SANITATION STANDARD OPERATING PROCEDURES

Objectives

To demonstrate mastery of SSOP, the trainee will:

1. Understand the meaning and significance of the following terms:
   a. SSOP
   b. Responsible person
   c. Regulatory control action
   d. Pre-operational sanitation procedures
   e. Operational sanitation procedures
   f. Inspection unit
   g. SSOP Implementation
   h. SSOP Maintenance
   i. SSOP Corrective Actions
   j. SSOP Recordkeeping

2. Select from a list the 5 requirements for SSOPs.

3. Choose from a list of PBIS procedures, those used for pre-operational sanitation and those used for operational sanitation inspection.

4. Explain the steps taken by FSIS to verify implementation of the SSOPs by the establishment; explain the steps taken by FSIS to verify the monitoring, recordkeeping, and corrective action components of the establishment's SSOP program.

5. Choose from a list of pre-operational and operational sanitation noncompliances, those that are SPS and those that are SSOP and identify by the correct ISP code.

6. List the three parts of corrective action the establishment must take and record for noncompliances found on establishment sanitation inspection.

7. List the record retention, authentication, data integrity and daily documentation requirements for SSOP records.

8. List two possible enforcement actions that could be taken when FSIS finds a noncompliance with pre-operational or operational sanitation.

9. Evaluate a list of example plant corrective and preventive measures to determine those that follow the regulatory requirements of §416.15.

10. Evaluate an example SSOP for regulatory compliance.

11. Explain the purpose of a Verification Plan.

12. Given situational materials, determine possible linkage of sanitation NRs.

SANITATION STANDARD OPERATING PROCEDURES
Reference: 9 CFR 416.11 through 416.17
FSIS Directive 5000.1, Chapter 1, CSI, Part XII

§416.11 General Rules

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOPs) in accordance with the requirements of this part.

Sanitation Standard Operating Procedures (SSOPs) are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product. The establishment must also maintain daily records sufficient to document the implementation and monitoring of the SSOPs and any corrective action taken. The establishment is required to maintain these written procedures on file, and they must be available to FSIS upon request. It is the establishment's responsibility to implement the procedures as they are written in the SSOPs. If the establishment or FSIS determines that the SSOPs fail to prevent direct contamination or adulteration of product, the establishment must implement corrective actions that include the appropriate disposition of product, restoration of sanitary conditions, and measures to prevent recurrence. It is also required that SSOPs should describe the procedures that the establishment will take to prevent direct contamination or adulteration of product.

§416.12 Development of SSOPs

(a) *The Sanitation SOPs shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).*
(b) *The Sanitation SOPs shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOPs as specified and will maintain the Sanitation SOPs in accordance with the requirements of this part. The Sanitation SOPs shall be signed and dated upon initially implementing the Sanitation SOPs and upon any modification to the Sanitation SOPs.*
(c) *Procedures in the Sanitation SOPs that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.*
(d) *The Sanitation SOPs shall specify the frequency with which each procedure in the Sanitation SOPs is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).*

Establishment Responsibilities

The establishment has the responsibility to develop written SSOPs that contain procedures that the establishment will implement to prevent direct contamination or adulteration of product. The establishment and inspection personnel should understand that there are not separate SSOPs for different operations or different shifts. The SSOPs cover the entire establishment and all shifts of operation.

These written procedures must:

- Contain all the procedures the establishment will conduct daily, before and during operation.

- Identify the procedures to be conducted prior to operations (pre-op) and address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

- Specify the frequency with which each procedure in the SSOPs is to be conducted and identify the establishment employee or position responsible for the implementation and maintenance of the procedures.

- Be signed and dated by the individual with overall authority on-site or a higher-level official of the establishment. This signature signifies that the establishment will implement the SSOPs as written and will maintain the SSOPs in accordance with the requirements of this part.

Inspection Verification

The basic regulatory requirements are described in §416.12. To determine if these requirements are met, the program employee will perform the 01A01 procedure and complete the FSIS Form 5000-2. This is a very simple form giving some basic questions to consider in the evaluation of the establishment's SSOP program. The first blocks on the form ask for the establishment's name and number, and the date the SSOPs were implemented. If all the required components are present, there should be no checkmarks (i.e. no "yes" responses to any questions) on the form when you have completed it.

The basic procedure (01A01) was performed on all existing SSOPs in 1997 or whenever an establishment began operations following 1997. There is no need to perform this procedure again just for the sake of performing it. The basic procedure is performed when a new plant is requesting a Grant of Federal Inspection to begin operations or when major changes to a plant's existing written SSOPs have been made. If you must perform the basic procedure, it should be recorded as an unscheduled procedure. A blank copy of the form is included in your materials.

For you to effectively verify the establishment's SSOPs, you need to understand the SSOP regulations (§416.11 - §416.17) and be familiar with the current SSOPs. FSIS Directive 5000.1 discusses the different roles and responsibilities of FSIS personnel.

At the time inspection is granted, the establishment must have an SSOP that meets the basic requirements. You perform the 01A01 procedure to verify that the written procedures meet the basic regulatory requirements. If you determine that the SSOP does not meet the regulatory requirements specified in §416.12, contact the IIC or the District Office. The District Office will provide direction as to whether you should issue a 30-day reassessment letter, or whether the District Office will institute an enforcement action specified in 9 CFR 500.

WORKSHOP I - Identifying the Elements of the Basic Compliance Requirements of SSOP Programs.

Carefully read the Sample SSOP. Evaluate the SSOP using the FSIS Form 5000-2 for compliance with regulatory requirements. After you have evaluated the SSOP, list any failures to comply.

BEEF SLAUGHTER ESTABLISHMENT 38M—SSOP

Owner – Joe Green

This SSOP is for Beef Slaughter Establishment 38M and becomes effective on January 28, 1998.

Pre-operational

All food contact surfaces of the facility, equipment, and utensils on the kill floor will be cleaned daily after production by rinsing, soaping, and sanitizing.
All cleaning will be monitored daily by Joe Green before production begins the next day.
Records will be kept on Form Pre-Op I by Joe Green.

Operational

Every day all equipment and surfaces on the kill floor will be kept as sanitary as necessary to prevent contamination or adulteration of the carcasses.
Every day all employees will follow hygienic practices to keep themselves from contaminating or adulterating carcasses.
These actions will be monitored by Joe Green once each day.
Records of this monitoring will be kept on Form Ops I by Joe Green.

Corrective actions taken during pre-operational sanitation inspection or during operations will be written on the back of the Form Pre-Op I or Form Ops I as necessary.

(Signature and date of 1/25/98)
Joe Green

Modification Log

1. *(signature and date of Joe Green, 12/11/98)*
2. *(signature and date of Joe Green, 6/17/99)*

Are there any failures to comply?

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

SANITATION SOP'S -- BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME	ESTABLISHMENT NO.	IMPLEMENTATION DATE

Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1, Part Three, Paragraph II.B.

	REQUIREMENT	YES (✓)
1. SANITATION SOP'S	The establishment does not have written Sanitation SOP's that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product(s) (§416.12(a)).	
	The Sanitation SOP's do not identify which of the procedures are pre-operational procedures (§416.12(c)).	
	The pre-operational procedures do not address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils (§416.12 (c)).	
	The Sanitation SOP's do not specify the frequency with which the establishment will conduct each procedure (§416.12 (d)).	
	The Sanitation SOP's do not identify the establishment employee or employees responsible for implementing and maintaining specified procedures (§416.12 (d)).	
2. RECORDKEEPING	The establishment does not have identified records that, on a daily basis, document implementation and monitoring of the Sanitation SOP's and any corrective actions taken (§416.16(a)).	
3. DATED SIGNATURE	The individual with overall authority on-site or a higher level official of the establishment did not sign and date the Sanitation SOP's (1) upon initial implementation, or	
	(2) upon a modification (§416.12 (d)).	

FSIS FORM 5000-2 (9/97)

Verification Procedures
Reference: FSIS Directive 5000.1, Chapter 1, Part XIII

There are two SSOP procedures for pre-operational sanitation verification (01B01 and 01B02) and two SSOP procedures for operational sanitation verification (01C01 and 01C02). You perform these procedures to verify that the establishment is meeting the SSOP regulatory requirements. Regardless of whether you are performing the recordkeeping procedures or the review and observation procedures, you are verifying that the same regulatory requirements are met. Those requirements are:

a. Implementation of SSOP (monitoring) (§416.13);

b. Maintenance of SSOP (effectiveness) (§416.14);

c. SSOP corrective actions (§416.15); and

d. SSOP recordkeeping (§416.16).

01B01 Procedure
Reference: FSIS Directive 5000.1, Chapter 1, CSI, Part XIII(B)

The 01B01 SSOP procedure is the pre-operational recordkeeping procedure. This recordkeeping procedure instructs you to review the daily documentation of the establishment's implementation and monitoring of the SSOP pre-operational procedures and any required corrective actions.

