

Module 6: The Revised PBIS

When HACCP is implemented FSIS will continue to use PBIS, but it'll be a new version. The Performance Based Inspection System has changed to make it more compatible with the pathogen reduction and HACCP approach to inspection.

As you know, HACCP won't be implemented in all plants until the year 2000. You'll use the new PBIS only in plants that are under HACCP inspection. All others will be subject to old PBIS techniques.

PBIS will still schedule your work and incorporate your inspection results into a central database. It'll also continue to create reports for supervisors and management. But the forms will look different.

Our new HACCP systems approach to inspection made PBIS changes necessary. The ISG was replaced. The plant profile, the monitoring plan, the assignment schedule, and the assignment schedule summary were changed. The NDG and "trend indicators" were developed to replace the DCG and deficiency classifications. PDRs became NRs.

I know that sounds like a lot of changes, but we're going to take them one at a time.

First, let's talk about the Inspection System Procedure Guide, or the ISP, which replaced the ISG. It's the foundation for all inspection duties in HACCP plants. Imagine that this pie represents the ISP. It's divided into slices called Activities. Each activity covers an area of plant responsibility. You know that plants must have SSOPs. They're covered in Activity 01. HACCP plans are in Activity 03. Economic and wholesomeness requirements come under Activity 04; all types of sampling are in Activity 05; and all other regulatory requirements are addressed in Activity 06. These are also the five areas in which you have the responsibility for regulatory oversight. In upcoming modules your facilitators will tell you about each piece of the pie, one slice at a time. You'll learn how to perform inspection duties, including how to take enforcement action.

The new PBIS applies to each Activity, but you have to know how to use it before you can conduct inspection procedures. So, for now, let's confine our thoughts to PBIS changes and the new forms that go with those changes.

First, the ISP itself ...it differs from the old ISG in more ways than just replacing "processes" with "Activities". In the ISP "Elements" replaced critical control points, and more than 500 tasks were grouped into less than 50 procedures.

You'll recall that ISG tasks tell you what to do at a specific step or point. Since they focus on a narrow part of the process, they only give a snapshot of what happened at the moment the task was performed. They don't give an overall picture, so they don't tell us much about process control. In other words, when a task is performed and a problem is found, it doesn't necessarily mean the process is out of control.

ISP procedures, on the other hand, were designed to verify both plant processes and controls. There are three types of procedures: those for sample collection, for SSOP

record verification, and for all other verifications. I didn't mention evaluations because there aren't any.

Sample collection procedures direct you to take a sample and submit it to the laboratory. SSOP record verifications ask you to look at records only. All other verifications require you to do any combination or all three of the following things: review records, take hands-on measurements, or make direct observations.

The next change we'll discuss is in the plant profile. The PBIS file needs to be updated to include HACCP information, so don't forget to complete a new profile. A good time to do this is during the awareness phase, which occurs around the time HACCP is actually implemented in the plant. You'll hear more about the awareness phase in an upcoming module. Right now, let's get back to the profile. It's a little different. QC information was deleted, and PEA stages were removed from the inspection system block. HACCP-related blocks were inserted. Instructions for preparation are in Attachment 1 of FSIS Directive 5400.5.

Another form that should be updated to include HACCP information is the old Establishment/Shift Monitoring Plan. It has a new name: the Establishment/Shift Procedure Plan. Complete a worksheet for each shift. Identify only the operations conducted on that shift. In HACCP plants work schedules are created from plans filled out for each shift, not for each inspector's work assignment.

Review each procedure listed. Mark those that apply. "CORE" Procedures, that is, those common to all plants, were removed from the Establishment/Shift Procedure Plan. Of course, you'll find that some procedures, like those for SSOPs, should always be "ex'd". Select HACCP procedures based on the processes performed by the establishment. The key to determining which HACCP block to mark is the final state of the product. For example, if the final product shipped from the establishment were raw and not ground, you'd mark the procedures under Element 03C for raw and not ground products.

