan and discover that residual chlorine in the water carcass chill system is identified as a CCP for the purpose of reducing *Salmonella* to an acceptable level. The critical limit is a continuous maximum level of chlorine equal to or less than 50 ppm residual at the chiller water inlet. Monitoring frequency by the plant is to be performed within 30 minutes of start up and randomly two additional times per shift, using a hand-held chlorine calibration meter. Verification frequency by the plant is to be performed two times per week for recordkeeping and one time per week for direct observation. If testing revealed the residual chlorine concentration to be inadequate, corrective actions to be implemented are:

(1) Stop the water chill system.
(2) Determine the cause of the deviation.
(3) Increase the residual chlorine level to the critical limit.
(4) Restart the chill system.
(5) Retest the chlorine level within 30 minutes after restarting the chiller.
(6) Increase the testing frequency to four times per shift for one week.
(7) Ensure that all affected product back to the last acceptable chlorine check complies with 417.3(a)(4).

a. What questions should you ask when determining whether the above-described CCP as established at the defined location and with the defined frequency is acceptable?

b. What questions would you ask when verifying the verification requirement?

c. Cite the regulations describing verification requirements.

As you review the establishment's records, you observe that verification results for direct observation have not been recorded for the previous two weeks.

d. Is this a noncompliance? Please explain.

e. Is a Noncompliance Record (NR) required? If so, what is the noncompliance classification indicator?

f. What other action should you take?

7. You are assigned to a young turkey slaughter operation that produces whole birds and deboned product. The establishment also has a mechanically separated turkey (MST) process using the deboned carcass shells as raw material.

The Procedure Schedule for today includes a 03C01 procedure.

a. How do you decide which of the regulatory requirements you will verify?

You decide to verify the recordkeeping requirement for the mechanically separated turkey. You review the plant's hazard analysis, which identified growth of pathogens as a biological hazard reasonably likely to occur. The HACCP plan addressed this hazard with a chilling CCP. The critical limit is a time-temperature requirement, "All MST product shall be $\leq 40°$ F within 8 hours of slaughter at the point of packaging." The monitoring procedure is that the product temperature is taken as the product exits the MST equipment, from each time-coded lot, and recorded on the Product Temperature Log.

b. What should you do if you have concerns about whether the relevant hazards have been considered?

You review the MST Product Temperature Log and observe that the last plant monitoring procedure was performed at 9:25 a.m. A checkmark was placed in the "temperature" column by the monitor, but no actual values were recorded. Also, the "comments" column of the record indicates that two pieces of metal approximately 8.0–10.0 mm in length were observed by the monitor on the deboned shells entering the process, during the monitoring check. The record states, "The 2 pieces of metal were manually removed. All product exiting the MST grinder was directly observed for the next 15 minutes with no sign of metal contamination." Nothing else was recorded. The hazard analysis addressed metal but found it not likely to occur.

c. Describe any noncompliances, identify the noncompliance classification indicators, and cite the appropriate regulatory reference.

d. When verifying compliance with 417.3(b)(4), what questions should you be asking yourself?

8. From Est. 38, on June 10, you sampled and mailed ground veal for MT43.

On June 13, the ground veal was reported as presumptive for *E. coli* O157:H7.

What action do you take?

On June 16, the ground veal sample is confirmed positive for *E. coli* O157:H7 and the plant did not find the same lot positive. If an NR is needed, complete the one on the next page with as much information as possible. *Note: If you decide to complete an NR, not all blocks can be completed based on the information in this scenario.*

What additional actions does FSIS perform?

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

TYPE OF NONCOMPLIANCE
☐ Food Safety ☐ Other Consumer Protection

1. DATE | 2. RECORD NO. | 3. ESTABLISHMENT NO.

4. TO (*Name and Title)* | 5. PERSONNEL NOTIFIED

6. RELEVANT REGULATION(S)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER

8. ISP CODE | 9. NONCOMPLIANCE CLASSIFICATION INDICATORS

10. DESCRIPTION OF NONCOMPLIANCE:

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT | 15. DATE

16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE | 17. DATE

Linking NR

You should link NR to provide notification to the establishment that the further planned actions are ineffective in preventing the noncompliance from recurring and that, if the trend continues, the repetitive NR would support an enforcement action under the rules of practice. You should be linking NR together only when the noncompliances are from the **same cause**.

How to Link NR

When you link one NR to another, you should **document:**

- **The previous NR number** and **date**
- The **further planned action** that was ineffective in preventing recurrence of the noncompliance.
- Any discussion with plant management during the weekly meeting, concerning the trend.
- A **statement in Block 10** of the NR stating that **continued failure to meet regulatory requirements can lead to enforcement actions as described in 9 CFR 500.4.**

NR should be linked **as they are issued**. Each noncompliance that you believe is linked to a previous noncompliance should be documented as linked at the time the NR is completed. Do not link the current noncompliance to more than one previous noncompliance.

You should continue to link NR together that derive from the same cause **until you determine that enforcement action is necessary** to bring the establishment into compliance with the regulations. When you determine that enforcement action is necessary, you should contact the District Office and always keep your supervisor apprised of the situation.

Good judgment is necessary when determining which NR to link together. Remember to follow the thought process, gather information by asking questions, assess the information, and make a sound, supportable conclusion. Some factors to consider are:

1. How much time has elapsed since the previous NR was written?
2. Was this noncompliance from the same cause as the previous NR?
3. Were the establishment's further planned actions implemented?
4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?
5. Is the establishment continuing to implement better further planned actions?

6. Are there NRs over the past three months that should be linked to other NRs?

7. Do the NRs establish that there is a persistent problem in the plant's approach to addressing noncompliances (e.g., the establishment's procedures led to repeated noncompliances)?

