Module 9c: Other Compliance/Noncompliance—SSOPs

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 SSOP procedures.

2. Be able to apply the SSOP inspection procedures.

3. Be able to document findings and take enforcement actions when SSOP inspection procedures are not met.

Introduction

By now, inspection personnel have had the opportunity to perform in-plant SSOP verification, documentation and enforcement activities. These inspection activities for SSOP were the introduction of implementation of the final rule for Pathogen Reduction/HACCP. This was the beginning of the culture change process for both inspection personnel and industry personnel. With the implementation of HACCP in large establishments, some things will change with our oversight of SSOPs, namely the directive and the terminology used to describe inspection performance. In non-HACCP establishments inspection personnel will continue to use the old directive, 11,100.3 and the old PBIS terms and procedures.

The information inspectors will need to perform in-plant SSOP verification, documentation, and enforcement activities is now contained in FSIS Directive 5000.1. The slaughter process verification methodology, completing the NR when more than one inspector performs the procedures in a large establishment, and supplementary instructions regarding enforcement actions are contained as Appendix A-C to Directive 5000.1. The terminology use has changed and is the same terminology you learned in the PBIS for HACCP module. The terminology is contained in FSIS Directive 5400.5.

It is important to remember that the way in which inspection personnel will perform their inspection and take enforcement actions are the same! Only the directive and the terminology have changed. They will perform inspection procedures to verify the adequacy and effectiveness of an establishment's Sanitation SOPs. They will still perform either a recordkeeping or review and observation procedure to determine if the establishment is complying with the requirements for:

- Implementation of SSOPs including monitoring of implementation (416.13),
- Maintenance of SSOPs (routine evaluation of effectiveness (416.4).)
- Taking corrective action(s) (416.15).

Since SSOPs lay the foundation for implementation of HACCP, the key concepts associated with inspectors' verification, documentation and enforcement activities are addressed in this part of the handout. The new concepts and methodology, that follow the flow of FSIS Directive 5000.1, are introduced as these activities are discussed.

An SSOP comparison chart, Attachment 2 of this handout, helps introduce the new terminology. This chart contains the terms used in both HACCP and non-HACCP plants to help inspection personnel quickly identify the differences.

Like the HACCP systems portion of the handout, this portion will also follow the regulatory process model, Attachment 1. The flow is identical to that introduced with HACCP. Blocks 7, 8, and 9 are again extensively discussed. FSIS Directive 5000.1 language including the regulatory cites are provided and the inspector's responsibilities are described at each of these steps in the regulatory process model. Examples are provided where appropriate.

SSOP Inspection Procedures

Inspection personnel will perform inspection procedures as indicated in block 7 of the regulatory process model/flow diagram.

There are two procedures, recordkeeping and review and observation, for both pre-operational and operational sanitation. The new ISP procedures are 01B01, 01B02, 01C01 and 01C02.

As before, the recordkeeping procedure is for reviewing the daily documentation of the establishment's implementation of their Sanitation SOP procedures and required corrective actions. The review and observation procedure, that was previously referred to as "hands-on" , is the procedure for direct observation of the establishment's implementation of the Sanitation SOP procedures and required corrective actions, assessment of sanitary conditions, and a review of related records.

For SSOP's, the procedures focus on four features or requirements:

- Sanitation SOP implementation (416.13);
- Maintenance or Sanitation SOP effectiveness (monitoring) (416.14);
- Corrective Actions (416.15); and
- Records (416.16)

Let's walk through each requirement and then discuss the inspector's responsibilities for the recordkeeping and review and observation procedures to verify these four requirements.

Sanitation SOP Implementation

Part Three of FSIS Directive 5000.1, III. B.1. (a-c) defines the regulatory requirements for the establishment to conduct pre-operational procedures before it begins its operations (416.13 (a)), to conduct during-operations procedures at the frequencies in its Sanitation SOPs (416.13(b)), and to monitor daily the implementation of procedures in its Sanitation SOPs (416.13(c)).

Maintenance or effectiveness of the SSOPs (Monitoring)

As defined by the regulation, Part Three of FSIS Directive 5000.1, III. B.3. (a-b) describes that it is the responsibility of the establishment to routinely evaluate the effectiveness of the procedures in its Sanitation SOPs in preventing direct contamination or product adulteration. The establishment is also required to revise the procedures in its Sanitation SOPs when necessary to keep them effective and current with respect to changes in its facilities, equipment, utensils, operations, or personnel. (§ 416.14.)