You should review the SSOP to become familiar with the pre-operational sanitation procedures. When you perform the 01B01 procedure, you are reviewing the daily pre-operational sanitation records. This procedure should be performed to verify that the establishment has daily records that demonstrate the establishment has implemented the pre-operational procedures, monitored those procedures, and taken corrective actions when necessary. You should also verify that the establishment employee responsible for the implementation and monitoring has authenticated the daily records with his or her initials and the date.

You should review the SSOP prior to beginning the review of the records to ensure that it has not been modified since you last reviewed it and that you are familiar with the pre-operational sanitation procedures. When performing the recordkeeping procedure for pre-operational sanitation, you should be reviewing the records to determine if the establishment is complying with the regulatory requirements.

You should be looking at the records to verify that the monitoring is conducted daily prior to the start of operations. You should review the records to verify that each time the establishment documents that direct contact surfaces are found to be unclean or contaminated product is observed, there are corrective actions documented that meet the requirements of §416.15. You should ensure that the corrective actions implemented and documented are adequate to: 1) ensure appropriate disposition of product, if necessary; 2) restore sanitary conditions; and 3) prevent recurrence. While reviewing the pre-operational sanitation records, you should also verify that the establishment employee responsible for the implementation or monitoring has authenticated the records with initials and date.

If the establishment has not recorded its monitoring activities, has not recorded corrective actions when direct contact surfaces or direct product contamination is observed, or has not initialed and dated the daily record for authentication, there is noncompliance.

01B02 Procedure
Reference: FSIS Directive 5000.1, Chapter 1, CSI, Part XIII(D)

The 01B02 SSOP procedure is a review and observation procedure for verifying pre-operational sanitation. When performing the review and observation procedure, you should verify all four requirements: implementation (monitoring), maintenance, corrective actions, and recordkeeping.

You must understand the procedures in the SSOP that the establishment is implementing to prevent direct contamination or adulteration of product to effectively verify that the establishment is meeting the regulatory requirements. Therefore you should review the SSOP to ensure that you are familiar with the current written pre-operational sanitation procedures and become familiar with any monitoring procedures and frequencies that may be included in the SSOP.

If you perform the 01B02 procedure and have reviewed the SSOP, you should verify the pre-operational sanitation requirements by: 1) observing the establishment conducting its monitoring, 2) performing an organoleptic examination of some of the establishment's facilities, equipment, and utensils to assess sanitary conditions (hands-on), and 3) comparing your findings with the plant records.

Before going into the establishment to assess the sanitation in one or more areas by performing the 01B02 procedure you should:

Select the area or areas of the plant where you will perform the inspection.

- In processing departments, select a piece or pieces of equipment in one or more rooms or departments of the establishment. If you select a part of the establishment where ready-to-eat product is prepared as one of the departments where you will perform this procedure, you should start in that part of the plant first to prevent spreading microorganisms from the raw product departments of the plant.

- *In slaughter operations, you select inspection units. Selecting inspection units in slaughter operations will not be discussed in this training.*

- Have a good flashlight.

- Have a pen or pencil.

- Have U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.

- Have a notepad to record your pre-operational findings.

If you have not been properly trained in lockout/tagout, you must not perform pre-operational sanitation procedure 01B02 on any machine or piece of equipment that must be locked out.

When you go to an area of the establishment to perform the 01B02 procedure, you should inspect direct contact surfaces of equipment, facilities, and utensils after the establishment has completed its monitoring. It is possible that you and the establishment might be in the same area at the same time. This provides you an excellent opportunity to observe the establishment conducting its monitoring.

When you are observing the establishment conducting its monitoring procedures, you should verify that the monitor is inspecting to find problems and not just going through the motions. You should be verifying that the monitoring activity is being conducted as is written in the SSOP.

In some cases, the establishment might conduct monitoring of the implementation of the SSOP procedures before inspection personnel arrive at the establishment. In these situations, you should ask your supervisor how frequently you should directly observe the establishment conduct the monitoring. The supervisor will consider several factors when making this decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from SSOP records.

When you have determined the equipment, facilities, and utensils that you will inspect, you should examine direct contact surfaces to determine that they are organoleptically clean. This means that the direct contact surfaces look clean, feel clean, and smell clean. You should visually examine the contact surfaces for product residues that might be left from previous days' operations. You should feel the contact surfaces to determine if there are residues present from previous days' operations that are not visible. You should be aware of any odors in these areas that may represent insanitary conditions.

Direct contact surfaces must be clean prior to operations to ensure the food that is produced is safe, wholesome, and unadulterated. If direct contact surfaces are contaminated with residues from previous days' operations, it is likely that these conditions will harbor microorganisms as well. Clean means that the contact surfaces are free of foreign material such as fat, blood, hair, rust, grease, and cleaning chemicals.

When you are assessing the sanitary condition of equipment and utensils prior to operation, you should look at those areas that are the most difficult to clean. These are the areas that are most likely to be missed when the establishment implements the procedures in its SSOP. These difficult areas are the areas that are also likely to be overlooked by the establishment's monitoring procedures.

Other areas that are not direct contact surfaces can also be a source of product contamination and should be inspected. For example, condensation, peeling paint, and scaling rust from overheads where products are processed, handled, or stored can contaminate products. In other words, you should inspect the environment in those areas you have selected to verify the products can be produced safely.

When you have completed your assessment of the sanitation in one or more areas of the plant, you should compare your findings to the establishment's sanitation findings. If the written records are not completed at the time you have completed this procedure, you may ask the establishment about its pre-operational findings and any actions taken.

If, after the establishment has completed its monitoring, you find any direct product contact surfaces or product that is contaminated, you should take a regulatory control action on that equipment or product. The establishment has the responsibility to take corrective actions that meet the requirements in §416.15. You should not remove the regulatory control actions until the establishment has proposed corrective actions, either verbally or in writing, that meet these requirements.

You should be aware that there are times the responsible plant employee might not be able to propose permanent preventive measures immediately. However, in these situations, the establishment should propose what they will do to determine a remedy.

Example:

For example, you identify a condensation problem in an area of the establishment that is contaminating product. You retain the product in the area and reject that area for use. When you notify the responsible establishment employee of the problem, he tells you that there is a structural problem in that area that will cost several thousand dollars to repair. He further explains that he does not have the authority to have the structure repaired. He states he will bring it to the attention of the plant owner and will inform you of the preventive measures that the owner proposes. You agree this is logical and when the appropriate disposition is made on the product and sanitary conditions in that area are restored, you relinquish the regulatory control actions. All of these corrective actions should be recorded in the plant records. You should keep notes of your findings while performing this procedure so that you can accurately document them on the NR.

01C01 Procedure
Reference: FSIS Directive 5000.1, CSI, Chapter 1, Part XIII(C)

The 01C01 SSOP procedure is the operational recordkeeping procedure. This recordkeeping procedure instructs you to review the daily documentation of the establishment's daily implementation and monitoring of the SSOP operational procedures and any required corrective actions.

You should review the SSOP to become familiar with the operational sanitation procedures. This procedure should be performed to verify that the establishment has daily records that demonstrate the establishment has implemented the operational procedures, monitored those procedures, and taken corrective actions when necessary. You should also verify that the establishment employee responsible for implementation and monitoring has authenticated the daily records with his or her initials and the date.

You should review the SSOP prior to beginning the review of the records to ensure that it has not been modified since you last reviewed it and you are familiar with the operational procedures. When performing the recordkeeping procedure for operational sanitation, you should be reviewing the records to determine if the establishment is complying with the regulatory requirements.

You should be looking at the records to verify that the monitoring procedures are being conducted as they are specified in the SSOP. If the SSOP specifies a frequency at which the monitoring procedures will be conducted, you should verify that the establishment is conducting the procedures at the frequency specified in the SSOP.

You should review the records to verify that each time the establishment documents that direct contact surfaces are found to be unclean or contaminated product is observed, there are corrective actions documented that meet the requirements of §416.15. You should ensure that the corrective actions implemented and documented are adequate to: 1) ensure appropriate disposition of product, if necessary; 2) restore sanitary conditions; and 3) prevent recurrence. While reviewing the operational sanitation records, you should also verify that the establishment employee responsible for the implementation or monitoring has authenticated the records with initials and date.

If the establishment has not recorded its monitoring activities, has not recorded corrective actions when direct contact surfaces or direct product contamination is observed, or has not initialed and dated the daily record for authentication, there is noncompliance.

01C02 Procedure
Reference: FSIS Directive 5000.1, Chapter 1, CSI, Part XIII(E)

You should perform the 01C02 the same way as you conduct the 01B02, though this procedure is conducted during operations. Again, you should first review the SSOP to become familiar with all the operational sanitation procedures in it.

You should verify that the establishment is meeting the SSOP regulatory requirements for operational sanitation by:

- Inspecting one or more areas of the establishment to ensure procedures are effectively preventing direct contamination or adulteration of product,
- Observing the establishment perform its monitoring procedures,
- Comparing your findings to what the establishment has documented.