Linking Example 1: *You issued an NR on April 5 for the establishment not performing the direct observation verification procedures as specified in the HACCP plan. Two weeks later you observe, at a different CCP in the same HACCP plan, that the establishment does not perform the direct observation verification procedures as specified in the HACCP plan. You decide that these two noncompliances have the same cause (not performing verification) and that you should link them in your documentation. You realize you could link these noncompliances even if it was across two different HACCP plans.*

Linking Example 2: *You issued an NR on April 12 when you took a measurement at CCP 3 and found that the critical limit was not met. On May 10, you observe that the establishment is not conducting the monitoring procedures as specified in the HACCP plan: they missed a monitoring check at CCP 2. Although these are both monitoring noncompliances and are both documented under the same procedure code, you determine that they are not from the same cause. You do not link them in your documentation.*

Linking Example 3: *You issued an NR on January 14 when you observed that the establishment did not perform one of the verification procedures. On November 23, you again observe that the establishment did not perform one of the verification procedures. Although these two noncompliances both have the same cause, you determine that the establishment has shown a substantial period of compliance, and you decide not to link this NR to the previous one.*

Linking Example 4: *You issued an NR on September 2, when the establishment had a deviation, and the corrective actions taken did not meet 417.3. They did not implement measures to prevent the recurrence of the deviation, and they did not take appropriate measures to ensure that the CCP was under control after the actions were taken. On November 4, the establishment has another deviation at the same CCP, and as you verify the corrective actions you observe that the establishment did not implement measures to identify and eliminate the cause of the deviation, and they did not implement measures to prevent the recurrence of the deviation. You determine that although some time has lapsed, the establishment has* ***not*** *shown a substantial period of compliance. You determine that both of these noncompliances are due to the same cause, which is, not completing all parts of the requirements for corrective action, and you decide to link them in your documentation.*

You can contact your supervisor if you need assistance in making this decision. The in-plant inspection team can also contact the Technical Service Center for assistance, if needed.

Workshop: Linking NR

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

Scenario: Today, June 15, 2003, you observe that an 01 procedure is assigned on your Procedure Schedule. You randomly chose to verify the monitoring requirements and have decided to perform the recordkeeping component. You review records and observe that yesterday there was a missed monitoring check that the verifier identified, and measures were taken to ensure that product produced during the time of the missed monitoring was within critical limits. You decide to perform the review and observation component and proceed to the production area. At 10:20 am you observe that the last check was recorded at 8:30 am. The HACCP plan states that this monitoring check will be done hourly. You take a measurement, which is within critical limits. You remain in the area until you observe the monitor perform and record the next check, at 10:25 am, which is within critical limits. You ask the monitor, Mr. Lewis, about the apparently missed monitoring check, but no explanation is given. You notify Mr. Marcus, the plant manager, of the situation and observe the plant manager's measures to ensure that product produced at the time of the missed monitoring check was within critical limits.

As you prepare to document the monitoring noncompliance on an NR, you recall that you had nearly the same results last week, and review the previous NR. It was record number 18-03, June 7, 2003, and the further planned action that was provided by plant management was "Mr. Lewis, the monitor assigned to this station, will be immediately retrained." You decide that these two noncompliances had the same cause, and that the further planned actions taken last week have not been effective in preventing the noncompliance from recurring, and that they should be linked.

Workshop: Complete an NR for this noncompliance, blocks 9 and 10 **only**. Then answer the following question, noting that as a training example, you do not have the amount of detailed data that you would have in real life.

What further actions would you take?

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

TYPE OF NONCOMPLIANCE
☐ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.

4. TO (*Name and Title)*

5. PERSONNEL NOTIFIED

6. RELEVANT REGULATION(S)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

10. DESCRIPTION OF NONCOMPLIANCE:

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

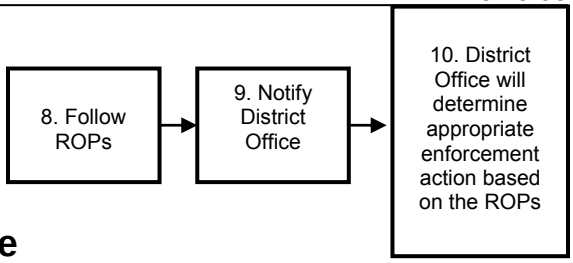
12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

Enforcement (Blocks 8, 9, & 10)



Block 8—Follow Rules of Practice

When a noncompliance determination is made, it may be necessary to take an **enforcement action** to prevent adulterated product from being produced and shipped. In accordance with the rules of practice, this enforcement action could be one of three types.

1. A "**regulatory control action**," is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

2. A "**withholding action**," is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

3. A "**suspension**," is an interruption in the assignment of program employees to all or part of an establishment.

Regulatory Control Actions

Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product. Examples of common regulatory control actions related to slaughter would be line stoppage, or carcass retention as a result of a slaughter food safety standard finding.

Regulatory Control Action Example 1*: You are performing beef carcass inspection procedures at the postmortem rail inspection station and you notice a fecal smear on the side of a carcass. The plant does not have an approved rail-out procedure, so you stop the production line and notify establishment personnel, who then proceed to trim the carcass.*

Regulatory Control Action Example 2: *You are performing the 03B01 procedure at a fresh pork sausage operation, and have selected the monitoring requirement to verify. The HACCP plan states that product temperatures will be taken by QC personnel hourly and recorded. You take a product temperature measurement, which is not within the critical limits for this CCP. You review the monitoring record for this CCP and compare your result to the plant's most recently recorded check, which was also not within critical limits. You investigate further and see no evidence of action being taken to address this deviation. You see that no supervisors are present. You decide to notify the plant manager but are told, "All managers are in a big HACCP meeting at another location." You return to the production room and observe that production continues to operate. You decide to take regulatory control action, and put a retain tag on all available product. Employees stop production.*

Withholding Action Without Prior Notice

There may be instances when it is necessary for you to take immediate enforcement actions to prevent imminent threat to public health, without giving the establishment prior notice. For example, if the establishment produced and shipped adulterated product, you would need to take an immediate withholding action. In these situations, first take the immediate withholding action, and then as soon as possible notify the District Office. For further information, refer to the Rules of Practice module.

