Module 7: Basic Compliance/Noncompliance of Plans

Because of the nature of the HACCP system, you'll naturally spend a lot of time talking to plant management. One of the very first things you'll discuss is the plant's HACCP plan. It's important to understand the plan prior to performing basic compliance/noncompliance procedures. In order to accomplish this, the IIC should hold an awareness meeting between inspection personnel and plant personnel.

Helpful communication techniques and tips that can make your meeting proceed more smoothly will be presented in a future module. Right now, though, let's think about preparing for the meeting.

First, the IIC will decide who will be involved in the meeting. Key management personnel and inspection personnel performing HACCP inspection procedures should participate in this meeting.

Second, the IIC will determine how much time will be needed for the meeting. The amount of time will vary according to the plant size and complexity of the plans. One to four days may be needed for these meetings in large plants. From four hours to one day may be all that is needed in small and very small plants.

In slaughter plants, the IIC will handle this as an assignment of work activity. The time allocated to inspectors may vary according to their area of responsibility. In processing plants without an on-site supervisor, the IIC will talk to the circuit supervisor to determine the amount of time to be spent on this activity.

The IIC might request an opportunity to review the HACCP plan prior to the awareness meeting to help decide how much time you'll need for the meeting. An outline can be made for the items to be discussed. Like the SSOP, however, the HACCP plan is property of the establishment.

When inspectors are involved in the awareness process and are responsible for carrying out the SSOP procedures, SSOP procedures will be accomplished first and then carry out the awareness activity. This includes following through to completion on the taking

of official control actions when they encounter adulterated or mislabeled products. Also, the accomplishment of the awareness process will not impact upon the giving of breaks to on-line inspection personnel.

Since HACCP plans are plant-specific, inspection personnel can't effectively perform HACCP procedures until they understand the plan. This meeting provides an opportunity for inspection personnel to familiarize themselves with the plan. They can also learn some things about the plan in operations, such as, where the HACCP records are kept, how to gain access to the computer, where the CCPs are located, etc.

According to the final rule, FSIS requires each HACCP establishment to have a HACCP plan to ensure food safety for each of its processes. The plant must develop a written HACCP plan. The plan must be validated prior to implementation. To keep the plan up-to-date and assure that it continues to work, the plant must reassess its HACCP plan.

Lets review what it takes to develop a written HACCP plan.

The first requirement is that whoever plant management assigns to develop the plan must have completed a course about the seven principles of HACCP and its application to meat and poultry product processing. The establishment is not required to furnish evidence of this training.

Since a HACCP plan is required that covers every product the establishment produces, the plant needs to consider, step by step, the process each product undergoes. Plan developers must think about hazards at every step in the process (hazards that might be encountered in production of the product). As you have probably guessed, this is the hazard analysis you heard about earlier. Whenever a hazard analysis reveals one or more hazards that are reasonably likely to occur during the process, a HACCP plan is necessary. Sometimes a single processing method might be used to produce more than one product. For example, cooked salami and bologna might undergo the same process. In cases like this, a single HACCP plan may be used for both products. In fact, a single HACCP plan may encompass multiple products within a single processing

category if the food safety hazards, critical control points, critical limits, and procedures are essentially the same. Any features unique to a specific product must also be addressed in the plan.

It's not impossible for a plant to find no food safety hazards during a hazard analysis. In that case, no HACCP plan is required for that product. For example, if an establishment is only reboxing packaged product, no safety hazard may exist. If a change occurs in the process that would result in a food safety hazard reasonably likely occurring in the operation, the plant is then required to have a HACCP plan for the process. In our example, if the establishment starts slicing and packaging the product they had previously been reboxing, they would be required to have a HACCP plan.

There are specific regulatory requirements for developing a HACCP plan. I mentioned that a hazard analysis must be conducted for each process. The plant must prepare a flow chart that describes the steps of each process and the flow of the product. They must state the intended use of the product or intended consumers. The HACCP plan must list the food safety hazards the plant identified which must be controlled. These points where a hazard could occur are called critical control points and must be listed in the HACCP plan. The plant must also set a limit that can be measured or observed at the critical control points. The limit is called critical limit. For example, a critical control point in the bologna process might be where cooking occurs. To make sure the product is properly cooked the company would set a critical limit on the internal temperature of the bologna before it leaves the oven – say the internal temperature must reach 160^{O} F. before the bologna is removed from the smokehouse. The temperature becomes the critical limit, that is, something that can be measured.

Once a critical limit is set for a critical control point, the plan must identify the procedure for monitoring the limit and the frequency at which the monitoring procedure will be conducted. For example, the plant smokehouse foreman might be responsible for measuring the product's internal temperature in four predetermined locations within the smokehouse.

Logically, the plan must also identify corrective actions that'll be taken if the critical limit is not met. It must identify which records the plant will use to document their monitoring activities, verification functions, and corrective actions.