Before going into the establishment to assess operational sanitation in one or more areas by performing the 01C02 procedure, you should:

- Select the area or areas of the plant where you will perform the inspection. In processing departments, select one or more rooms or departments of the establishment. If you select a part of the establishment where ready-to-eat product is prepared as one of the departments where you will perform this procedure, you should start in that part of the plant first to prevent spreading microorganisms from the raw product departments of the plant.
- Have a good flashlight.
- Have a pen or pencil.
- Have U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.
- Have a notepad to record your operational findings.

Product and product contact surfaces must be kept free of contamination during operation. Other areas that are not direct contact surfaces can also be a source of product contamination and should be inspected. For example, condensation, peeling paint, and scaling rust from overheads where products are processed, handled, or stored can contaminate products. You should inspect the environment in those areas you have selected to verify the products are produced safely. You have the responsibility to verify that the establishment has met all operational sanitation regulatory requirements.

There are three parts to the 01C02 procedure: 1) observing the establishment conducting its monitoring, 2) performing an inspection of some of the establishment's facilities, equipment, utensils, product handling practices, etc. to verify sanitary conditions (hands-on), and 3) comparing your findings with the plant records. You should verify that the establishment is implementing the procedures in the SSOP. You should also verify that the establishment is monitoring the effectiveness of those procedures in preventing direct contamination or adulteration of product.

When you are performing 01C02, you should observe equipment, employees, and facilities to ensure that product contamination is not occurring during operation. For example, employees might contact contaminated surfaces with their hands and clothing and return to handling product without first cleaning their hands or changing their outer clothing. If you observe contaminated direct contact surfaces or contaminated product, there is SSOP noncompliance whether there is a procedure written in the SSOP to cover that situation or not.

When you go to an area of the establishment to perform the 01C02 procedure, you should inspect direct contact surfaces of equipment, facilities, and utensils. You should also observe the establishment conducting its monitoring activity when possible. Some establishments conduct the monitoring of operational sanitation once or twice daily; therefore it might be difficult to observe this activity. When you have completed your assessment of the sanitation in one or more areas of the plant, you should compare your findings with the establishment's sanitation findings. If the records are not complete at the time you have completed this procedure, you might ask the establishment if they have conducted their monitoring and what observations were made. We will now discuss the SSOP regulatory requirements.

§416.13 Implementation (Monitoring) Requirement
(Reference: FSIS Directive 5000.1, Chapter 1, CSI, Part XIV)

a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations.

b) Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified.

c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOPs.

1. Establishment Responsibilities

The establishment is responsible for developing written procedures that are sufficient to prevent direct contamination or adulteration of product. The establishment also has the responsibility for implementing the procedures in the written SSOPs. If the establishment writes a procedure in its SSOP, it must implement that procedure and monitor it daily. In other words, the establishment is responsible for doing what it said it would do.

2. Inspection Verification

You should verify that the establishment is meeting these regulatory requirements by performing the recordkeeping and review and observation procedures.

When you are verifying the implementation requirement while performing the 01B01 and 01B02 procedures, you are verifying that the establishment is meeting the regulatory requirements for implementation of the procedures that will be conducted before the start of operations. When you are verifying the implementation requirement while performing the 01C01 and 01C02 procedures, you are verifying that the establishment is implementing the procedures that will be conducted during the operations.

When verifying compliance with §416.13, you should seek answers to the following type of questions:

- Is the establishment implementing the pre-operational procedures in the SSOP prior to the start of operations?

- Is direct contamination or adulteration of product, or unclean direct product contact surfaces observed by FSIS or the establishment?

- Is the establishment conducting the procedures in the Sanitation SOP as written?

- Does the SSOP contain monitoring frequencies?

- If the SSOP does not contain monitoring frequencies, is the establishment monitoring the implementation of the procedures in the SSOP daily?

NOTE: If environmental sampling is included in the SSOP, you should verify that the establishment is following those procedures. You should observe the establishment collecting samples, review sample results, and verify that the corrective actions specified in the SSOP are taken when necessary when results do not meet the criteria of the procedures. This verification should be completed as part of the SSOP verification procedure.

Example:

An establishment has an SSOP that lists the following procedures:

- The trash and debris will be removed from the production area. All equipment in the production areas will be rinsed with warm water. The equipment will then be foamed and scrubbed as necessary to remove product residues. The equipment will then be rinsed with potable water and a sanitizer applied to all product contact surfaces. These procedures will be conducted daily prior to operation.

- A production employee will observe all overheads in product storage areas and remove condensation as necessary during operation.

- If product incidentally drops on the floor in the raw product area, the utility person will promptly remove the product from the floor, trim the contaminated surfaces, wash the product at the product wash station, and re-inspect it for any contamination before placing it back into production.

Monitoring

- QA personnel will monitor all equipment with contact surfaces for acceptability daily prior to operations.

- QA personnel will monitor the production employee conducting the procedure designed to prevent condensation from contaminating product.

- QA personnel will monitor the product reconditioning procedure.

The CSI should consider the following when verifying the company's implementation of this SSOP:

If the establishment does not conduct the procedures for cleaning the production areas prior to operation daily, there is noncompliance with §416.13(a).

If the production employee is not performing the procedure to prevent condensation from directly contaminating or adulterating product, there is noncompliance with §416.13(b).

If the establishment is not monitoring the production employee conducting the procedure designed for condensation control daily, there is noncompliance with §416.13(c).

If the establishment is not monitoring the product reconditioning procedure daily, there is noncompliance with §416.13(c).

§416.14 Maintenance Requirement
Reference: FSIS Directive 5000.1, Chapter 1, CSI, Part XV

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

1. Establishment Responsibilities

Each establishment has two primary obligations it must meet to comply with the requirements for the SSOP maintenance regulation. The first responsibility requires establishments to evaluate the effectiveness of all SSOPs that have been implemented in their production operations and the second requires that the company revises the SSOP as needed in order to ensure that it is reflective of the operation and that the SSOP is effective. This regulatory requirement encourages establishments to develop a system that would help them evaluate the effectiveness of their written SSOPs in order to prevent direct contamination or adulteration of product.

Before federally inspected meat or poultry establishments are permitted to operate, they must develop SSOPs that prescribe sanitation measures to prevent product adulteration or contamination. This means establishments can only speculate about which sanitation measures should be included in their SSOPs to prevent the occurrence of insanitary conditions in their production process. The effectiveness of these measures is unknown initially. Therefore, it is necessary for establishments to evaluate the effectiveness of their SSOPs once they are implemented.

Although establishments must identify the members of their management team who will be responsible for implementation and evaluation of their SSOPs, they are not required to identify the methods the individuals employ to perform the evaluations. The methods used within the establishment's evaluation system will vary from one plant to the next plant. The regulation only requires that establishments perform an evaluation of the effectiveness of their SSOPs; it does not dictate how establishments should perform this evaluation.

Example:

An example of an evaluation process an establishment may use to evaluate the effectiveness of the SSOPs. The establishment-appointed persons would conduct the evaluation as prescribed by the establishment. The establishment evaluation system may require the plant representatives to gather all of the data that pertains to the SSOP. Data used in this evaluation may consist of the different components of the SSOP records, such as the monitoring checks and corrective action log. It may also include noncompliance records (NRs) issued to the establishment by the FSIS inspection team.

These records may include records that reflect clean-up procedures, or product-handling training programs for their employees. The representatives would examine the results recorded on the sanitation documents that pertain to product or food contact zones addressed by the SSOP. They will identify instances within these documents where the implementation of the SSOP failed to prevent direct contamination or adulteration of product and review the establishment's copies of NRs documenting noncompliances in this area. The representatives may use this information to determine the effectiveness of the SSOP.

It is also a responsibility of the establishments to revise their SSOPs to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. These regulations list examples of changes that may occur within an establishment that could alter the effectiveness of an established SSOP. However, the methodologies used to evaluate their SSOPs and to determine their effectiveness do not need to be recorded. If the establishment determines the SSOPs are no longer effective and current, the SSOPs must be revised.

2. Inspection Verification

FSIS is responsible for verifying that the establishment meets the maintenance regulatory requirements. You should verify this requirement while performing the recordkeeping (01B01 and 01C01) or review and observation (01B02 and 01C02) procedures. When verifying this requirement, you must understand that you might have to review the SSOP records and NRs over a period of time to determine whether this requirement is met. Just because you find an unclean surface while performing the review and observation procedure for pre-operational sanitation does not mean that the establishment needs to evaluate the effectiveness of the SSOPs.

However, if you look at several weeks' SSOP records, you might see that the SSOPs have repeatedly been ineffective in preventing direct contamination or adulteration of product. During this same period of time you might also find that there have been several NRs documenting the ineffectiveness of the SSOPs in preventing direct contamination or adulteration of product. You will have to use your professional knowledge and good judgment in determining whether the SSOP is meeting the maintenance regulatory requirement. You should discuss your concerns with the establishment. If the establishment does not modify the SSOP and you observe contaminated product, you should take regulatory control actions. You might not accept preventive measures that do not include re-evaluation of the SSOP as an effective means of preventing direct contamination or adulteration of product.