Immediate Withholding Action Example: *You are performing your regular duties when you become aware that a deviation from a critical limit took place yesterday afternoon, after you left the establishment for another plant on your patrol. A main refrigeration unit malfunctioned, and product was out of the critical limit for temperature for two monitoring checks. You decide to verify that all parts of corrective action have taken place, and ask for the corrective action log. You observe that the establishment documented that it identified and eliminated the cause, the CCP was brought under control, and that measures were implemented to prevent recurrence. However, you can find no evidence that the establishment identified or segregated any product affected by the deviation. You ask for any documentation that the safety of the product was verified, but nothing is provided. You verify that pre-shipment review was completed, and that all product produced has left the control of the establishment. You determine that the establishment produced and shipped adulterated or misbranded product. You notify the establishment that the marks of inspection are being withheld pending further instructions from your District Manager. You immediately page your supervisor and call the DO.*

Block 9—Notify the District Office

If you determine that an inadequate system may exist, you should notify the District Office. Provide the DO all of the information about the situation. You should request that a Notice of Intended Enforcement be issued to the establishment. The DO will provide direction about further actions you need to take. The DO may assign an EIAO to evaluate the establishment's HACCP system.

Block 10—District Office Determines Enforcement Action

After evaluating all of the facts of the case, the District Office will determine the appropriate enforcement action based upon the rules of practice.

Withholding and Suspension Actions With Prior Notification

Keep in mind that some withholding and suspension actions require prior notification according to the rules of practice. The most common withholding or suspension actions related to HACCP noncompliance are those in which the HACCP system is found inadequate due to **multiple or recurring noncompliances**. Withholding or suspending inspection for this cause does require prior notification to the establishment. The prior notice is in the form of a written Notice of Intended Enforcement Action (NOIE). Remember that a suspension may only be issued by a District Manager or higher FSIS official.

Enforcement Action Example: *On February 12, you issue an NR when you observe that the establishment did not conduct the monitoring procedures as specified in the HACCP plan. Instead of taking two temperatures of incoming product per load as the HACCP plan states, the establishment took one. On February 20, you document that the same monitoring personnel again took one incoming product temperature instead of two as specified in the plan, and on this NR you document that this noncompliance is linked to the one on February 12. Similar NR are written on March 4 and 18. On each, you document the linkage that further planned actions are not effective or not implemented, and discuss the NR and the developing trend with plant management at the weekly meeting. On March 18, after providing the NR to plant management, you decide that documentation on the NR demonstrates that further enforcement actions are necessary to bring the establishment into regulatory compliance. You call the DO. You explain that repetitive NR indicate a need to take further enforcement actions and request that a Notice of Intended Enforcement Action be issued to the establishment. The DO issues an NOIE to the establishment the next day.*

Workshop: Enforcement

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

1. You are reviewing HACCP records and make the following observations.

A HACCP monitor identified fecal material on a carcass at the chiller exit. His finding was recorded at 9:32 a.m., but plant records show that corrective action did not start until 10:03 a.m. Therefore, there was a 31-minute time period during which product was continuing to be produced and no corrective action was being taken. The corrective actions documented by the plant failed to identify this time difference between hazard identification and the initiation of corrective action. The pre-shipment review has been completed for this product. You do not know if any affected product has left the plant's control.

a. What should you do first?

b. Has a noncompliance occurred?

c. Could this indicate an inadequate system?

d. Should a Noncompliance Record be generated?

e. Should the incident be reported to the District Office?

f. Would you expect the plant to reassess their HACCP plan?

2. While performing the 03B01 procedure in a raw ground beef operation to verify the recordkeeping requirements for supporting documentation, you review the establishment's HACCP plan. During this review, you notice that the establishment has documented a reassessment of its HACCP plan. You go to plant management and ask what event triggered the reassessment. The plant manager indicates that the reassessment was performed in response to a positive *E. coli* O157:H7 result from its microbiological testing of the finished raw ground beef patties. This microbiological testing program is not referenced in the plant's HACCP plan. It is performed as a supplier requirement for their customer. You request the plant to provide the results of their microbiological testing of the finished raw ground beef patties. The plant provides this data to you. You observe that the last sample analyzed was found to be positive for *E. coli* O157:H7. You request information about corrective actions taken and are shown an unforeseen hazard log that documents that the establishment segregated and held affected product. The plant also has records to show that it performed a review to determine the acceptability of affected product; and took action to ensure that no product injurious to health entered commerce by diverting the positive product into a fully cooked product produced at the establishment. Documentation that the product received a full lethality treatment is provided. The log further shows that a reassessment was performed, and the establishment determined that this was not a hazard likely to occur in its process. It made no alterations to the hazard analysis or the HACCP plan. The basis for this decision is documented as: "It is the only positive ever received. We require that all suppliers provide certification that products have been subjected to a validated antimicrobial carcass treatment. The certification requirement for our suppliers should continue to be sufficient in the future. This result is a fluke. No changes to the HACCP plan are necessary at this point." When asked for supporting documentation, the QC manager provides all the finished product microbiological test results for the past year. You perform an 02 procedure on this specific production. You verify that all HACCP requirements, including pre-shipment review, were met for all CCP, other than what is described above.

a. Has the establishment supported its decision about the results of the reassessment?

b. What are the questions you would seek answers to as you gather information to determine whether or not to document this as a noncompliance, and what conclusion would you make?

c. What regulations need to be considered?

d. Is there a HACCP noncompliance? Please explain your answer.

e. If you determine that a noncompliance should be documented, what noncompliance classification indicator would you use?

f. What are the questions you would seek answers to as you gather information to determine whether or not there is an inadequate system, and what conclusion would you make?

g. If you determine that you would document an NR, please complete blocks 9 and 10 **only** on the next page.

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

TYPE OF NONCOMPLIANCE
☐ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.