Corrective Actions

Part Three of FSIS Directive 5000.1, III. B.2. provides guidance on the establishment's responsibilities for corrective actions. **ALL** of the **regulatory components for corrective action must be taken and documented** by the establishment whenever the establishment or FSIS determine that the establishment's Sanitation SOPs--or the procedures specified therein or their implementation or maintenance--may have failed to prevent direct product contamination or adulteration. The corrective actions include:

- ensure the appropriate disposition of products that may be contaminated,
- restore sanitary conditions, and
- prevent recurrence of direct product contamination or adulteration, including appropriate reevaluation and modification of Sanitation SOP procedure(s) or appropriate improvements in the execution of Sanitation SOP procedure(s). (§ 416.15).

Recordkeeping

Part Three of FSIS Directive 5000.1, III. B.4. (a-d) describes the recordkeeping requirements that the establishment must meet for SSOPs. The establishment's daily records must document implementation of its Sanitation SOPs, monitoring of its Sanitation SOPs, and corrective actions taken (if any). (§ 416.16(a)).

For purposes of authenticity, the establishment's records must be initialed and dated by the establishment employee identified in the Sanitation SOPs as responsible for implementing and monitoring specified procedure(s) (§ 416.16(a)).

For purposes of data integrity, the establishment is required to have implemented controls to ensure data integrity for part 416-required records maintained on computers (if any). (§ 416.16(b)).

The establishment is required to retain records required by part 416 for at least 6 months. Records required by part 416 must be maintained on-site for at least 48 hours, and must be available within 24 hours of an FSIS employee's request if stored off-site after 48 hours. (§ 416.16(c).)

Performance of Inspection Procedures

Now that the establishment's requirements have been reviewed, let's discuss how inspection personnel are expected to perform their inspection procedures to determine if the establishment is meeting the requirements.

As they did prior to the implementation of HACCP, inspection personnel will perform daily procedures for pre-operational and operational sanitation inspection, by either review and observation or recordkeeping. For SSOPs, they will look at all four requirements when they perform these procedures.

The inspector's review and observation procedure performance should include three parts:

- direct observation of the establishment's implementation and monitoring of the Sanitation SOP procedures and required corrective actions;
- assessment of sanitary conditions through organoleptic examination of a sample of facilities, utensils and equipment; and
- a comparison of inspection findings with plant records.

When inspection personnel perform this procedure, they will be verifying all four requirements, that is, implementation, effectiveness, corrective actions, and recordkeeping.

The methodology that they use to perform this procedure has not changed. For pre-operational sanitation in slaughter operations they should use Appendix A to FSIS Directive 5000.1. It is identical to what was instructed in FSIS Directive 11,100.3. For other operations, they would continue to check one or more areas or departments.

Even though we need to provide the establishment the opportunity to execute their SSOP, it is possible that inspection personnel might be performing their review and observation procedure at the same time the establishment is monitoring their pre-operational procedures. This provides an excellent opportunity to perform the observation part of this procedure. For example, the Establishment 38 has specified in their Sanitation SOP procedures that they will perform monitoring of their pre-operational sanitation form 6:00 am until 6:30 am using a randomized sampling methodology. FSIS performs the review and observation procedure from 6:00 am until 6:30 am (plus whatever time is necessary for lockout/tagout). In this scenario, if an inspector finds noncompliance in Department A at 6:35 am and the establishment personnel are still monitoring Department A, the inspector should allow the plant the opportunity to conduct the procedures in their SSOP. The inspector could either compare his/her findings to this point with plant records, if available, or observe the establishment conducting their monitoring procedures. Regulatory actions, if any, would be based on information the inspector obtained from performing **all three** components of the review and observation procedure.

The inspector's recordkeeping procedure also encompasses all four requirements. Inspection procedure performance must include:

- verification that SSOP procedures are being followed by plant personnel before and during operations;
- monitoring activities are conducted at the specified frequency;
- all 3 requirements of corrective actions according to 416.15 are implemented and documented as required; and
- establishment employees/positions specified in the SSOPs are assuming the implementation and monitoring of the SSOP procedures by authenticating the records with their initials and date.

An additional aspect to the recordkeeping procedure is to verify that the establishment has implemented controls to ensure data integrity for computer records, e.g., individual digital signatures, identification passwords, etc. Also, the records should be accessible, completed and made available within realistic timeframes. The establishment should make records available to the inspector upon request, and must meet the time retention requirements. Remember, if the inspector requests a record one day, and it is not complete, it should be available for the inspector to review the following day.

During the recordkeeping procedure the inspector should also determine if there is any evidence of misrepresentation or falsification of SSOP records. As always, anytime the inspector suspects a plant has engaged in illegal activity (e.g., falsified records) he or she should take actions necessary to protect the public health immediately and report suspected violations to the appropriate District Enforcement Operations official.

Determining Noncompliance

According to block 8 of the regulatory process model, inspection personnel have to decide whether their findings during the performance of the procedure represent noncompliance with the performance standard and/or regulatory requirement.