When verifying compliance with §416.14, you should seek answers to questions similar to the following:

- Has the establishment routinely evaluated the effectiveness of the SSOPs in preventing direct contamination or adulteration?

- If changes were made in the facilities, equipment, utensils, operations, or personnel, have the SSOPs been revised to keep them effective?

- Does the establishment routinely review the SSOP records to determine if there are trends occurring showing that the SSOP needs revising?

Keep in mind, the establishment needs to revise the procedures as necessary to keep them current and effective. They may change frequently. The establishment is not obligated to notify FSIS when it revises its written SSOPs since FSIS does not approve the SSOP or SSOP revisions. However, the SSOP must be signed and dated when any modification is made.

Example of noncompliance

Changes were made in the facilities, equipment, utensils, operations, or personnel, and the SSOP is no longer effective in preventing direct contamination or adulteration of product.

Note: When documenting this noncompliance, utilize the Trend Indicator that best represents the aspect of the SSOP that is no longer effective.

WORKSHOP II: Monitoring

A. You are performing inspection verification procedure 01B02 at Establishment 38 M/P. You have chosen to observe the monitor, Ms. Mary Jones (the sanitation manager), during her pre-operational sanitation inspection. You accompany Ms. Jones to the fabrication floor. Several members of the cleaning crew also accompany you. Four of the fabrication lines will be operating today. Ms. Jones walks down the aisle between lines 1 and 2 and then down the aisle between lines 3 and 4. Ms. Jones inspects the visible portion of the band saw blade. You notice that Ms. Jones does not open the door to the band saw cabinet. After she releases the area for operation, you go back to the band saw and open the door to the cabinet. You find that the rest of the saw blade, as well as the inside of the cabinet, has meat, bone, and fat scraps adhering to the surfaces.

1.) Based on your observations, is there SSOP noncompliance? What actions would you take?

2.) Do you need to gather additional information in order to assess this situation ? (i.e. is this noncompliance an SSOP development issue or an implementation issue?)

3.) If there is an SSOP noncompliance, what regulation(s) would be pertinent?

4.) Would you issue an NR? If so, what is the appropriate ISP procedure code and trend indicator you would use to document the noncompliance?

B. You are a Consumer Safety Inspector (CSI) performing procedure 01C02 on the slaughter floor of a large finished cattle slaughter operation. You decide to observe operational sanitation in the area of edible offal. One of the procedures the plant conducts is to prepare large intestines for export. This product will bear the marks of inspection. After the intestines leave the moving evisceration table, they are washed from the inside with a spiral tube washer. The worker removes the intestines after washing by looping them across her hands until the entire piece is removed. You notice that as she does this, the end of the loops slap against the side of the wash tank and then contacts the floor. The sides of the tank are not considered a product contact surface and are contaminated with intestinal splash from loading the intestines onto the washer tube.

1.) Do you need to gather additional information in order to assess this situation?

If Yes, what information would assist you with your assessment?

If No, explain your thought process.

2.) Based on your observations and any additional information that you have gathered, is there SSOP noncompliance?

3.) If there is an SSOP noncompliance, what regulation(s) would be pertinent?

4.) Would you issue an NR? If so, what is the appropriate ISP procedure code and trend indicator you would use to document the noncompliance?

§416.15 Corrective Action Requirement
Reference: FSIS Directive 5000.1, Chapter 1, CSI, Part XVI

(a) *Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).*

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOPs or the procedures specified therein.

1. Establishment Responsibilities

These regulations require the establishment to take corrective actions when either the establishment or FSIS determines the SSOPs fail to prevent direct contamination or adulteration of product. Regardless of the type or cause of the failure, corrective actions must be taken. There are three parts to corrective action and all three of these requirements must be met and recorded each time a failure occurs. These corrective actions include appropriate disposition of product that may have been involved. When the establishment finds direct contact surfaces that are unclean during its monitoring of pre-operational sanitation, corrective actions must be taken that meet these regulatory requirements. Most of the time, however, there will not be product involved during pre-operational sanitation monitoring. If product is not involved, the establishment must still take corrective actions that will restore sanitary conditions and prevent recurrence.

The establishment is not required to notify inspection personnel when product contamination occurs, but has the responsibility to implement corrective actions that will meet the requirements of §416.15. The establishment should take full responsibility for the corrective actions meeting the three requirements of these regulations. Those regulatory requirements are:

- Appropriate disposition of products that may be contaminated;
- Restoration of sanitary conditions; and
- Prevention of recurrence of direct contamination or adulteration of products.

Note: The establishment might have a procedure in its SSOPs for reconditioning product that incidentally falls on the floor. The procedure might be that they will

remove product from the floor in a timely manner, trim contaminants from the surface area, wash the product at a product wash station, and inspect it before returning it to production. In this scenario there are occasional instances of product contamination. If the establishment is following its written procedures and monitoring these procedures, the establishment would not be required to take corrective action that meets the requirements of §416.15 every time product falls on the floor. If the establishment does not have a procedure in its SSOP, it would be required to take corrective actions that meet the requirements of §416.15 each time product falls on the floor.

2. Inspection Verification

You should verify this regulatory requirement when performing the SSOP verification procedures. Every time the establishment implements corrective actions, you should verify that the regulatory requirements in §416.15 are met. You can verify this requirement by performing any of the verification procedures (01B01, 01B02, 01C01, or 01C02). When performing the 01B01 procedure, you should request the daily pre-operational sanitation records you want to review. You should review the monitoring records to determine if there were occasions documented of direct contact surfaces or product being contaminated. If there is documentation showing the establishment had found contact surfaces or product contamination during pre-operational monitoring, there should also be documentation of the corrective actions taken for these situations. You should review these corrective actions and compare them to the regulatory requirements to verify that they have been met. Did the establishment document corrective actions that were adequate to restore sanitary conditions? Did the establishment document corrective actions to prevent recurrence of direct contamination or adulteration of product? If product contamination occurred, did the establishment have adequate documentation to demonstrate appropriate disposition of the affected product?

When performing the 01C01 procedure, you should request from the establishment the daily operational sanitation records that you want to review. You should review the monitoring records to determine if there were instances of direct contact surfaces or product being contaminated. If there is documentation showing the establishment had found contact surfaces or product contamination during the operational monitoring, there should also be documentation of the corrective actions taken for these situations. You should review these corrective actions and compare them to the regulatory requirements to verify that they have been met. Did the establishment document corrective actions that were adequate to restore sanitary conditions? Did the establishment document corrective actions to prevent recurrence of direct contamination or adulteration of product? If product contamination occurred, did the establishment have adequate documentation to demonstrate appropriate disposition of the affected product?

When you are performing the 01B02 procedure and find direct contact surfaces that are contaminated, you should take a regulatory control action on the piece or pieces of equipment. You should keep that control action in place until the establishment has given you the corrective actions and preventive measures they plan to implement to restore sanitary operations and prevent recurrence. If what they are proposing does not meet these regulatory requirements, the regulatory control action should be left in place until the plant proposes corrective actions that will meet these requirements. This also provides you the opportunity to verify that the establishment implements the corrective actions that they proposed. You should also verify that the corrective actions they document are the same as those they implemented.

If you are observing the establishment performing the monitoring as part of the 01B02 procedure and the monitor finds a contact surface or product contaminated, this provides you an opportunity to observe the establishment implementing corrective actions. You can observe the establishment taking actions that restore sanitary conditions. You can observe the establishment to verify that they make appropriate disposition of product, if necessary. If they put preventive measures in place immediately, you can verify the preventive measures.

Note: You should realize that many times the establishment might not be able to propose preventive measures until later because decisions might involve others in the establishment. For example, if you have identified a problem and the person in that area cannot propose the preventive measures because of the amount of capital involved, they should inform you that they will have a meeting with top management. This should be documented on the SSOP records. After the meeting, when the preventives have been decided, the establishment should document those preventive measures in the SSOP records.

When you are performing the 01C02 procedure and find direct product contact surfaces or product that are contaminated, you should take a regulatory control action on the piece or pieces of equipment or product. You should keep that control action in place until the establishment has given you the corrective actions and preventive measures they plan to implement to restore sanitary operations and prevent recurrence. They must also implement corrective actions to ensure the appropriate disposition of affected product. If what they are proposing does not meet these regulatory requirements, the regulatory control action should be left in place until the plant proposes corrective actions that will meet these requirements. This also provides you the opportunity to verify that the establishment implements the corrective actions that they proposed. You should also verify that the corrective actions they document are the same as those they implemented.

If you are observing the establishment performing the monitoring as part of the 01C02 procedure and the monitor finds a contact surface or product

contaminated, this provides you an opportunity to observe the establishment implementing the corrective actions. You can observe the establishment taking actions that restore sanitary conditions. You can observe the establishment to verify that they make appropriate disposition of product. If they put preventive measures in place immediately, you can verify these preventive measures.