4. TO (*Name and Title)*

5. PERSONNEL NOTIFIED

6. RELEVANT REGULATION(S)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

10. DESCRIPTION OF NONCOMPLIANCE:

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

3. Review the following NR.

a. Describe the logical thought process that you would use in evaluating the situation.

b. Decide upon and describe a course of action, if any, that may be needed.

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

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
2-01-03	**20-03**	**00042-P**

4. TO (*Name and Title*) **Ms. Bernice Walters, Plant Manager**

5. PERSONNEL NOTIFIED **Mr. Steve Milton, Plant Superintendent**

6. RELEVANT REGULATION(S)

381.65(e), 417.2(c)(4)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	1		

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS
HACCP - Monitoring

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 10:30 am, I performed a zero tolerance fecal check as part of the 03J01 procedure. I randomly selected 10 birds from each of the four evisceration lines past the final washers and prior to the chillers. I found a ½ inch fecal smear (on the intact skin covering the body in front of the thigh) on one of the 10 birds from evisceration line number 2. There were no plant employees between me and the chiller when I performed this check therefore it is reasonable to conclude the contaminated bird would have entered the chiller in violation of regulation 381.65(e). I notified Mr. Steven Milton of the noncompliance. I informed him that this was a deviation from the critical limit of no visible fecal contamination at CCP 1. This serves as written notification of monitoring noncompliance. This document also serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

John Smith

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
All product was retained back to the last acceptable monitoring check. Increased the rate of overflow of the chiller. Verified chlorine content at the chiller intake at 20 ppm. Visually inspected all birds coming out of chiller. Put all birds exiting chiller through 20 ppm chlorine inside outside bird washer.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
Schedule a visit with a field manager concerning feed withdrawal on production units supplying birds to this plant. Ensure proper functioning of final washer.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
Bernice Walters	**2-2-03**

16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

17. DATE

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

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
2-05-03	**25-03**	**00042-P**

4. TO (*Name and Title)*
Ms. Bernice Walters, Plant Manager

5. PERSONNEL NOTIFIED
Mr. Steve Milton, Plant Superintendent

6. RELEVANT REGULATION(S)

381.65(e), 417.2(c)(4)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	1		

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS
HACCP - Monitoring

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 11:05 am, I went to perform a zero tolerance fecal check on the evisceration lines past the final wash and prior to the chiller. Performance of this check is part of procedure 03J01. I randomly selected ten birds from each of the four evisceration lines and inspected them for visible fecal contamination. All of the birds examined from lines 2, 3, and 4 were found to be in compliance. I observed material composed of plant material held together in an aggregate by a pasty brown substance (¾ inch in diameter) on the inside of the right body wall. Since there were no plant employees between me and the chiller when I performed this check, it is reasonable to conclude the contaminated bird would have entered the chiller in violation of regulation 381.65(e). I notified Mr. Steven Milton of the noncompliance. I informed him that this was a deviation from the critical limit of no visible fecal contamination at CCP 1. See Attachment.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

John Smith

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
All product was retained back to the last acceptable monitoring check. Increased the rate of overflow of the chiller. Verified chlorine content at the chiller intake at 20 ppm. Visually inspected all birds coming out of chiller. Put all birds exiting chiller through 20 ppm chlorine inside outside bird washer.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
Scheduled appointment with field manager today to discuss feed withdrawal. Ensure Pac-man properly adjusted for size birds being run.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
Bernice Walters	**2-06-03**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD CONTINUATION SHEET

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. Date	2. Record No.	3. Establishment No.
	25-03	

4. To (*Name and Title*)

5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Est. Procedure Plan | HACCP | SOP | OTHER

8. ISP Code

9. Noncompliance Indicator

10. Description Of Noncompliance:

Similar noncompliance was documented on NR 20-03 on 2/1/03. The further planned actions proposed included contacting the field manager in reference to feed withdrawal and ensuring final wash functioning as intended. In verifying these previous preventive actions, Ms. Walters indicated they had not had an opportunity to discuss feed withdrawal with their field manager. Mr. Milton indicated they were routinely assessing water pressure at the final washer. The previous preventive measure of feed withdrawal has not been implemented. This serves as written notification of monitoring noncompliance. This document also serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

11. Signature of Inspection Program Employee

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

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
2-09-03	**29-03**	**00042-P**

4. TO (*Name and Title)*
Ms. Bernice Walters, Plant Manager

5. PERSONNEL NOTIFIED
Mr. Steve Milton, Plant Superintendent

6. RELEVANT REGULATION(S)

381.65(e), 417.2(c)(4)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	1		

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS
HACCP - Monitoring

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 1:10 pm, I was in the reprocessing area and observed a plant employee hanging birds out of a vat onto the reprocessing line that goes directly into the bird chiller. The vat containing the birds was identified as lot "123" had a QA tag on it that had been initialed by the QA technician that the product in the vat had been checked and found to be acceptable at 1:00 pm. I selected ten birds from this vat and observed feces covering a 1" by ½" area on the cut surface approximately an inch lateral from the tail where the skin had been removed on one of the ten birds. This finding constitutes a deviation from the critical limit of CCP 1. Since the QA technician had already checked the birds and found them acceptable, it is reasonable to conclude the contaminated bird would have entered the chiller in violation of regulation 381.65(e). I notified Mr. Steven Milton of the noncompliance. I informed him that this was a deviation from the critical limit of no visible fecal contamination at CCP 1. See Attachment.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

John Smith

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
product was retained back to the last acceptable monitoring check. Increased the rate of overflow of the chiller. Verified chlorine content at the chiller intake at 20 ppm. Visually inspected all birds coming out of chiller. Put all birds exiting chiller through 20 ppm chlorine inside outside bird washer.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
Implement shortened feed withdrawal program on 2/15/03. Continue to ensure that equipment is properly adjusted.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
Bernice Walters	**2-10-03**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD CONTINUATION SHEET

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. Date | 2. Record No. **29-03** | 3. Establishment No.