After completing the new worksheets, submit them to the District Office.

The next change is in the Inspector Assignment Schedule Summary. It's called the Establishment Schedule Summary in HACCP plants. It'll only be issued to inspectors responsible for conducting in-plant activities at more than one establishment. Aside from changing its name, the Summary hasn't been altered much. The unit designation and the inspector's name were removed. You may discard the form at the end of the week.

Let's move to the Inspector Assignment Schedule. It's called the Procedure Schedule, or the PS, in HACCP plants. Every week the IIC receives a PS for each shift. Scheduled procedures will be randomly selected based on public health significance. They'll vary from day to day. The IIC and floor inspectors should work together to decide who is responsible for each procedure.

The PS has several changes. The columns are gone. The inspector's name was removed. The activity and element are preprinted above the procedure code and descriptor. "P-R-I" stands for "Priority", and it represents the public health significance assigned to the procedure. The higher the number the greater the food safety significance. Procedures with high food safety priority should always take precedence

over others. “Page” refers to a page number in the ISP. “Rate” represents the number of days the procedure should be scheduled over a year. The column on the right is for documenting results.

Here’s how to document your findings. Always circle only one result for each procedure.

Any time you collect a sample, whether it’s scheduled or not, circle “performed”. Recall that sample collection is the only type of procedure that isn’t called verification. It simply directs you to collect and submit a sample to the lab.

When any other procedure is performed there are two possible outcomes. The verification either shows compliance with the regulations or it doesn’t. If there’s compliance, circle “performed” in the “results” column.

If there’s noncompliance circle the most descriptive trend indicator. Circling the word serves two purposes. First of all it indicates that the procedure was performed. Then it categorizes the noncompliance. We’ll get into more detail about how-to-select noncompliance trend indicators in a few minutes.

If, for any reason, you don’t perform a procedure, circle “not performed”. You don’t need to explain why the procedure wasn’t conducted. The PS doesn’t have “not performed” codes.

If the scheduled procedure isn’t performed because it doesn’t apply in the establishment, enter the letter “K” next to “not performed”. This will alert the District to remove it from the procedure plan.

The new PBIS is the same as the old PBIS when it comes to substituting. You always have the authority to substitute unscheduled procedures for scheduled procedures. Rely on your professional judgment, your experience, and your knowledge of establishment conditions.

Unscheduled procedures may be documented on a blank PS, or, if there’s room, on the bottom of the preprinted schedule. Here’s how. If you’re using a blank PS, write in the establishment number, the shift, and the visited date at the top. When the results are in compliance, write the procedure code in the left column and the letter “a” in the right column. When the results show noncompliance, write in the procedure code and the letter for the appropriate trend indicator. The reason for performing an unscheduled procedure isn’t needed any more.

Send the completed PS to the District Office at the end of each week.

Another change in PBIS is that PEA has been eliminated in HACCP plants. You won’t document a lengthy history of “unwillingness or inability to prevent recurring deficiencies” and go through a whole series of steps before withholding operations. When you identify an inadequate system, you’ll immediately withhold inspection. You’ll get more details about inadequate systems and enforcement actions in later modules.

Before we can discuss how to categorize or document inspection findings, there are two new PBIS words you should understand.

The first is noncompliance...the term that replaces deficiency in a HACCP plant. It means failure to comply with a regulatory requirement or with a performance standard. Noncompliance doesn't have degrees of severity. It doesn't come in minor, major, or critical classifications. It stands alone. And noncompliance can lead to an inadequate system.

The second word, "deviation", is an old term with a new definition. In a HACCP plant it has nothing to do with QC programs. Instead, it describes the plant's failure to meet the critical limit assigned to a specific point in a process. A deviation by itself doesn't mean there's noncompliance. Establishment employees must take corrective action any time there's a deviation. If they do, there isn't a problem. However, if they don't, the uncorrected deviation becomes noncompliance. And you just learned that noncompliance can lead to an inadequate system.

