

## Module 7: Basic Compliance/Noncompliance of Plans

**Goal** To provide instructions to in-plant inspection personnel for determining the compliance/noncompliance of an establishment's plans.

**Objectives** After completing this module, participants will be able to:

1. Know the regulatory requirements for HACCP plans/procedures.  
**Pages 4-5**
2. Be able to verify that HACCP plans/procedures meet regulatory requirements using checklists. **Pages 15-16**
3. Be able to document findings and take enforcement actions when regulatory requirements are not met. **Pages 6, 7, 10 and 11**
4. List the preparatory steps for a plant level awareness meeting.  
**Page 2, paragraphs 1-8**
5. Answer whether an inspector may take the plant's HACCP plan to the government office to review prior to an awareness meeting.  
**Page 2**
6. State the purpose, time allocation, and scheduling of the HACCP awareness process. **Page 1, paragraph 5**

**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 SSOP and HACCP Basic pieces on the graphic representation of the components of the HACCP-Based Inspection System.

Explain to participants that in this module, Basic Compliance checks for the HACCP and SSOP requirements will be introduced. These are performed to be sure that the establishment's plan meets the basic requirements outlined in the regulations. Explain that the chart should help participants visualize the components of the HACCP-Based Inspection System.

Show the video

Go over the participant's handout

Discuss questions and Facilitator Notes

Cover instructions to workshop

Walk through the example in Part 1 of the workshop using the checklist

Review the completed Noncompliance Record (NR) in Part 1 of the workshop. This NR may be used as an example for completing other parts of this workshop.

Have the participants complete the workshop

Pass out answer keys and review

Answer any remaining questions on Module 7

Take down the SSOP and HACCP Basic pieces. The chart will be re-introduced at the beginning of Module 8.

**Questions:**

1. What is the purpose of the plant awareness meeting?

Answer: To help the inspection personnel who will be performing HACCP inspection procedures understand the plant's HACCP plan. Since HACCP plans are plant-specific, inspection personnel cannot effectively perform HACCP procedures until they understand the plan.

2. What inspection procedure code is utilized when performing the HACCP basic compliance/noncompliance procedure?

Answer: Procedure 03A01 is performed and documented as an unscheduled procedure each time inspection personnel determine basic compliance/noncompliance of a HACCP plan.

3. What regulatory action is taken if noncompliance is found with the basic regulatory requirements?

Answer:

- Advise establishment management orally of the findings on which the intended action is based and (as soon as possible and by the end of the tour of duty) confirm with a copy of the NR that documents the noncompliance finding(s).
- Refuse to permit the labeling, stamping, or tagging of any livestock product or poultry product produced under the noncomplying conditions as "inspected and passed" or "inspected for wholesomeness."
- Identify all possible adulterated livestock and/or poultry products as "U.S. Retained."
- Notify the DO of the action(s) taken, and if the establishment does not initiate action immediately to bring itself into compliance—  
Notify the DO (which will assign a CO), and  
In conjunction with the CO, develop a case file and take further actions as appropriate.

4. What is the new procedure code that will be utilized by inspection personnel to determine compliance/noncompliance with the SSOP basic requirements?

Answer: Procedure 01A01 is performed and documented as an unscheduled procedure each time inspection personnel determine basic compliance/noncompliance of SSOP procedures.

**Facilitator Note:** Please reiterate =>

FSIS regulation 417.7 requires the establishment to utilize an individual that has met the following training requirements to develop the HACCP plan and perform any reassessment and modification of the HACCP plan. The requirements are: completion of a course in the application of the seven HACCP principles to meat or poultry processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Because FSIS does not approve these courses, there is no requirement for the establishment to provide evidence of the training. However, it is expected that the evidence of this training will be demonstrated in the ongoing day to day operations of the HACCP plan. That is, it is expected that FSIS other verification procedures will find evidence of noncompliance if the establishment has failed to meet the requirements of 417.7.

**Additional Facilitator Notes**

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**Emphasize the following points after completion of the module.**

- The plant awareness process should begin anytime after the receipt of this training. This action is necessary because the 1999 implementation contains many assignments with multiple plants on them. Circuit Supervisors and/or multi-IPPS supervisors should be contacted for guidance if conflicts arise in scheduling the plant awareness meetings amongst plants on the assignment.
- It will be important to start the plant awareness process earlier than last year so that small plants can have the **opportunity (not required!)** to practice, de-bug, and validate their HACCP plans between 12/1/98 and 1/25/99.
- The plant awareness process is specific to the establishment and the HACCP plan(s) within that establishment.
- The plant awareness is a process! This is usually accomplished through meeting(s), but it is important to understand that it is a process. During the process, communications between the inspection personnel and plant management is imperative!
- Topics covered by the plant awareness process as well as the length of the process will vary because of differences in the plants and plans. Some suggested topics include: where the plant records are kept, CCP locations, how the establishment will accomplish pre-shipment review, monitoring procedures, verification procedures, etc.
- Just because you have had a plant awareness “meeting” does not mean the plant awareness process has ended. If you have questions concerning the establishment’s HACCP plan(s) after the meeting has been completed, communicate these with plant management.
- Remember, the BASIC compliance/noncompliance checklist can not be completed until after the plant awareness process! You might however, study the checklist to get ideas of things to look at during the plant awareness process.