Note: You should realize that many times the establishment might not be able to propose preventive measures until later because decisions might involve others in the establishment. For example, if you have identified a problem and the person in that area cannot propose the preventive measures because of the amount of capital involved, they should inform you that they will have a meeting with top management. This should be documented on the SSOP records. After the meeting, when the preventives have been decided, the establishment should document those preventive measures in the SSOP records.

When verifying compliance with §416.15, you should seek answers to the following:

- When FSIS or the establishment determines that the SSOPs fail to prevent the direct contamination or other adulteration of product during operation, does the establishment implement corrective actions that restore sanitary conditions?

- When FSIS or the establishment determines that the SSOPs fail to prevent the direct contamination or other adulteration of product during operation, does the establishment implement corrective actions that prevent recurrence?

- When FSIS or the establishment determines that the SSOPs fail to prevent the direct contamination or other adulteration of product during operation, does the establishment implement corrective actions that ensure appropriate disposition is made of any product that may be contaminated?

- Do the corrective actions include the reevaluation and modification of the SSOPs or improvements in the execution of the procedures when necessary?

Note: If the establishment is monitoring the pre-operational sanitation procedures, finding noncompliance, and taking the corrective actions required in §416.15, and you are not finding direct contact surfaces unacceptable, you should focus on whether the overall implementation of the SSOP is effective in preventing direct contamination or adulteration of product. You should not focus on the fact that the preventive measures being used by the establishment are the same as previous preventive measures. When you find direct contact surfaces unclean or direct contamination or adulteration of product, you should take a

regulatory control action. That regulatory control action should not be relinquished until the establishment has proposed an acceptable preventive measure. There is no noncompliance if the establishment finds noncompliance and takes the appropriate corrective actions. These corrective actions include restoring sanitary conditions, making appropriate disposition of product, and implementing measures to prevent recurrence.

This would not pertain to situations that permitted product to become contaminated. Since the SSOP must contain procedures to prevent direct contamination or adulteration of product, FSIS would expect to see the establishment have procedures in place to prevent the contamination of product.

Examples of Noncompliance

- As an example, you are performing the 01B01 procedure by reviewing the previous day's pre-operational sanitation records. The establishment had documented that the monitor found product residue from the previous day's production on the top of the conveyor belt between the blender and emulsifier. The establishment had also documented that they cleaned, sanitized, and re-inspected the conveyor belt before operations.

There is noncompliance with §416.15(b), because the establishment did not implement preventive measures to prevent recurrence.

- In a second example, you are performing procedure 01C02 on Tuesday morning by observing the operational sanitation monitor. The monitor observes rail dust from the overhead rails on carcasses hanging in the cooler. You decide to verify the establishment's corrective actions as part of this review and observation procedure. The establishment performed an inspection of all carcasses in the cooler and retained all carcasses with visible contamination. All carcasses were removed from the cooler. All retained carcasses were trimmed to remove all visible contamination. The establishment documented preventive measures such as cleaning and coating the rails with white oil over the weekend.

This is noncompliance with §416.15(b) because the establishment did not implement corrective actions to restore sanitary conditions. They should discontinue the use of the cooler until the overhead rails are free of rail dust.

- In another example, you are performing the 01C01 procedure by reviewing the operational sanitation records from the previous day. You observe an entry on the record of condensation dripping into a vat of beef trimmings. The corrective actions documented that the product was removed from the area, the condensation was removed from the overhead, and a ceiling fan will be installed after production is completed. You are aware the fan has been installed.

This is noncompliance with §416.15(b) because the establishment did not take measures to ensure appropriate disposition of the product.

WORKSHOP III: Corrective Actions

Notice that this situation is very close to the one used in Monitoring.

A. You are performing inspection verification procedure 01B02 at Establishment 38 M/P. You have chosen to observe the monitor, Ms. Mary Jones, the sanitation manager, during her pre-operational sanitation inspection. You accompany Ms. Jones to the fabrication floor. Several members of the cleaning crew also accompany you. Four of the fabrication lines will be operating today. Ms. Jones walks down the aisle between lines 1 and 2 and then down the aisle between lines 3 and 4. As she walks, she stops and points out a section of the band saw blade to the cleaning crew. The saw blade still has some meat scraps and protein residue on it from the previous day's production. A sanitation crew member cleans the visible portion of the saw blade, applies the sanitizer to it, and tells Ms. Jones that the band saw is ready for reinspection. Ms. Jones quickly reinspects the visible portion of the blade and determines that the blade is acceptable for use. You notice that Ms. Jones does not open the door to the band saw cabinet. After Ms. Jones releases the area for operation, you go back to the band saw and perform the direct observation component of the 01B02 procedure. You open the door to the cabinet and you find that the remainder of the saw blade, as well as the interior of the cabinet, is unclean with meat, bone, and fat scraps.

1.) Based on your observations, is there SSOP noncompliance? What actions would you take?

2.) If there is an SSOP noncompliance, what regulation(s) would be pertinent?

3.) Would you issue an NR? If so, what is the appropriate ISP procedure code and trend indicator you would use to document the noncompliance?

Evaluate the establishment's corrective actions for each of the following situations to see if they meet the regulatory requirements.

B. **FSIS finding**: In the second processing department you observed two plant employees pick up five poultry carcasses off the floor and place them onto the moving sizing belt which is a product contact surface. The contaminated carcasses were placed on top other poultry carcasses that were present on the sizing belt. You initiated a regulatory control action

due to the cross contamination of all poultry carcasses on the sizing belt. You issue an an NR for 01C02, SSOP, with a monitoring trend indicator.

Company's corrective action: Stopped the sizing belt and removed the affected product. Will retrain and certify all sizing belt personnel on product handling procedures. Three additional SSOP monitoring checks will be performed for the next two months to assure that the training for sizing belt personnel is effective.

Do these corrective actions meet the regulatory requirements?

If not, what requirements are not met?

C. **FSIS finding**: The SSOP for product reconditioning requires that fabricated meat pieces which have incidentally fallen on the floor to be picked up immediately and be placed in a meat wash sink. The procedure also details trimming and washing these pieces of meat before they can be returned to production. You are in the processing area performing the Review and Observation component of the 01C02 operational sanitation verification procedure and you note that several pieces of meat have fallen on the floor. All pieces of product were picked up immediately by a plant employee and placed in the bottom of the meat wash sink. You continue to observe and in your assessment of the situation, you note that there are no activities being conducted at the meat wash sink. You proceed to the meat wash sink and you observe approximately a dozen pieces of meat sitting in the bottom of the sink. You initiate a regulatory control action due to the cross contamination of product occurring in the meat wash sink. You write an NR coded 01C02, SSOP, using the Monitoring trend indicator.

Company's corrective action: All pieces of meat were removed from the meat wash sink and placed on an adjacent table. The sink was thoroughly cleaned and sanitized. The surfaces of all affected product were trimmed and washed before being returned to production. The adjacent table was cleaned and sanitized. A written copy of the SSOP procedure for product reconditioning was laminated and posted next to each sink. All supervisors in the areas with meat wash sinks were trained in the procedure.

Do these corrective actions meet the regulatory requirements?

If not, what requirements are not met?

§416.16 Recordkeeping Requirement
Reference: FSIS Directive , Chapter 1, CSI, Part XVII

(a) *Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.*

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

1. Establishment Responsibilities

§416.16 requires the establishment to maintain **daily** records sufficient to document the implementation and monitoring of the SSOPs and any corrective actions taken. The establishment must have records documenting that monitoring has been conducted daily for each of the procedures specified in the SSOPs. If the establishment has specified a monitoring frequency in the SSOP that is more frequent than daily, the documentation would have to reflect that the monitoring activities had been conducted at the specified frequencies. The establishment employee specified in the SSOPs as being responsible for the implementation and monitoring of the procedures shall authenticate these records with initials and date.

There must also be a written record of any corrective actions required by §416.15. These records must be maintained daily. **The establishment has until the beginning of the same shift the following day to complete these records.**

§416.16(b) provides the establishment the flexibility to maintain these records on a computer system provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

The records must be kept on-site for 48 hours and must be maintained for at least 6 months. After the initial 48 hours, the records may be kept off-site as long as they can be retrieved for a program employee within 24 hours of the request.

2. Inspection Verification

You should perform the recordkeeping procedures (01B01/01C01) when verifying that the establishment is meeting recordkeeping regulatory requirements. You should perform the 01B01 when verifying compliance with the pre-operational sanitation recordkeeping requirements and 01C01 when verifying compliance with the operational sanitation recordkeeping requirements. You should verify that these daily records contain:

- Documentation of the monitoring of the SSOPs;
- Documentation of any corrective actions taken; and
- Authentication (initials of responsible person and the date).

You should also verify that:

- The establishment has appropriate controls to ensure the integrity of electronic data maintained on computers;
- The SSOP records are accessible to FSIS;
- The SSOP records are maintained for at least 6 months;
- The SSOP records are maintained on-site for 48 hours after completion
- The SSOP records are available to FSIS with 24 hours of request, if they are maintained off-site.

