

Module 9b: Other Compliance/Noncompliance—HACCP Systems

Goal To provide instructions to in-plant inspection personnel for determining an establishment's compliance with HACCP, SSOP, *Salmonella* and other non-related HACCP and Pathogen Reduction requirements.

Objective After completing this module, participants will be able to:

1. Define what "Other compliance/noncompliance" means related to HACCP. **Page 2, paragraph 5**
2. Be able to apply the HACCP system inspection procedures.
Throughout document
3. Be able to document findings and take enforcement actions when HACCP system inspection procedures are not met. **Pages 24, 25, 26**

Steps Introduce the video by reading the goal and objectives of this module.

Tell participants that you will put what will be covered in the module in perspective with the HACCP-Based Inspection System.

Post the HACCP Other piece on the graphic representation of the components of the HACCP-Based Inspection System in its place.

Explain to participants that this module will introduce the nine “other” processing categories, each represented by a different element in the HACCP inspection program activity. Official establishments will develop a HACCP plan that will fit into one or more of these nine categories. Explain that the chart should help participants visualize the components of the HACCP-Based Inspection System.

Show the video

At the “Stop and Review” prompt, go over the related portion of the participant’s handout

Upon completion of video, discuss questions

Have the participants complete HACCP trend indicator workshops

Pass out keys and review

Discuss HACCP walk-thru examples

Have the participants complete HACCP workshops

Pass out answer keys and review

Answer any remaining questions on Module 9b

Take down the HACCP Other piece. The chart will be re-introduced at the beginning of Module 9c.

Go to Module 9c.

FACILITATOR NOTES:

Play the video for Module 9b. Then stop the tape. Ask the participants the following questions. Participants can refer to page 27 of their handout to follow along. Use these questions as “talking points”.

1. What are the five regulatory requirements that the ongoing operations of the establishment’s HACCP system must meet?

Answer: The five regulatory requirements are -- monitoring, verification, recordkeeping, corrective actions and reassessment.

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

Answer: The 01 procedure is for reviewing a random sample of the regulatory requirements in operation. Any combination of the 5 requirements can be randomly verified.

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

Answer: The 02 procedure is for looking at an entire lot or shipment of product. When performing the 02 procedure all of the requirements are verified.

4. What are the two components of the other compliance/noncompliance procedures for HACCP?

Answer: Both the 01 and 02 procedures have review and observation and recordkeeping components.

5. If noncompliance is determined while performing the 01 HACCP procedure, what is the appropriate action?

Answer: When noncompliance is found while performing the 01 procedure, you would document the noncompliance on an NR and then perform the 02 procedure on that lot or shipment of product.

6. What requirements must the establishment meet if they determine there is a deviation from a critical limit?

Answer: Any time a deviation occurs, the corrective action taken by the establishment must meet **all** 4 of the regulatory requirements in 417.3. That is: The cause of the deviation is identified and eliminated; the CCP will be under control after the corrective action is taken; measures to prevent recurrence are established; and no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

7. Will FSIS document noncompliance when the establishment fails to meet one of the regulatory requirements, but the system is not determined to be inadequate?

Answer: Even if the system is not determined to be inadequate, FSIS will document noncompliance with the 5 regulatory requirements.

8. When noncompliance is determined, the next decision is whether there is an inadequate system. What are the 4 questions used in making this determination?

Answer: 1) Did the establishment review the records associated with the production of the product? 2) Was adulterated product produced or shipped? 3) Is there noncompliance with the same root cause? 4) Has the establishment met the basic regulatory requirements?

9. What is the appropriate enforcement action if the system is determined to be inadequate?

Answer: If the system is determined to be inadequate, withhold inspection and notify the establishment. Provide plant management a copy of the NR. Notify the DO of actions taken. The DM will assign a CO who will visit the establishment and initiate a case file. The DM will provide instructions for enforcement actions from this point.

Facilitator Note: The ISP indicates that the 02 procedures are performed on a given shipment of product. 417.5 of the regulations requires the establishment to conduct a pre-shipment review on records associated with the production of that product. Therefore, the establishment should be able to identify which production of product will be/was included in the pre-shipment review. This should be discussed at the plant awareness meeting so that the establishment understands this responsibility. If the establishment has not identified this, the inspector will need to use their judgement based on knowledge of the operations to make the determination of what product to include in the performance of the 02.