- Do NOT perform the Basic compliance procedure until after completing the plant awareness process and after 1/24/99!

**Have participant's turn to Tab 12 and review the following:**

**Federal Register Vol. 62, No. 229, Friday, November 28, 1997 – Livestock and Poultry Carcasses Contaminated With Visible Fecal Material:**

- This Federal Register Notice clarifies that the Agency views its “zero tolerance” for visible fecal material as a food safety standard. Slaughter establishment HACCP plans should be designed to ensure that at any point following the final rail inspection of livestock carcasses or when poultry carcasses enter the chilling tank, no visible fecal material is present.

**Federal Register Vol. 63, No. 20, Friday, January 30, 1998 – Contents of HACCP Plans:**

- This Federal Register Notice re-emphasized the regulatory requirements for the HACCP plan, such as CCPs, critical limits, monitoring procedures, verification procedures, and corrective actions. This Notice also clarified that the Agency does not view good manufacturing practices (GMPs) as satisfying the requirements for the contents of a HACCP plan. Specifically, the Notice defines that references to GMPs rather than stating the CCPs, critical limits, monitoring and verification procedures, and corrective actions themselves is insufficient to satisfy the requirements of 417.2(c).

**Federal Register Vol. 63, No. 20, Friday, January 30, 1998 – Contents of HACCP Plans; Critical Control Points:**

- This Federal Register Notice was published to clarify that the Agency's regulations require that a HACCP plan list critical control points for each food safety hazard identified as reasonably likely to occur in the production process. The number of CCPs will depend on the production process and the hazard. The critical limit must be designed to ensure that applicable targets or performance standards and any other requirements in the Agency's regulations pertaining to the specific process or product are met.

**Federal Register Vol. 63, No. 44, Friday, March 6, 1998 – Establishment Review of Production Records:**

- This Federal Register Notice clarifies that for purposes of the pre-shipment review the establishment must determine that all critical limits were met and, when appropriate, that corrective actions were taken. Establishments must also ensure the completeness of their records before shipping the product for distribution. FSIS has not prescribed how establishments comply with this requirement. The establishment can review production records at any point after processing and before shipping the product. Examples include, at the end of each day of production before product goes into on-site storage, during preparation of shipping documents

before assembling product for transportation from the establishment, or he checks could be initiated earlier in the process and the review accomplished in stages.

**Federal Register Vol. 63, No. 62, Wednesday, April 1, 1998 – HACCP Plan Requirements and Meat and Poultry Product processing Categories; Policy Clarification:**

- This Federal Register Notice clarifies that an establishment producing multiple products that fall within a single processing category can be included in one HACCP plan. It also clarifies that a single HACCP plan could be developed for a single product that passes through multiple processing categories. For example, an establishment that slaughters and grinds might choose to develop and implement one HACCP plan.

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

**General**

- Revised the Hazard Analysis Worksheet for clarification
- Removed CCP Determination Guide – not needed after Hazard Analysis Worksheet revised.
- Reduced number of CCPs in the HACCP plan to more accurately reflect real-life plans.
- Added completed procedure schedules with keys
- Introduced the concept that even when Basic Noncompliance is found, the establishment might be able to remedy the failure without delay e.g., verification procedures and frequency not included in the plan – establishment might have these determined on their hazard analysis and only need to type them into the plan.

**Specifics**

- Scenario 4 is the only one changed. Monitoring procedure and frequency left out of the HACCP plan for one CCP.

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Facilitator Note - Module 7 Workshops

The second block of FSIS form 5000-1, "The hazard analysis" block, contains two parts. The first part is an assessment of whether the establishment has identified within their hazard analysis food safety hazards that are reasonably likely to occur in the production process. The second part of "The hazard analysis" block is an assessment of whether the establishment has identified preventive measures for those food safety hazards determined to be reasonably likely to occur. The hazard analysis in the workshops portrays that there are many ways an establishment might meet this requirement. For example, on page 21, the establishment has determined that there is a biological food safety hazard reasonably likely to occur. The preventive measures at this step of the hazard analysis is that the establishment determined to include a CCP at this step. A CCP, by definition, can be considered a preventive measure. On page 23, a biological hazard has also been determined reasonably likely to occur. In this section, the hazard analysis includes specific preventive measures as well as stating there will be a CCP.

There is no specific way that an establishment must meet this requirement. This hazard analysis demonstrates different ways the requirement might be met. If you are unsure that preventive measures are identified, ask this during the plant awareness process. Inspection personnel will need to use a sound thought process in making this determination.