Some of the questions that you need to consider as you evaluate the plant's records are listed below. As in all the other evaluations of the plant's SSOP system, you will need to be very familiar with exactly what the SSOP says in relation to the records they are keeping. As well as knowing what is in the SSOP, you will also need to understand the regulatory aspect of recordkeeping.

- Are the SSOP records available to FSIS upon request?
- Are the records completed prior to the start of the same shift the next day?
- Are the records completed in the manner specified in the SSOP?
- Are the records' entries legible?
- Was all monitoring done and recorded at the prescribed frequency?
- Are the records initialed and dated?

WORKSHOP IV: Recordkeeping Situations

A. You elect to perform ISP procedure 01C01 in the QC office at the beginning of your shift. You ask the QC manager for the SSOP records from yesterday. The QC manager tells you that the records are not available.

1.) What regulation applies to this situation?

2.) What does this regulation state about records availability?

3.) What actions should you now take?

Enforcement
Reference: FSIS Directive 5000.1, Chapter 4, CSI, Part III

When you determine that an establishment does not meet one of the regulatory requirements in §416.11 through §416.16 of 9 CFR, you should immediately notify the establishment's management about the SSOP noncompliance and take the appropriate regulatory control action if one is necessary. You will need to document the findings of the SSOP noncompliance on a Noncompliance Record (NR), FSIS Form 5400-4. Make sure that you mark the most appropriate SSOP trend indicator and the food safety box. You should use only one trend indicator for each NR issued.

You should take regulatory control actions when noncompliances result in direct contamination or adulteration of product or food contact surfaces. A regulatory control action is the retention of product, the rejection of equipment or facilities, the slowing or stopping of lines, or the refusal to allow the processing of specifically identified product. You must use sound professional judgment before you take a regulatory control action.

When you take a regulatory control action, you need to apply FSIS Form 6502-1 (U.S. Rejected/U.S. Retained tag) to the affected product, equipment, or facility. It informs the establishment that you have identified regulatory noncompliance, and that you have control of that equipment, product, operation, etc.

You are required to notify the appropriate establishment management official when you take regulatory control action. Under the Rules of Practice, §500.2(b), FSIS is required to immediately notify the establishment orally or in writing of the action and the basis for the action. As a federal official, you are accountable for the actions you take and should always think before you take any action.

When you have identified a noncompliance, you should complete a Noncompliance Record. The following descriptions will help you decide which of the four SSOP trend indicators to use:

Monitoring

> You should mark the monitoring trend indicator when you determine that the establishment fails to monitor its pre-operational or operational sanitation procedures daily or at the frequency specified in the SSOP. When you observe contaminated product or contamination of direct contact surfaces that the establishment monitor did not detect, the monitoring trend indicator is used.

Corrective Action

You should mark the corrective action trend indicator when the establishment does not meet the corrective action requirements. This trend indicator should be marked on the NR when the establishment does not take corrective actions to meet the requirements in §416.15. This trend indicator should be used when you determine that the corrective actions taken are not adequate to restore sanitary conditions. It would be the appropriate trend indicator to use if the establishment did not implement measures adequate to prevent recurrence. If the establishment did not implement corrective actions to ensure appropriate disposition of contaminated product, this would be the appropriate trend indicator.

Recordkeeping

You should use the recordkeeping trend indicator when there is noncompliance with §416.16. This trend indicator would be marked when the records are not being maintained daily or retained for the required period of time, or the plant fails to record the results of the monitoring check. This is the appropriate trend indicator to use when the establishment is not documenting the corrective actions taken when FSIS or the establishment determines the SSOP did not prevent direct contamination or adulteration of product. This trend indicator would also be marked on the NR when the records have not been initialed and dated.

Implementation

You use the implementation trend indicator when you find two regulatory requirements that have not been met during the performance of one procedure. For example, if you are performing the 01C02 procedure and find that the establishment is not monitoring the operational procedures at the stated frequency and did not initial and date the daily sanitation records, the appropriate trend indicator to use is implementation.

Documentation/Enforcement

If you do not observe any noncompliance when you perform the 01B02 procedure, you document the 01B02 procedure as performed on the Procedure Schedule.

If you find direct product contact surfaces with foreign materials on them, there is noncompliance and you document this finding on a Noncompliance Record (NR) using the 01B02 procedure code and the monitoring trend indicator. If you find direct contact surfaces with foreign materials on them and an insanitary condition on noncontact areas, you document both findings using the 01B02 procedure code and the monitoring trend indicator.

While performing the 01B02 procedure, if the only insanitary condition you observe is a non-food contact surface, you record the 01B02 procedure as performed on the Procedure Schedule and document the noncompliance on the NR using the 06D01 procedure and the product-based trend indicator. The 06D01 would be recorded on the Procedure Schedule as an unscheduled procedure if it is not already a scheduled procedure for that day.

Linking Sanitation Noncompliance Documentation
Reference FSIS Directive 5000.1, Chapter 4, CSI, Part VI

Regardless of which of the four SSOP verification procedures were involved, documenting linkage for NRs written for SSOP requires thought. It is necessary for you to establish a trend for ongoing sanitation SOP noncompliance occurring within an establishment before further enforcement actions can be taken by FSIS.

When establishing a history or a trend, make sure you include only those NRs that document a sanitation noncompliance as it occurred. It is inappropriate for you to link an NR documenting a particular noncompliance to previous NRs without documenting a chronological history for that noncompliance within your earlier regulatory documentation. If the noncompliance is derived from a similar cause, the NRs should be linked together as each NR is issued. You should communicate your concern about the noncompliance trend to the establishment at weekly meetings.

Do not get caught in the process of trying to link a specific type of sanitation noncompliance in the documentation of an NR with similar SSOP noncompliance that were not documented previously. Under these circumstances, it becomes difficult for you substantiate your recommendation for an enforcement action to be taken against the establishment if all relevant SSOP failures were not documented.

Establishing a link between an NR and other NRs requires you to identify situations where the noncompliances were attributed to the same cause. For example, if repetitive condensation findings are occurring, you should link together NRs that document the cause of the trend. This trend may be caused by the establishment's failure to implement its SSOPs or its proposed preventive measures. Sometimes the establishment has implemented its proposed preventive measures; nevertheless, these measures are not effective in controlling the condensation problem.

The process of establishing a trend does not include only NRs that cite an SSOP noncompliance with the same trend indicator only. A trend can be identified between NRs documenting several different noncompliance classification categories or SSOP trend indicators. You have to remember that the implementation trend indicator indicates that more than one type of problem was documented on that NR. Frequently recordkeeping and corrective action NRs or monitoring and corrective action NRs can be linked because they deal with the same cause of a problem.

SPS, SSOP, or HACCP noncompliances may be linked together to the same cause in certain circumstances. An NR written under procedure 06D01 for

condensation can be linked to an NR written for condensation under procedure 01C02 if the cause of the noncompliance is the same.

However, an NR written for condensation under 01C02 should not be linked to an NR written under 01C02 for water dripping from the ceiling that has been attributed to a roof leak. Both may be documented under the same procedure code and same trend indicator; however, the causes for the two noncompliances are different. You should use professional judgment.

When you link one NR to a previous NR in your regulatory documentation, make sure that you reference the following information from the previous NR: the NR number, the date when the NR was issued, and the establishment's ineffective further planned action as it was stated on the NR. This reference information should be included in your description of this repetitive noncompliance in the new noncompliance record. Make sure to indicate that further planned action of the establishment was ineffective in preventing recurrence of the noncompliance.

You should continue to link NRs that derive from the same or related cause for the noncompliance until it is determined that an enforcement action is necessary to bring the establishment into compliance with the regulations.

Example:

On January 27 you issued NR-15 for condensation. The establishment provided a preventive measure for this noncompliance that states, "We will install fans to increase the air flow in the area."

On February 8, you observe condensation again; the establishment's preventive measure did not prevent recurrence the noncompliance.

Under the circumstances, you should document in your description of this noncompliance that a similar noncompliance occurred on January 27 and was documented on NR-15. The further planned action of installing fans was ineffective in preventing recurrence of the condensation noncompliance. You should also include any discussions or weekly meetings held with the establishment's management concerning this issue in your documentation.

Remember that the purpose of linking NRs is to provide notification to the establishment when further planned actions are ineffective in preventing recurrence of the noncompliance. Therefore, it is necessary for you record all pertinent information in this repetitive NR to support an enforcement action under 9 CFR 500, The Rules of Practice. A statement indicating that continued failure to meet regulatory requirements can lead to enforcement actions should be included in the conclusion of your description.

Some of the factors you need to consider when are establishing a trend between noncompliance records:

1. How much time has lapsed since the previous noncompliance occurred?
2. Does this noncompliance have the same cause as a previous noncompliance?
3. Were the establishment's further planned actions from the previous noncompliance with the same cause implemented?
4. Were these further planned actions effective in preventing recurrence or reducing the frequency of recurrences of this noncompliance?
5. Has the establishment implemented better further planned action because of its failure to prevent or reduce recurrences of this noncompliance?
6. Why does this noncompliance continue to recur?