4. To (*Name and Title*) | 5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Est. Procedure Plan | HACCP | SOP | OTHER

8. ISP Code | 9. Noncompliance Indicator

10. Description Of Noncompliance:

Similar noncompliance was documented on NR 25-03 (2/5/03). The further planned actions proposed previously included assessment of current feed withdrawal, ensuring final wash functioning as intended and ensuring Pac-man adjusted for the size birds being run. In verifying these previous preventive actions, Ms. Weathers indicated the field manager would begin a shortened feed withdrawal program with producers on 2/15/03, but these preventive measures had not yet been implemented. The plant was assessing the feed withdrawal and Pac-man for proper adjustments. The previous preventive measure of feed withdrawal has not been implemented. This serves as written notification of monitoring noncompliance. This document also serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

11. Signature of Inspection Program Employee

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

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
2-12-03	**35-03**	**00042-P**

4. TO (*Name and Title)*
Ms. Bernice Walters, Plant Manager

5. PERSONNEL NOTIFIED
Mr. Steve Milton, Plant Superintendent

6. RELEVANT REGULATION(S)

381.65(e), 417.2(c)(4)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	1		

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS
HACCP - Monitoring

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 8:05 am, as part of the 03J02 procedure I was measuring the temperature of birds exiting the chiller to determine if they had met the temperature requirement of the HACCP plan. I randomly selected 5 birds to measure the temperatures. While measuring the temperature on the fourth bird, I observed a 1/8" x 1/8" green to brownish glob of feces under the right wing of the bird. Since the feces was found on the bird after the chiller, it is in violation of regulation 381.65(e). I notified Mr. Steven Milton of the noncompliance. I informed him that this was a deviation of a critical limit of no visible fecal contamination at CCP 1. This serves as written notification of monitoring noncompliance. I had a discussion with Ms. Walters in reference to the monitoring noncompliance developing a trend. See Attachment.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

John Smith

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
All product was retained back to the last acceptable monitoring check. Increased the rate of overflow of the chiller. Verified chlorine content at the chiller intake at 20 ppm. Visually inspected all birds coming out of chiller. Put all birds exiting chiller through 20 ppm chlorine inside outside bird washer.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
New feed withdrawal to be fully implemented on 2/15/03. We continue to assess equipment functioning as intended.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
Bernice Walters	**2-13-03**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD CONTINUATION SHEET

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. Date	2. Record No.	3. Establishment No.
	35-03	

4. To (*Name and Title*)

5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Est. Procedure Plan | HACCP | SOP | OTHER

8. ISP Code

9. Noncompliance Indicator

10. Description Of Noncompliance:

Similar noncompliance documented on NR 29-03 (2/9/03). Further planned actions proposed included assessment of current feed withdrawal, ensuring final wash functioning as intended and ensuring Pac-man adjusted for size birds being run. In verifying previous preventive measures it was noted feed withdrawal change was not scheduled until 2/15/03. Plans are in place for all farms supplying birds to this establishment to have shortened feed withdrawal in place by 2/15/03. The plant will assess the effectiveness of the program after it has been implemented. I did observe Eric Echol making adjustments to equipment based on bird size being run. The previous preventive measure of feed withdrawal has not been implemented. This serves as written notification of monitoring noncompliance. This document also serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

11. Signature of Inspection Program Employee

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

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
2-18-03	**38-03**	**00042-P**

4. TO (*Name and Title)*
Ms. Bernice Walters, Plant Manager

5. PERSONNEL NOTIFIED
Mr. Steve Milton, Plant Superintendent

6. RELEVANT REGULATION(S)

381.65(e), 417.2(c)(4)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	1		

8. ISP CODE

9. NONCOMPLIANCE CLASSIFICATION INDICATORS
HACCP - Monitoring

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 2:10 pm I performed a zero fecal check as part of the 03J01 procedure. I randomly selected 10 birds from each of the four evisceration lines past the final washers and prior to the chillers. I found a ¾" fecal smear on the intact skin covering the body on the back side of the tail on one of the ten birds from evisceration line #3. I found fecal material green in color semi-solid consistency approximately ¼" x 1/8" on the inside of the upper back on one of the ten birds on evisceration line #4. There were no plant employees between me and the chiller when I performed this check therefore it is reasonable to conclude the contaminated bird would have entered the chiller in violation of regulation 381.65(e). I notified Mr. Steven Milton. I informed him that this was a deviation from the critical limit of no visible fecal contamination at CCP 1. See Attachment.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

John Smith

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
Bernice Walters	**2-19-03**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD CONTINUATION SHEET

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. Date | 2. Record No. **38-03** | 3. Establishment No.

4. To (*Name and Title*) | 5. Personnel Notified

6. Relevant Regulation(s)

7. Relevant Section/Page of Est. Procedure Plan | HACCP | SOP | OTHER

8. ISP Code | 9. Noncompliance Indicator

10. Description Of Noncompliance:

Similar noncompliance was documented on NR 20-03 (2/1/03), 25-03 (2/5/03), 29-03 (2/9/03), and 35-03 (2/12/03). Previous further planned actions proposed included assessment of current feed withdrawal, ensuring final wash functioning as intended and ensuring Pac-man adjusted for size birds being run. In verifying previous preventive actions, Ms. Walters indicated field manager had implemented shortened feed withdrawal program with approximately 80% of the producers. I observed Mr. Echol adjusting equipment. The previous preventive measure of feed withdrawal has not been effective. This serves as written notification of monitoring noncompliance. This document also serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

11. Signature of Inspection Program Employee

Random Number Generator

You can use a computer with the FSIS FAIM load to select a random number. This is one way to randomly select the regulatory requirements to verify during the 01 procedure. You will need to randomly select a number between one and three to represent which of the three regulatory requirements you are going to verify. Remember that you may also choose to verify more than one regulatory requirement. You can use the random number generator to choose any amount of random numbers.