Now, let's consider how to categorize types of noncompliance. You'll use the NDG, the Noncompliance Determination Guide. It's the new PBIS tool that replaced the DCG.

Trend indicators are not associated with severity. In other words, one trend indicator doesn't represent a more serious failure to comply with the regulations than another indicator.

SSOP-related noncompliance has four trend indicators: monitoring, corrective action, recordkeeping, and implementation. Choose a trend indicator depending on the type problem you identify. For example, if plant personnel didn't conduct pre-op inspection, you'd select the monitoring trend indicator because the plant didn't monitor its SSOP. Be sure to use the same trend indicator when you document results on the PS.

For HACCP-related noncompliance the four trend indicators are monitoring, corrective action, recordkeeping, and verification.

Here's an example. Suppose the HACCP plan required the plant monitor to take the internal temperature of cooked beef and to record it. When you checked a record for that critical control point in the process you found that the monitor quit entering the temperature. Instead, of recording the actual value he documented his findings with the word "OK" and with check marks. This is noncompliance. You'd select the HACCP monitoring trend indicator.

Economic and wholesomeness noncompliance has 3 Product trend indicators: economic, misbranding, and protocol. For example, if you found that the plant produced a product containing more added solution than allowed by regulation there would be an economic noncompliance. You would mark the economic trend indicator.

The sampling activity has only one trend indicator, called "other", for noncompliance with plant *E. coli* testing requirements. For example, if you found that the plant's *E. coli* test results were recorded in a table as positive or negative instead of in numbers of colony-forming units as required by regulations, you'd mark the "Other" trend indicator.

Under the broad category facilities, there are 4 trend indicators in Activity 06: lighting, structural, outside premises, and product-based. For example, if you measured light intensity at the prechill station and found only 140 footcandles where 200 footcandles are required, you'd select the lighting trend indicator.

You'll have a chance to work with the NDG and practice selecting trend indicators in upcoming workshops.

Once you identify noncompliance you must document it. The Noncompliance Record, or NR, replaced the PDR in HACCP plants. Like the PDR, the NR is a legal record documenting a plant's failure to comply with regulatory requirements. It serves as official notification of noncompliance to plant management. It's extremely important to accurately complete an NR for every noncompliance you identify.

Although the NR is very similar to the PDR, several changes make it more compatible with HACCP. Right now let's concentrate only on those changes. For more details consult your notebook.

Let's start with Block 8 entitled ISP Code. This is where you enter the code for the procedure you performed.

Block 9, entitled Noncompliance Classification Indicators, is for marking a trend indicator. Select the type of noncompliance first. Then use the NDG to select the most appropriate trend indicator. The NDG is found in Directive 5400.5. A condensed version of it is on the back of the NR.

If noncompliance is related to SSOPs, select the most appropriate SSOP trend indicator. If it's in one of the plant's HACCP plans, select the most appropriate HACCP trend indicator. The same goes for categories of noncompliance relating to Product, Facility, and *E. coli*. The trend indicator you mark should be the same trend indicator you document on the PS.

Block 10 is called Description of Noncompliance. The term Noncompliance is new on the form. It replaced the word deficiency, but the description is written the same way. Always describe your findings in clear, concise detail, including the exact problem, the location, and the effect it has on product. If more space is needed for the description use an NR Continuation Sheet.

The NR Continuation Sheet may be used when multiple inspectors conduct pre-op. But it may also be used when you need extra space to write a description. When used for extra space, be sure to check the "Attachment" box at the top of the Continuation Sheet.

Blocks 12 and 13 of the NR are for plant management's response. These blocks have been renamed. "Immediate action" replaced "corrective action" and "further planned action" replaced "preventive measures". However, "Immediate action" is still the action the plant takes to correct noncompliance, and "further planned action" is still what the plant proposes to prevent recurrence.

We've covered several changes to PBIS in a short time. A reference chart comparing the old and the new PBIS is in your notebook. Copies of the new forms and FSIS Directive 5400.5 are also in your handout.