As before, inspection personnel should continue to utilize what is known for a fact and what is reasonable to assume before determining noncompliance exists. The establishment should be given the opportunity to implement their SSOP procedures before the inspector determines noncompliance. For example, let's say the inspector is performing the review and observation procedure for operational sanitation and he or she sees meat dropped on the floor. The establishment's SSOP procedures indicate that the floor supervisor will monitor at a specified frequency and verify that all meat on the floor will be properly disposed of, either through reprocessing or condemnation. The last monitoring check documented on the plant record by the floor supervisor was within their specified frequency. The amount of product on the floor is not excessive and it is reasonable to assume that the floor supervisor is in fact performing their monitoring as described in the establishment's SSOP's. The establishment should be given the opportunity to let their Sanitation SOP procedures work. Part of the inspector's performance of this inspection procedure might in fact be returning to the area to either observe the monitoring and/or the records documented by the floor supervisor. As long as the supervisor returns and performs their monitoring and takes the actions described in the SOP procedures, there is no noncompliance.

What is noncompliance then? Noncompliance is failure to meet any regulatory requirement. For Sanitation SOP procedures, noncompliance exists when either the establishment is not implementing their Sanitation SOPs or when their Sanitation SOPs fail to prevent direct contamination or adulteration of product. Therefore in our example, if the floor supervisor does not monitor at the frequency described in the SSOPs; if the floor supervisor fails to take the actions described in the SSOPs to properly dispose of the meat there is noncompliance.

Inspection personnel need to keep in mind that when they make a determination that noncompliance exists, they will need to determine the most appropriate noncompliance trend indicator to mark when they document noncompliance.

SSOP Trend Indicators

One of four trend indicators must be circled on the PS and marked on the NR, when inspection personnel determine that an establishment's is not following its written SSOPs. The four trend indicators correspond to the regulatory requirements in Part 416. They are also outlined in FSIS Directive 5000.1. They are:

Monitoring (Maintenance)

This indicator addresses the establishment's actions, observations and records for maintenance of the SSOP. It should be marked in cases of noncompliance when the establishment fails to routinely evaluate the effectiveness of the SSOP in preventing direct product contamination or adulteration. For example, the plant fails to evaluate and update, as necessary, its Sanitation SOPs based on a change in operations. In cases where the establishment is not monitoring at all, the noncompliance would be recorded under the basic procedure 01A01.

Corrective Action

This indicator addresses the establishment's corrective actions and records when the SSOP fails to prevent contamination. It should be marked in cases of noncompliance where the plant does not take all of the corrective actions required by section 416.15 of the regulations. For example, the plant fails to clean and sanitize contaminated equipment they found during pre-op inspection prior to using it. It may also be marked when corrective actions taken are not appropriate to restore sanitary conditions, or do not include measures to prevent the recurrence of direct contamination or adulteration of products.

Recordkeeping

This indicator should be marked in cases of noncompliance when the records required by SSOP aren't maintained. For example, SSOP records are not initialed and dated, the records are not maintained daily, they're not kept for the required period of time, or the plant fails to record the results of a monitoring check. If there were an instance of noncompliance where the plant is not maintaining <u>any</u> records at all, the results of the procedure would be documented under procedure code 01A01 as basic noncompliance.

Implementation

Many establishment activities are involved in implementation. It should be marked in cases of noncompliance where the plant fails to perform pre-op inspection after equipment is cleaned and sanitized prior to the start of operations, fails to perform operation sanitation inspection, or is not monitoring sanitation activities at the frequency stated in the SSOP.

A second occasion for which "implementation" is the appropriate trend indicator involves failures in more than one of the indicators. This is an indication that the establishment is not implementing its SSOPs. In other words, use this indicator when more than one indicator applies. For example, if two inspectors performed an SSOP verification and one found noncompliance that would fit the recordkeeping trend and the other inspector found noncompliance that would fit under the corrective action trend, the overall trend indicator for the procedure would be implementation. By selecting implementation, inspectors document the fact that more than one trend indicator applies to the noncompliance finding.

The next decision to be made in the regulatory process model is whether the noncompliance represents a system failure. This is block 9 of the model.

Just like in the HACCP systems portion of the training, when inspection personnel find noncompliance, they will need to determine if the system has failed. Inspection personnel will use the same thought process to assess the situation.

The first question they should answer is --- **Was adulterated product produced?**

Remember if the implementation or maintenance of the Sanitation SOPs failed to prevent direct contamination or adulteration of product(s) there is either a design failure or execution failure of the Sanitation SOPs. While this does constitute an SSOP failure, this is not enough information to determine there is a system's failure. For Sanitation SOPs, inspectors need to ask the next question.