Additionally, the specific circumstances in which we determine noncompliance could dictate what is looked at under 02. For example, if there is a deviation from a critical limit, the inspector needs to determine that the establishment met the corrective action requirements for all the affected product.

New Facilitator Note: Emphasize the following after the completion of the module.

- Throughout the module the term “lot” is used to describe specific production. 417.5(a)(3) identifies that establishment should have records including product code(s), product name or identity, or slaughter production lot. Specific production is generally that production that the establishment has performed the pre-shipment review on. The establishment might designate this specific production as a lot, a batch, by a timeframe, etc.
- Corrective actions proposed by an establishment should be verified by inspection personnel as part of the HACCP 01 and 02 procedures.
- Remember, the HACCP 01 and 02 procedures both have a review and observation and a recordkeeping component. It is important that inspection personnel incorporate both components into their inspection procedures. In the past, inspection determinations were made primarily by on-site measurements or tests. With the HACCP 01 and 02 procedures, inspection determinations that could result in further enforcement actions can be made by reviewing the establishment’s records or observing of the establishment implementing their program.
- There are a variety of ways in which the establishment can meet the pre-shipment review requirement. It is up to the establishment to determine how they will meet this requirement.

Module 9b, Workshop 1

For Facilitator information only, the following updates have been made to the workshop.

General

- Changed dates to coincide with the next round of implementation
- Eliminated names in scenarios as much as possible to reduce confusion
- Added real-life examples
- Added completed procedure schedules with keys (*Note: other modules include the opportunity for participant's to complete the procedure schedule.*)

Specific

- Scenario 1 – same scenario as last year with minor changes for clarity
- Scenario 2 – changed this scenario to be more realistic
- Scenario 3 – added to help inspection personnel understand that if corrective action is taken but not documented, the most appropriate trend indicator is recordkeeping
- Scenario 4 – added a fourth scenario into the packet because it deals with zero tolerance and we did not have this in training last year
- Scenario 5 – added to illustrate to inspection personnel that process monitoring equipment covers more than just hand-held thermometers

Module 9b, Workshop 2

For Facilitator information only, the following updates have been made to the workshop:

General

- Included zero tolerance examples
- Included more slaughter examples
- Made scenarios more realistic
- Added completed procedure schedules with keys
- Added practical application from Module 11 to Scenarios 1, 3, and 5.

Specific

- Walk-through examples did not change.
- Scenario 1 – changed to better reflect the corrective action noncompliance that was the greatest concern of inspection personnel during the first wave of implementation.
- Scenario 2 – replaced last year's scenario with this slaughter scenario. This scenario is to help inspection personnel understand that if monitoring is missed and the pre-shipment review is performed, but the establishment can demonstrate that the critical limits are met with some other means, the system is not inadequate. There is monitoring noncompliance but the system is not inadequate.
- Scenario 3 – Same as it was last year with some records changed for clarity and legibility. No pre-shipment review performed by the establishment but all critical limits are met or corrective action is implemented if necessary, there is recordkeeping noncompliance, not an inadequate system.
- Scenario 4 – Poultry slaughter zero tolerance scenario. Inadequate system because the plant did not implement 417.3(a)(4) to prevent the shipment of adulterated product.
- Scenario 5 – Red meat zero tolerance scenario. This scenario illustrates that the plant can have a zero tolerance CCP anywhere but FSIS's point of verification is at or after the final rail. If fecal contamination is found before it reaches the plant's CCP, there is still monitoring noncompliance and a deviation from a critical limit.
- Scenario 6 – Represents a small plant that monitors each batch rather than on a time frequency. Depicts an unforeseen hazard (metal contamination) and the corrective action required by the establishment when an unforeseen hazard occurs. No noncompliance in this scenario.

Module 9b, Workshop 3

For Facilitator information only, the following updates have been made to the workshop.

General

- Replaced scenario with a more realistic scenario

Specific

- Workshop is a poultry zero tolerance example
- Workshop includes example of IIC contacting DO to issue “Notice of Intent to Suspend Inspection”
- Workshop re-emphasizes decision making process for repetitive noncompliance