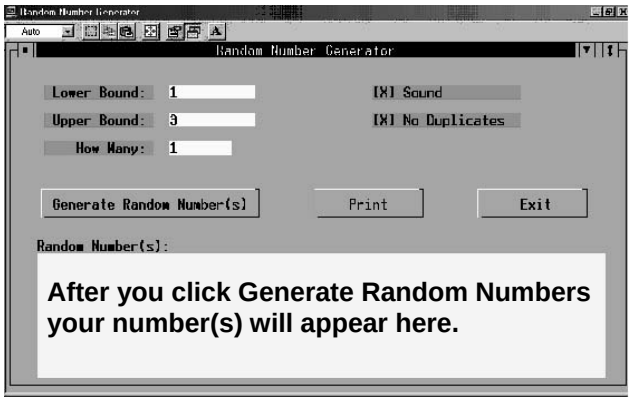
1-Monitoring
2-Verification
3-Recordkeeping

Here are some instructions on how to do this on your computer.

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

Example: To select one out of the three regulatory requirements:

- Enter “1” in Lower Bound
- Enter “3” in Upper Bound
- Enter “1” in How Many
- Then click Generate Random Numbers.
- To select two of the three regulatory requirements, repeat the same instructions, but enter “2” in How Many.



Appendix 2

FSIS Directives and Notices

FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, 6/06

FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel, 3/04

FSIS Directive 5400.5, Inspection System Activities, 11/97

FSIS Directive 5730.1 Responsibilities in Dual Jurisdiction Establishments, 6/05

FSIS Directive 6030.1, Religious Exemption for the Slaughter and Processing of Poultry, 8/05

FSIS Directive 6420.2, Verification of Procedures for controlling Fecal Material, Ingesta, and milk in Slaughter Operations, 3/04

FSIS Directive 7120.1, Amend 10, Safe and Suitable Ingredients used in the Production of Meat and Poultry Products, 1/07

FSIS Directive 7160.3, Rev.1, Advanced Meat Recovery Using Beef Vertebral Raw Materials, 8/03

FSIS Directive 7310.5, Presence of Foreign Material in Meat or Poultry Products, 5/03

FSIS Directive 10,010.1, Microbiological Testing Program for *Escherichia coli* O157:H7 in Raw Ground Beef Products, Raw Ground Beef Components and Beef Patty Components, 3/04

FSIS Directive 10,011.1 Enforcement Instructions for the *Salmonella* Performance Standards, 1/98

FSIS Directive 10,200.1, Assessing Laboratory Sample Identification via LEARN, 7/01

FSIS Directive 10,210.1, Unified Sampling Form, 6/99

FSIS Directives, Notices and FSRE modules are available on:

http://www.fsis.usda.gov and Outlook, and *Inside FSIS*

Other References

Alcide Corporation, Sanova, http://www.sanova.com

American Meat Institute (AMI). 2000. New Technologies in Meat Processing and Packing. American Meat Institute. Washington, DC.

Bacon RT, Belk KE, Sofos JN, Clayton RP, Reagan JO, Smith GC. Extent of microbial contamination in United States pork retail products. J Food Prot. 2001 Feb;64(2):172-8.

Bacon, R.T., K.E. Belk, J.N. Sofos, R.P. Clayton, J.O. Reagan, and G.C. Smith. 2000. Microbial Populations on Animal Hides and Beef Carcasses at Different Stages of Slaughter in Plants Employing Multiple-Sequential Interventions for Decontamination. . J Food Prot. 63: 1080-1086.

Bacon RT, Sofos JN, Belk KE, Hyatt DR, Smith GC. Prevalence and antibiotic susceptibility of *Salmonella* isolated from beef animal hides and carcasses. J Food Prot. 2002 Feb;65(2):284-90.

Barham AR, Barham BL, Johnson AK, Allen DM, Blanton JR Jr, Miller MF. Effects of the transportation of beef cattle from the feedyard to the packing plant on prevalence levels of *Escherichia coli* O157 and *Salmonella* spp. J Food Prot. 2002 Feb;65(2):280-3.

Beach JC, Murano EA, Acuff GR. Prevalence of *Salmonella* and *Campylobacter* in beef cattle from transport to slaughter. J Food Prot. 2002 Nov;65(11):1687-93.

Centers for Disease Control and Prevention (CDC), Division of Bacterial and Mycotic Diseases, Disease Information, http://www.cdc.gov/health/default.htm

Capita R, Alonso-Calleja C, Rodriguez-Perez R, Moreno B, Garcia-Fernandez Mdel C. Influence of poultry carcass skin sample site on the effectiveness of trisodium phosphate against *Listeria monocytogenes*. J Food Prot. 2002 May;65(5):853-6.

Castillo, A., L.M. Lucia, K.J. Goodson, J.W. Savell, and G.R. Acuff. 1998. Comparison of Water Wash, Trimming, and Combined Hot Water and Lactic Acid Treatments for Reducing Bacteria of Fecal Origin on Beef Carcasses. . J Food Prot. 61: 823-828.

Castillo A, Lucia LM, Goodson KJ, Savell JW, Acuff GR. Decontamination of beef carcass surface tissue by steam vacuuming alone and combined with hot water and lactic acid sprays. J Food Prot. 1999 Feb;62(2):146-51.

Castillo A, Lucia LM, Goodson KJ, Savell JW, Acuff GR. Use of hot water for beef carcass decontamination. J Food Prot. 1998 Jan;61(1):19-25.

Castillo A, Lucia LM, Kemp GK, Acuff GR. Reduction of *Escherichia coli* O157:H7 and *Salmonella typhimurium* on beef carcass surfaces using acidified sodium chlorite. J Food Prot. 1999 Jun;62(6):580-4.

Castillo A, Lucia LM, Mercado I, Acuff GR. In-Plant evaluation of a lactic acid treatment for reduction of bacteria on chilled beef carcasses. J Food Prot. 2001 May;64(5):738-40.

Castillo A, Lucia LM, Roberson DB, Stevenson TH, Mercado I, Acuff GR. Lactic acid sprays reduce bacterial pathogens on cold beef carcass surfaces and in subsequently produced ground beef. J Food Prot. 2001 Jan;64(1):58-62.