The second question then is-- **Is there noncompliance with the same root cause?**

For instance, is there the same and/or related noncompliance occurring due to the negligence, ineffective method, or incomplete execution by the plant? (FSIS Directive 5000.1 III. C.1.). If yes, it is possible that a system failure exists. There is still no magic number to determine when a systems failure exists due to the same and/or related noncompliance. The NRs should document ongoing failures of the plant's maintenance or implementation of the SSOP and/or execution of effective immediate and further planned actions to bring themselves back into regulatory compliance. Professional analysis must be used when making this determination. Inspection personnel will want to be certain that their documentation made the linkage to the previous noncompliance. They might look at previous NRs (and PDRs) noncompliance trend indicators to help make this linkage. If they are able to make this determination and the documentation supports it, then a systems failure exists.

Lastly, inspection personnel should ask if the establishment has met the Basic regulatory requirements? That is, if the establishment is not implementing some or all of their SSOPs, then they have not met the Basic regulatory requirements. For example, if an establishment doesn't maintain any records or if it doesn't monitor the SSOP at all, then the establishment has not met regulatory requirements. FSIS considers this an inadequate system because the establishment has not met the Basic regulatory requirements and therefore inspection personnel aren't able to determine that the establishment is not producing adulterated product. This would be documented under the Basic procedure 01A01.

Enforcement Action

If the inspector determines that there is a system failure, he or she should follow the enforcement action in Part Three of FSIS Directive 5000.1 III. C.1. This action is:

- Withhold inspection and notify the establishment. Provide plant management a copy of the NR. Notify the DO of actions taken. The DO 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. (The action is identical to that which is taken if the establishment fails to meet the basic regulatory requirements.)

It is important to reiterate that the inspection personnel are to contact the District office in cases of a withholding action due to a system failure.

If the inspector is not able to determine that there is a system failure then, the enforcement action is according to Part Three of FSIS Directive 5000.1 III.C. 2.:

- Take official control action as appropriate, (in cases where the SSOPs failed to prevent direct product contamination or adulteration it is always appropriate to take official control action! In these cases, the official control action should remain in place until the establishment has taken the corrective actions required in 416.15. In other cases of noncompliance, the inspector should make a determination of the necessity of the official control action)

- Advise establishment management by providing a copy of the NR that documents the noncompliance finding(s),

- Complete documentation of establishment action(s) to bring itself into compliance (see FSIS Directive 5400.5), and

- Notify the DO if the establishment does not bring itself into compliance.

It is important to re-emphasize that if the inspector makes a determination that the SSOPs failed to prevent direct product contamination or adulteration then there is either a design failure or execution failure of the SSOPs. In all cases this is noncompliance, official control action should be taken, and the noncompliance should be documented on an NR with the most appropriate noncompliance trend indicator marked. The official control action should not be removed until the

establishment has met all the requirements for corrective action described in 416.15. With SSOP failures, inspection personnel should always be alert to the same and/or related noncompliance that have resulted in direct product contamination or adulteration. It is documentation of this recurring pattern of noncompliance that leads to the determination of a system failure!

There is one more concept that needs to be addressed. While performing the SOP procedures the inspector may also determine that there is noncompliance with another regulatory requirement. That is, the establishment is implementing and maintaining their SSOP procedures, and he or she determines there is noncompliance that does NOT result in direct contamination or adulteration of product(s). This noncompliance should also be documented and the appropriate noncompliance trend indicator marked. For example, while performing the review and observation pre-operational procedure you observe a 4 inch glob of fat from the previous days operation on the leg of the final inspection stand on the beef slaughter floor. This is not direct product contamination, and therefore is not a failure of the SSOPs. However, this is noncompliance with 308.8 and should be documented on an NR. The “product based” noncompliance trend indicator under facilities would be marked. Although the inspector was performing the SSOP procedure, he or she would document this noncompliance as unscheduled using procedure code 06D01. If the inspector found no other noncompliance during the performance of the SSOP procedure, he or she will document it as performed on the procedure schedule.

However, if SSOP noncompliance is also determined, all noncompliance should be documented on one NR with the most applicable SSOP trend indicator marked.

The regulatory process for SSOPs is essentially the same. Some new terminology and methodology, however, were introduced due to the implementation of the Pathogen Reduction/HACCP system regulations. Inspection personnel should refer to FSIS Directive 5000.1 when they begin to perform the SSOP inspection procedures. As always, if inspection personnel have questions concerning SSOPs, their supervisor should be able to provide assistance.

1. What are the major changes concerning inspection of SSOPs?

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2. The ongoing operation of an establishment's SSOP procedures must meet what 4 regulatory requirements?

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3. What are the two inspection procedures for determining noncompliance with the other SSOP requirements?

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4. What are three parts of the review and observation procedure?

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5. Performance of the recordkeeping procedure includes:

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6. What are the regulatory (416.15) requirements for the corrective action that an establishment must take when either the establishment or FSIS determines that the establishment's SSOP's failed to prevent direct contamination or adulteration of product(s)?

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7. If SSOP noncompliance is determined – what questions need to be answered to determine if there is an inadequate system?

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

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