

Module 6: The Revised PBIS

Goal To identify the changes made to PBIS to support HACCP-based inspection.

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

1. Describe the new structure and components. **Script pages 1-5**
2. Describe the differences between the new Inspection System Procedure (ISP) Guide and the old ISG. **Script pages 1-2; Handout pages 2-6**
3. Describe the changes to the Plant Profile. **Script page 2, paragraph 3; Handout pages 6-7**
4. Complete an Establishment/Shift Inspection Procedure Worksheet. **Script page 2, paragraphs 4 & 5; Handout pages 7-8 and pages 33-34**
5. Explain how to properly complete a Procedure Schedule. **Script pages 2-3; Handout pages 11-12**
6. Explain how to properly complete a Noncompliance Record (NR). **Script page 5; Handout pages 13-15**
7. Describe the Noncompliance Determination Guide (NDG). **Script pages 4-5; Handout pages 15-16**
8. Define noncompliance trend indicators. **Script pages 4-5; Handout pages 17-24 and page 47**

Facilitator's Notes

FOR FACILITATOR INFORMATION ONLY:

Module 6 was updated and re-sequenced so that it more closely follows FSIS Directive 5400.5.

□ Allow participants to read Directive 5400.5

□ Introduction of Module:

The next module that will be covered in the training session is Module 6, PBIS Modifications for HACCP systems.

PBIS will provide the structure and framework for accomplishing the Regulatory Oversight Model that was introduced in Module 5.

The system's approach to inspection under HACCP requires changes in the components of PBIS and the activities FSIS has conducted under this system. The ISG, plant profile, establishment/shift monitoring plan, inspector assignment schedule, inspector assignment schedule summary, and the corrective action system have been modified to meet the system requirements.

The video will introduce the PBIS policies, forms, and instructions that will be used for the system's approach to inspection.

This module lays the foundation for the HACCP technical training that will be presented in Modules 7,8, and 9. This module is only designed to introduce the tools and support materials necessary for HACCP-Based Inspection. We are simply going to learn how to use the tools here in Module 6. Their applications will come in later Modules.

□ Read the objectives that are on flipchart.

□ Inform participants that video script is included in the material for later reference or if they wish to follow along, however, there will be parts of the video that they will want to watch.

□ Play video

□ Introduce the Pie Chart

Tell participants that you will now put what is covered in module 6 in perspective with the HACCP-Based Inspection System.

Show the graphic representation of the components of the HACCP-Based Inspection System without the pieces, such as “Other,” “Basic.”

Explain that each piece represents a different inspection activity to help inspectors make determinations about compliance with the HACCP, SSOP, and other consumer protection requirements that form the HACCP-Based Inspection System.

Point out that each piece is associated with the activity number in PBIS (e.g., SSOP is 01; HACCP is 03).

Explain that the size of the pieces on the chart are not reflective of the amount of time inspection personnel may be performing any of these verification activities, and that the size has no relation to the importance of one activity over another. Point out that each represent regulatory requirements. Therefore, each activity and their associated procedures are important.

Indicate that this is an introduction to the HACCP-Based Inspection System. Explain that the chart will be used during each of the Modules that follow to help participants visualize the HACCP-Based Inspection System.

This chart will be referred to again at the beginning of Module 7.

❑ ***Discussion Points to be covered by facilitator, method and order to be determined by facilitator team.***

- Allow participants time to read Module pages
- Review important points in the Module pages (e. g., trend indicators, etc...)
- Turn to the PBIS Comparison Chart and discuss the changes
- Discuss the pages of key points
- Complete the workshops and then discuss them
- Review the Directive
 - ◆ ISP Guide
 - ◆ Plant Profile
 - ◆ Establishment Inspection Procedure Worksheet
 - ◆ Procedure Schedule
 - ◆ Review Noncompliance Record blocks
 - ◆ Noncompliance Determination Guide
 - ◆ Compliance/Noncompliance Categories
 - ◆ Trend Indicators

Key Points

1. Both the old and the new versions of PBIS will be in use until HACCP is implemented in all establishments in the year 2000.
2. The procedures in the ISP guide reinforce FSIS's regulatory oversight role, because they focus on the establishment preventing problems in the process rather than inspection detecting them.
3. Except for the two SSOP record procedures that direct records verification only, inspection personnel may review applicable records, take a on-site measurements, make direct observations, or use any combination of these activities to verify that the requirements have been met when performing a procedure.
4. The plant profile form was modified to capture information about establishment's HACCP system.
5. For the ADP system to generate procedure schedules the week of January 25, 1999, inspection personnel will need to develop an establishment/shift procedure plan for each shift near the end of the HACCP awareness period and send it the district office.

Only one procedure plan per shift will be developed.

6. Only one PS will be generated per shift per establishment. When there are two or more inspectors assigned to the plant/shift, the IIC and inspectors will jointly review the work to be performed and decide who will perform it. Should agreement not be reached, the immediate supervisor will assign the work.
7. Only *one* inspection result shall be entered on the schedule for a procedure. Either performed, not performed, or a noncompliance trend indicator will be circled.
8. Under HACCP, an establishment's failure to comply with a regulatory requirement will be identified and documented as "noncompliance".
9. The NDG identifies and describes the trend indicators applicable to the regulatory areas that make up the Pathogen Reduction/HACCP-based inspection system. Indicators are used to categorize noncompliance. Over a period of time, from the accumulation of the *same* indicator, a trend in noncompliance may emerge. Hence, we have the term "trend indicators".
10. The trend indicators provide information on trends in noncompliance and thereby improve FSIS's ability to evaluate establishment performance and

process control. FSIS will use trend indicators in determining whether to take additional regulatory or administrative action based on establishment performance. This is why it's very important that inspection personnel use the NDG to uniformly select the trend indicator that **best describes** the noncompliance.

11. Inspection personnel must complete a Noncompliance Record or NR each time results of performing a procedure indicate noncompliance. The NR serves as official notification to plant management about noncompliance observed during the performance of procedures.
12. When inspection personnel take official control action, they need to provide establishment management with oral notification of the action including the basis for the action as soon as possible. They need to confirm their actions with a copy of the NR that documents the noncompliance findings. In the event that the plant management official is not available the NR will be left in the "NR drop site" agreed upon by plant management and inspection personnel.
13. Plant management's written response on an NR is not mandatory.

In the event plant management elects not to respond in writing on the NR to an identified noncompliance, inspection personnel will record management's oral response in each "immediate action (s)" block, and in the "further planned action(s)" block where appropriate.

In the event plant management elects not to respond orally, inspection personnel will record their response and identify the required correction date on the NR. Be sure that you provide plant management a copy of the NR.

FOR FACILITATOR INFORMATION ONLY:

The last sentence in Key Point #4 was removed. Key Points #8 and #10 were removed. The remaining Key Points were renumbered and additional updates are highlighted.