NRs are legal documents. If an FSIS administrative enforcement action is appealed by an establishment, an administrative law judge, who will make a decision concerning the case, will review all the evidence supporting this enforcement action. In many of these cases, the NR generated by the in-plant FSIS inspection personnel may be the only evidence provided to the judge that supports FSIS' actions. You will not be there. Therefore, all of the NRs provided to the judge in those cases must speak for themselves. This can be accomplished by ensuring that each NR written for SSOP noncompliance is concise, descriptive and accurate.

You continue to document noncompliances in this manner until you determine that you have adequate documentation to support an enforcement action as described in §500.4. There is no specific number of NRs required, but the documentation must be adequate to demonstrate that the SSOPs are ineffective.

WORKSHOP V: Linkage

Look at the following five NRs. Answer the following questions:

1.) Should any or all of these NRs be linked?

2.) If any of these NRs should not be included in the linkage, identify the NRs and state why it should not be included.

3.) What are the types of comments you would use in linking these NRs?

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
05/13/02	**27-02**	**00038-M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
QC Supervisor	**Foreman**

1. RELEVANT REGULATION(S)
§ 416.13

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN ≡	HACCP	SSOP	OTHER

8. ISP Code
01B02

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS	A. ☒ SSOP	☒ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ PRODUCT		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ FACILITY		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 0400 hours after plant pre-operational inspection and prior to start of production while performing procedure 01B02, I observed rust and meat particles on three band saw blades stored on the boning table; rust, meat particles and a white residue on the cuber parts. These are all direct product contact surfaces. I applied US Reject tags # B1468923 and B 1468924 to the blades and cuber parts respectively. I informed the foreman. Sanitary conditions were restored by disposing of the band saw blades and by soaking the cuber in an acid solution to remove all rust, meat particles, and white residue. The regulatory control actions were relinquished when sanitary conditions were restored and the further planned actions of including procedures in the SSOPs were proposed.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE
(signature of Inspector)

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
The three band saw blades were disposed of. The sanitation crew soaked the cuber parts in acid solution to remove rust, meat specs and white residue.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
The SSOP will be modified to include a procedure for cleaning the saw blades in a manner that will prevent rust formation. A procedure will also be included for soaking the cuber in an acid solution.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
(signature of QC Supervisor)	**May 15, 2002**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE
(signature of Inspector)	**5/21/02**

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
05/23/02	**29-02**	**00038-M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
QC Supervisor	**Foreman**

2. RELEVANT REGULATION(S)
§ 416.13

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN ≡	HACCP	SSOP	OTHER

8. ISP Code
01B02

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS	A. ☒ SSOP	☒ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ PRODUCT		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ FACILITY		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 0410 hours after plant pre-operational inspection and prior to start of production I performed procedure 01B02. The following noncompliances were observed: Rust on the auger and auger throat of the #2 grinder, rust on the auger and blender arms of the small Hobart grinder, rust on the crossbar on top of the hopper to the stuffer, and dried residue on the blade guides and the bottom of the pulley on both band saws. I applied US Reject tags # B 1469277, B 1469278, B1469279, B 1469280, and B 1469281 to the #2 grinder, the small Hobart grinder, the stuffer, and both band saws respectively. I informed the foreman who immediately had the equipment appropriately cleaned to restore sanitary conditions. The preventive measures proposed were to increase the amount of time spent conducting pre-op monitoring and giving instructions to the cleaning crew to be more observant. Similar noncompliance was documented on NR 27-02, dated May 13, 2002. The preventive measures of modifying the SSOPs to include a procedure for cleaning the saw blades in a manner that will prevent rust formation and a procedure for soaking the cuber in an acid solution were not implemented or were ineffective in preventing recurrence. Continued failure to meet these regulatory requirements could result in additional regulatory or administrative action.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE
(signature of Inspector)

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
All items were cleaned and sanitized. The deficiency occurred because of the sanitation supervisor was not working last evening.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
The pre-op crew will be instructed to start pre-op monitoring 30 minutes earlier each day to provide them more time for inspection. The sanitation supervisor has been instructed to work more closely with the sanitation crew to ensure procedures are being appropriately implemented.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
(signature of QC Supervisor)	**May 25, 2002**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE
(signature of Inspector)	**5/29/02**

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
06/03/02	**33-02**	**00038-M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
QC Supervisor	**Foreman**

3. RELEVANT REGULATION(S)
§ 416.3

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN	HACCP	SSOP	OTHER

8. ISP Code
06D01

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT ☐ PROCESS ☐	A. SSOP ☐	Monitoring ☐	Corrective Action ☐	Recordkeeping ☐	Implementation	
	B. HACCP ☐	Monitoring ☐	Corrective Action ☐	Recordkeeping ☐	Plant Verification	
☐ C. PRODUCT	☐	Economic ☐	Misbranding ☐	Protocol		
☐ D. **X** FACILITY	☐	Lighting	Structural	Outside Premises	**X** ☐ Product Based	
☐ E. E. COLI		Other				

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 0415 hours while performing the 01B02 procedure, the following was observed: rust on the outer surfaces of the product brine tank; dried meat particles on the outer surface of the band saw cabinet; dried fat and meat particles on one of the legs of the boning table. All sanitation findings were observed after the plant pre-operational monitoring and prior to the start of production. The foreman was notified of the sanitation noncompliance. The foreman instructed the sanitation crew to initiate immediate corrective actions. No sanitation records for this date were available when this procedure was completed. Similar noncompliance was documented on NR 29-02, dated May 23, 2002. The preventive measures of instructing the pre-op crew to start pre-op monitoring 30 minutes earlier each day to provide them more time for inspections and instructing the sanitation supervisor to work more closely with the sanitation crew to ensure procedures are being appropriately implemented were not implemented or ineffective in preventing recurring noncompliance. Continued failure to meet these regulatory requirements could result in additional regulatory or administrative action. The developing trend of noncompliance and the ineffectiveness of the preventive measures were discussed with plant management during the weekly meeting on this date. I also informed plant management at this meeting that continued failure to comply with these regulatory requirements could result in further enforcement action.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE
(signature of Inspector)

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
No product was involved. The boning table, brine tank, and band saw were re-cleaned and sanitized immediately. All deficiencies were documented on the pre-op sanitation report.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
We will instruct the sanitation crew to check all pieces of equipment for rust and meat particles after cleaning. The sanitation foreman will assess the cleaning process for the equipment more closely.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
(signature of QC Supervisor)	**6/5/02**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE
(signature of Inspector)	**6/5/02**

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
06/23/02	**35-02**	**00038-M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
QC Supervisor	**Foreman**

4. RELEVANT REGULATION(S)
§ 416.13

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN ≡	HACCP	SSOP	OTHER

8. ISP Code
01B02

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS	A. ☒ SSOP	☒ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ PRODUCT		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ FACILITY		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 0412 hours after plant pre-operational inspection and prior to start of production while performing the 01B02 procedure, the following noncompliances were observed: Frayed plastic edges on four bone dust scrapers; rust on the blender arm and in the bottom of the hopper of the small Hobart grinder; rusty tenderizer needles; and rust on the hand contact surface of the edible product shovel was rusty. No sanitation records were available when the procedure was performed. I placed US Reject tags B 1472001, B 1472002, B 1472003, and B 1472004 respectively. I notified the foreman of the noncompliances and she initiated corrective action. After sanitary conditions had been restored and preventive measures were proposed, I relinquished the regulatory control actions. Similar noncompliance was documented on NR 33-02, dated 06/03/02. The preventive measures of instructing the sanitation crew to check all pieces of equipment for rust and meat particles after cleaning and the sanitation foreman assessing the cleaning process for the equipment more closely were not implemented or were ineffective in preventing recurrence of the noncompliance. Continued failure to meet these regulatory requirements could result in additional regulatory or administrative action. The ineffectiveness of the preventive measures in preventing recurrence of noncompliance was discussed with plant management in the weekly meeting held this afternoon. I also notified establishment management that continued failure to meet these regulatory requirements could result in further enforcement actions.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE
(signature of Inspector)

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
The affected areas were re-cleaned and sanitized. The deficiency occurred due to lack of following procedures by the night manager. No product was adulterated due to the deficiency.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
The operations manager will re-address the importance of following the already in place procedures and completing the sanitation checklist. The production manager will check the room before the pre-op sheet is signed.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
(signature of QC Supervisor)	**June 24, 2002**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE
(signature of Inspector)	**6/25/02**

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE
☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
06/28/02	**36-02**	**00038-M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
QC Supervisor	**Foreman**