Cutter, C.N., 1998. New Intervention Technologies. 51st Annual Reciprocal Meat Conference Proceedings-American Meat Science Assn., Vol. 51, 1998.

Cutter CN, Dorsa WJ, Handie A, Rodriguez-Morales S, Zhou X, Breen PJ, Compadre CM. Antimicrobial activity of cetylpyridinium chloride washes against pathogenic bacteria on beef surfaces. J Food Prot. 2000 May;63(5):593-600.

Cutter CN, Rivera-Betancourt M. Interventions for the reduction of *Salmonella Typhimurium* DT 104 and non-O157:H7 enterohemorrhagic *Escherichia coli* on beef surfaces. J Food Prot. 2000 Oct;63(10):1326-32.

Delazari I, Iaria ST, Riemann HP, Cliver DO, Mori T. Decontaminating beef for *Escherichia coli* O157:H7. J Food Prot. 1998 May;61(5):547-50.

Delmore RJ Jr, Sofos JN, Schmidt GR, Belk KE, Lloyd WR, Smith GC. Interventions to reduce microbiological contamination of beef variety meats. J Food Prot. 2000 Jan;63(1):44-50.

Dorsa WJ, Cutter CN, Siragusa GR. Effectiveness of a steam-vacuum sanitizer for reducing *Escherichia coli* O157:H7 inoculated to beef carcass surface tissue. Lett Appl Microbiol. 1996 Jul;23(1):61-3.

Duffy EA, Belk KE, Sofos JN, LeValley SB, Kain ML, Tatum JD, Smith GC, Kimberling CV. Microbial contamination occurring on lamb carcasses processed in the United States. J Food Prot. 2001 Apr;64(4):503-8.

Eggenberger-Solorzano L, Niebuhr SE, Acuff GR, Dickson JS. Hot water and organic acid interventions to control microbiological contamination on hog carcasses during processing. J Food Prot. 2002 Aug;65(8):1248-52.

FDA, Food Microbiological Control, 1998, available through FSIS, CEDL Lending Library

Federal Register, Vol. 67, No 194/ 10-7-02, E. coli 0157:H7 Contamination of Beef Products, FSIS website

Fred W. Pohlman, Ph.D. Overview of Post-Processing Pathogen Reduction Strategies. Meat-ami.org website.

FSIS Food Standards and Labeling Policy Book

FSIS Guideline No. 6, A Glossary of Meat and Poultry Terms, April 1992

FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants, August 26, 1999, FSIS website

FSIS, Technical Services Center, Frequently Asked Questions, FSIS website

FSIS Technical Services Center, IKE Scenarios, FSIS website

FSIS Very Small Plant Outreach materials at
www.fsis.usda.gov/oa/HACCP/outreachsmall.htm.
(202) 690-0520

Galland JC, Hyatt DR, Crupper SS, Acheson DW. Prevalence of *Salmonella* in beef feeder steers as determined by bacterial culture and ELISA serology. Vet Microbiol. 2000 Sep 25;76(2):143-51.

Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products: Guidance for Minimizing Impact Associated with Food Safety Hazards in Raw Ground Meat and Other FSIS Regulated Products, FSIS website

Guidance for Minimizing the Risk of *Escherichia coli* O157:H7 and *Salmonella* in Beef Slaughter Operations, FSIS website

Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings, FSIS website

Guidance on risk reduction during animal production, FSIS website

Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products, FSIS website

Guidebook for the Preparation of HACCP Plans and Generic HACCP Models, September 1999, FSIS website

Hancock DD, Besser TE, Kinsel ML, Tarr PI, Rice DH, Paros MG. The prevalence of *Escherichia coli* O157.H7 in dairy and beef cattle in Washington State. Epidemiol Infect. 1994 Oct;113(2):199-207.

Hardin, M.D., G.R. Acuff, L.M. Lucia, J.S. Oman, and J.W. Savell. 1995. Comparison of Methods for Decontamination from Beef Carcass Surfaces. J Food Prot. 58:368-374.

Inoculated with *Escherichia coli* 0157:H7, *Listeria innocua*, and *Clostridium sporogenes*. J Food Prot. 60:114-119.

Institute of Food Technologists, Evaluation and Definition of Potentially Hazardous Foods, A Report of the Institute of Food Technologists for the Food and Drug Administration of the U.S. Department of Health and Human Services, December 31, 2001, http://www.foodprotect.org/pdf/hazard_foods/front.pdf

Interpretation of the Risk Estimates for Intact and Non-Intact Beef Cooked to Temperatures ≤140°F, March 22, 2002, FSIS website

Interpretive Summary, Comparative Risk Assessment for Intact (non-tenderized) and Non-intact (tenderized) Beef, March 18, 2002, FSIS website

Kang DH, Koohmaraie M, Dorsa WJ, Siragusa GR. Development of a multiple-step process for the microbial decontamination of beef trim. J Food Prot. 2001 Jan;64(1):63-71.

Kang DH, Koohmaraie M, Siragusa GR. Application of multiple antimicrobial interventions for microbial decontamination of commercial beef trim. J Food Prot. 2001 Feb;64(2):168-71.

Kim JW, Slavik MF. Cetylpyridinium chloride (CPC) treatment on poultry skin to reduce attached *Salmonella*. J Food Prot. 1996 Mar;59(3):322-6.

McEvoy JM, Doherty AM, Sheridan JJ, Blair IS, McDowell DA. Use of steam condensing at subatmospheric pressures to reduce *Escherichia coli* O157:H7 numbers on bovine hide. J Food Prot. 2001 Nov;64(11):1655-60.

National Advisory Committee on Microbiological Criteria for Foods, 1998. Hazard analysis and critical control point principles and application guidelines. *Journal of Food Protection*, 61:762.