Verification is conducted by plant employees throughout the process and before product leaves the establishment. Verifications double check the original monitoring of critical limits at critical control points. The plan must list the verification procedures that'll be used and the frequency at which they'll be performed. Lastly, the plan must be signed and dated by a responsible establishment official.

When HACCP is implemented, you'll conduct 03A01 as an unscheduled basic compliance procedure to determine if the HACCP plan meets regulatory requirements. You'll actually review each of the plant's HACCP plans. You'll look for the hazard analysis. You'll look for critical control points in the plan. You'll determine whether the plant has records of validation activities used to determine the plan is functioning as intended. Of course, you'll look for the signature of the responsible establishment official and the date. Since there are quite a few HACCP requirements to remember, a HACCP Systems Basic Compliance Checklist was developed. This checklist is an official form (FSIS Form 5000-1) and should be used when performing a basic compliance/noncompliance procedure. This form is an attachment to FSIS Directive 5000.1. Copies of the form are in your notebook. You'll practice using the form in the workshop session. It'll be available in the field when you conduct a basic compliance procedure.

The HACCP/Pathogen Reduction Regulation will be implemented on January 26, 1998, in large plants, January 25, 1999, in smaller establishments, and January 25, 2000, in very small establishments. You'll perform and document on a blank process schedule the HACCP basic compliance procedure, 03A01, as an unscheduled procedure at the time of initial implementation and each time the HACCP plan is modified. This procedure must also be performed annually—again as an unscheduled procedure—shortly after the anniversary date of implementation, even if the plan was revised during the year.

When you perform the basic compliance procedure, you won't in any way be approving the HACCP plan. Instead, you'll use the HACCP Checklist to determine if the regulatory requirements are met. Some plants will have several HACCP plans. If that's the case, you'll perform procedure 03A01 and complete the checklist for each plan. If the establishment hasn't met regulatory requirements for one HACCP plan, but has for the others, withholding action will be taken only against production from the one noncompliant HACCP plan. For example, if the establishment has a HACCP plan for fresh pork sausage and one for frankfurters, and the frankfurter HACCP plan meets the regulatory requirements but the plan for fresh pork sausage doesn't, you'll withhold inspection only for the fresh pork sausage production.

An IIC who determines that an establishment has not met one or more of the basic HACCP regulatory requirements should take the following steps.

Withhold inspection and notify the establishment right away. Document the findings on an NR. As soon as possible, and at least by the end of the tour of duty, give management a copy of the NR.

If noncompliance with the requirements involves **only** a failure that the responsible establishment official can correct immediately, the IIC should give management an opportunity to bring the establishment into compliance without withholding inspection. For example, if the HACCP plan is not signed or dated and the establishment immediately signs and dates the plan, inspection shouldn't be withheld. But you'll still document the noncompliance on an NR. Include a statement that the situation was corrected immediately.

If the establishment doesn't initiate action immediately to bring itself into compliance, the IIC should notify the District Office about the actions taken. The District Office will direct the next enforcement action. The District Manager will assign a Compliance Officer who'll work with the IIC to develop a case file. The District Manager will give you further instructions to take, as appropriate. Based on the specific findings, the District Manager may place the withholding action in abeyance. When this is done, the plant is required to provide written assurances that it will bring itself into compliance. This does not mean

the enforcement action has ended. If the plant fails to follow it's written assurances and bring itself into compliance the withholding will be reinitiated.

Let's shift gears now and discuss SSOPs in HACCP plants. What we called evaluation of the SSOP on January 27, 1997, is now a procedure called SSOP basic compliance in HACCP plants. The procedure number for SSOP basic compliance is 01A01. Only the name has changed. Your responsibility is still to determine that the SSOP meets the five basic regulatory requirements. And you'll still conduct an unscheduled SSOP basic procedure whenever modifications are made to the plan. You don't need to perform an SSOP basic procedure just because HACCP is being implemented.

An SSOP Checklist, similar to the HACCP Checklist I talked about earlier, except for SSOPs this time, has been developed. The Sanitation SOPs Basic Compliance Checklist (FSIS Form 5000–2) is also in FSIS Directive 5000.1. It lists the regulatory requirements and gives you a place to record your findings.

You'll use the same steps to document SSOP basic noncompliance as for HACCP basic noncompliance. That is, you'll verbally notify management. Then you'll document the noncompliance on an NR. Provide management a copy of the NR as soon as possible. Enforcement actions will be the same. The IIC will withhold inspection unless the establishment can take immediate corrective action. For example, if the SSOP is modified and the modification hasn't been signed and dated, return the modification to the establishment for signing and dating without withholding inspection. Be sure to document the noncompliance on an NR along with the statement that the finding was immediately corrected.

If the basic noncompliance can't be corrected immediately by the plant, involve the District Office. Follow the same steps I mentioned earlier. This information is in FSIS Directive 5000.1, which is included in your notebook.