Nutsch AL, Phebus RK, Riemann MJ, Kotrola JS, Wilson RC, Boyer JE Jr, Brown TL. Steam pasteurization of commercially slaughtered beef carcasses: evaluation of bacterial populations at five anatomical locations. J Food Prot. 1998 May;61(5):571-7.

Ramirez AJ, Acuff GR, Lucia LM, Savell JW. Lactic acid and trisodium phosphate treatment of lamb breast to reduce bacterial contamination. J Food Prot. 2001 Sep;64(9):1439-41.

Robert O. Elder, et al, "Correlation of Enterohemorrhagic *Escherichia coli* O157:H7 Prevalence in Feces, Hides, and Carcasses of Beef Cattle During Processing," Proc Natl Acad Sci USA. Mar 2000. 97(7): 2999-3003)

Rose BE, Hill WE, Umholtz R, Ransom GM, James WO. Testing for *Salmonella* in raw meat and poultry products collected at federally inspected establishments in the United States, 1998 through 2000. J Food Prot. 2002 Jun;65(6):937-47.

Sanchez MX, Fluckey WM, Brashears MM, McKee SR. Microbial profile and antibiotic susceptibility of *Campylobacter* spp. and *Salmonella* spp. in broilers processed in air-chilled and immersion-chilled environments. J Food Prot. 2002 Jun;65(6):948-56.

Smith, D, Blackford M, Younts S, et al. 2001. Ecological relationships between the prevalence of cattle shedding *E. coli* O157:H7 and characteristics of the cattle or conditions of the feedlot pen. J. Food Prot. 64(12): 1899-1903

Sofos JN, Kochevar SL, Bellinger GR, Buege DR, Hancock DD, Ingham SC, Morgan JB, Reagan JO, Smith GC. Sources and extent of microbiological contamination of beef carcasses in seven United States slaughtering plants. J Food Prot. 1999 Feb;62(2):140-5.

Sofos JN, Kochevar SL, Reagan JO, Smith GC. Extent of beef carcass contamination with *Escherichia coli* and probabilities of passing U.S. regulatory criteria. J Food Prot. 1999 Mar;62(3):234-8.

Sofos JN, Kochevar SL, Reagan JO, Smith GC. Incidence of *Salmonella* on beef carcasses relating to the U.S. meat and poultry inspection regulations. J Food Prot. 1999 May;62(5):467-73.

Sofos JN, Smith GC. Nonacid meat decontamination technologies: model studies and commercial applications. Int J Food Microbiol. 1998 Nov 10;44(3):171-88. Review.

Stevenson, K.E., & Bernard, D.T., 1999. *HACCP: A systematic approach to food safety, a comprehensive manual for developing and implementing a hazard analysis and critical control point plan*. The Food Processors Institute.

Supporting Documentation Materials for HACCP Decisions, Prepared for the Food Safety and Inspection Service, USDA, by Mary Kay Folk and Lynn Knipe, Ph. D., Department of Animal Sciences and Food Science and Technology, The Ohio State University, September 2002.
http://www.ag.ohio-state.edu/~meatsci/HACCPupport.html

Tamblyn KC, Conner DE, Bilgili SF. Utilization of the skin attachment model to determine the antibacterial efficacy of potential carcass treatments. Poult Sci. 1997 Sep;76(9):1318-23.

USDA, ARS Pathogen Modeling Program at http://www.arserrc.gov/mfs/pathogen.htm.

Technical Report, Comparative Risk Assessment for Intact (non-tenderized) and Non-intact (tenderized) Beef, March 18, 2002, FSIS website

Van Donkersgoed J, Graham T, Gannon V. The prevalence of verotoxins, *Escherichia coli* O157:H7, and *Salmonella* in the feces and rumen of cattle at processing. Can Vet J. 1999 May;40(5):332-8.

Van Netten P, Mossel DA, Huis In 't Veld J. Lactic acid decontamination of fresh pork carcasses: a pilot plant study. Int J Food Microbiol. 1995 Mar;25(1):1-9.

Warren, D.J., C.N. Cutter, and G.R. Siragusa. 1997. Effects of Steam Vacuuming and Hot Water Spray Wash on the Microflora of Refrigerated Beef Carcass Surface Tissue Keen JE, Elder RO. Isolation of shiga-toxigenic *Escherichia coli* O157 from hide surfaces and the oral cavity of finished beef feedlot cattle. J Am Vet Med Assoc. 2002 Mar 15;220(6):756-63.

Xiong H, Li Y, Slavik MF, Walker JT. Spraying chicken skin with selected chemicals to reduce attached *Salmonella typhimurium*. J Food Prot. 1998 Mar;61(3):272-5.

Yang Z, Li Y, Slavik M. Use of antimicrobial spray applied with an inside-outside birdwasher to reduce bacterial contamination on prechilled chicken carcasses.
J Food Prot. 1998 Jul;61(7):829-32.

Appendix 3

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 417--HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Sec.

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.
Source: 61 FR 38868, July 25, 1996, unless otherwise noted.

Sec. 417.1 Definitions.

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

Corrective action - Procedures to be followed when a deviation occurs.
Critical control point - A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.
Critical limit- The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
Food safety hazard- Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
HACCP System- The HACCP plan in operation, including the HACCP plan itself.
Hazard - SEE Food Safety Hazard.
Preventive measure - Physical, chemical, or other means that can be used to control an identified food safety hazard.
Process-monitoring instrument - An instrument or device used to indicate conditions during processing at a critical control point.

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

Sec. 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. (2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified. (3) Food safety hazards might be expected to arise from the following:

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

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

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

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points,

critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) Upon initial acceptance;

(ii) Upon any modification; and

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

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

Sec. 417.3 Corrective actions.

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

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

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

(3) Measures to prevent recurrence are established; and

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

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

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

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

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

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

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

Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

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

(i) The calibration of process-monitoring instruments;

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

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

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

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

Sec. 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;

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

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

(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.

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

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

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

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

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

Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;

(d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or

(e) Adulterated product is produced or shipped.

Sec. 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.

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

Sec. 417.8 Agency verification.

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

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.