5. RELEVANT REGULATION(S)
§ 416.13

7. RELEVANT SECTION OF ESTABLISHMENT PROCEDURE/PLAN ≡	HACCP	SSOP	OTHER

8. ISP Code
01B02

9. NONCOMPLIANCE CLASSIFICATION INDICATORS

PLANT PROCESS	A. ☒ SSOP	☒ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ PRODUCT		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ FACILITY		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

10. DESCRIPTION OF NONCOMPLIANCE:
At approximately 0400 hours, I performed procedure 01B02 in the processing area. The inspection was done after plant's pre-operational sanitation inspection was completed. The following observations were made while performing this procedure: raw material (meat) particles were scattered on the metal wire guard of the packing machine; and an accumulation of raw material (meat) from the previous day's operation in the seams of the paddles and paddle cogs of the Hobart mixer. I took a regulatory control action on the packing machine and the Hobart mixer with US Reject B 1472103 and B 14721204 respectively. Plant management was notified of these observations. After sanitary conditions were restored and preventive measures were proposed, I relinquished the regulatory control actions. The sanitation record was not available when this procedure was performed. Similar noncompliance was documented on NR 35-02 dated 06/23/02. The further planned actions of the operations manager re-addressing the importance of following the procedures and completing the sanitation record and the production manager checking the room before the pre-op record is signed were either not implemented or were ineffective in preventing recurrence. Continued failure to meet these regulatory requirements could result in additional regulatory or administrative action.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE
(signature of Inspector)

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):
The areas found to be deficient were re-cleaned and sanitized before processing began for the day. The cause of the deficiency was a lack of training the sanitation crew and pre-op crew. No product was adulterated due to the deficiency.

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*
The sanitation crew has been trained on how to properly clean the areas in question and the night manager has been instructed to inspect these and other areas more thoroughly each night. To prevent recurrence we have done the above training and also require that our pre-op personnel check these areas specifically for the next 2 weeks.

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
(signature of QC Supervisor)	**June 29, 2002**
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE
(signature of Inspector)	**6/30/02**

Application of the Rules of Practice
Reference FSIS Directive 5000.1, Chapter 4, Rules of Practice

The Rules of Practice regulations (§500.3 and §500.4) describe the enforcement actions that can be taken if the establishment's SSOPs do not meet regulatory requirements. These two sections of the Rules of Practice regulations describe the enforcement actions that can be can be imposed on an establishment when the SSOP regulatory requirements are not met. §500.3(a)(1) states that FSIS may take a withholding action or impose a suspension without providing the establishment prior notification if 1) *The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602* or 2) *The establishment does not have Sanitation Standard Operating Procedures as specified in §§416.11-416.12 of this chapter.*

1. Shipping contaminated or adulterated product

   If the SSOP does not prevent contaminated or adulterated product from being produced and shipped, you should impose a withholding action as described in §500.3.

   Since contaminated or adulterated product was shipped, there is an imminent threat to the public health and you should take an immediate withholding action. When contaminated or adulterated product has been produced and shipped, you are not required to notify the establishment in advance that you are taking the withholding action. FSIS will provide the establishment written notification later. An NR is written documenting the noncompliance. The District Office will review the circumstances and advise the IIC on how to proceed when further enforcement actions are necessary.

2. Failure to meet the basic regulatory requirements

Before inspection is granted, the establishment must have developed a written SSOP that meets the requirements of §§416.11-416.12. Unless the establishment is a new facility applying for inspection, FSIS has already verified that the SSOPs meet these requirements. However, there may be situations where failures to meet the basic regulatory requirements may occur in an existing establishment.

Note: If the establishment's management modifies the SSOP and you determine that the SSOPs do not meet the basic regulatory requirements, an NR should be written under the 01A01 procedure code for SSOP basic compliance. The SSOP trend indicators should not be used with this procedure code. You should notify the establishment about the noncompliance and contact the District Office for directions. The District will provide instruction on whether you should issue a 30-day reassessment letter**,** or to impose an enforcement action specified in §500.3.

Section 500.4 of the Rules of Practice states: *FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because: the Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§416.13 through 416.16 of this chapter.*

3. Repetitive SSOP failures

   This means that you must have adequate documentation to support the determination that the SSOPs have repeatedly not been implemented and maintained to be effective in preventing direct contamination or adulteration of product. It is not necessary for you to determine that contaminated or adulterated product has been shipped to impose the enforcement actions described in §500.4. It is necessary that you have adequate documentation to demonstrate that the establishment is unable to prevent repeated failures of the SSOPs. There are two reasons why SSOP failures can occur. Either the SSOP is not designed adequately to prevent contamination or adulteration of product, or the SSOPs are not properly implemented.

   You must link the SSOP failures to the same cause identified within the NRs generated at the establishment. For this reason, accurate documentation is very important. Each linked NR should reference the previous NR number, the NR date, the specific preventive measures that were not implemented or were ineffective in preventing the recurrence of the SSOP failures.

   When you determine there is adequate documentation to support an enforcement action as specified in §500.4, you should contact the district office and request the issuance of a Notice of Intended Enforcement Actions (NOIE). There is no specific number of NRs required for the issuance of an NOIE, but your documentation should support your requested enforcement action. The district office will issue the Notice of Intended Enforcement Actions to the establishment.

Verification Plan

A verification plan is designed by the District Office based on the establishment's response to one of the Agency letters, e.g., NOIE, 30-day Reassessment, Notice of Suspension. A verification plan is an additional tool for you to use to verify the specific corrective actions proposed. Any failure to meet the conditions of the proposed action would support FSIS imposing further enforcement actions. These specific corrective actions are conducted as part of your regular verification procedures. Even though these corrective actions are not part of the HACCP plan or SSOP, you must verify these actions because the establishment proposed them as a means to meet the regulatory requirements. If the establishment proposes corrective actions that are outside of the regulatory requirements, you are required to verify them as well.

The District Office will provide a copy of the verification plan to the plant and to the FSIS in-plant inspection team for verifying the plant's progress in implementing the proposed corrective and preventive actions. You are responsible for verifying the proposed actions in conjunction with the other requirements as part of your verification procedures.

WORKSHOP VI: Verification Plan

Read the following scenario.

On January 13, you performed pre-operational inspection at a slaughter plant and found dripping condensation on the ceiling and carcass rails of both product coolers. Since condensation was dripping onto exposed product in these areas, the CSI took a regulatory control action as prescribed in 9 CFR 500.2. The product coolers were rejected for use, the affected product was retained, and the establishment was notified. The CSI immediately discussed this noncompliance with the IIC to determine if any further enforcement action was necessary.

Over the past two months, there had been several noncompliance records written documenting the establishment's failure to control condensation. Some noncompliances involved the adulteration of product, and others did not. The establishment had proposed numerous preventive measures that were not adequate in maintaining effective Sanitation SOPs.

The IIC informed the District Office about the establishment's repetitive failures to properly implement and maintain their SSOPs as specified in Parts 416.13 through 416.16. The IIC requested that the District Office issue a Notice of Intended Enforcement action (NOIE) to take further enforcement actions to suspend operations at the establishment.

After a careful review of the documentation, the District Office issued an Notice of Intended Enforcement Action (NOIE) to the establishment dated January 14.

In response to the NOIE, the establishment issued a letter stating their corrective and preventive measures.

(Excerpts from establishment's letter dated January 15.)

After a re-evaluation of Sanitation Standard Operating Procedures, we determined that the following changes would be made to our program:

- *Plant personnel will be assigned to monitor condensation hourly in all departments. If condensation is found, it will be removed immediately. All deficiencies will be documented in the Condensation Log.*

- *QA will perform condensation verification monitoring checks at pre-op and twice per shift during operations in all departments. All visible deficiencies, as well as the corrective actions, will be documented on the Condensation Assurance Form.*

In addition to the modifications to our SSOPs, we will do the following:

- *Replace the seals on the north door of product cooler #1 will be replaced by January 29.*

- *Install stationary ceiling fans in strategic locations throughout the two product coolers to increase the airflow in these areas. Ceiling fan installation will be completed by February 3.*

The District Office accepts the establishment's response and notifies them with a deferral letter. Attached to this letter is the verification plan. The IIC receives a copy of the letter and verification plan.

Verification Plan - Revised SSOP		
Establishment Plan	Regulation	CSI Verification/ISP Procedure
Plant personnel monitor condensation hourly; remove if it is found; and document on Condensation Log	9 CFR 416.13(b)	01B01 01B02 01C01 01C02 Verify modification of SSOP. Verify that the establishment is monitoring hourly.
QA will perform condensation verification monitoring checks at pre-op daily; during operation twice/shift. Deficiencies and corrective actions documented on Condensation Assurance Form	9 CFR 416.13(c)	01B01 01B02 01C01 01C02 Verify modification of SSOP Verify that QA conducts verification monitoring as described in the SSOP.

Note: Inspection program personnel will perform 01B01, 01B02, 01C01 and 01C02 procedures to verify the adequacy and effectiveness of the establishment's SSOP including the sanitation procedures specified in the SSOP.

	Plant Improvement Plan	
Product Coolers Improvements	Anticipated Completion Date	Actual Completed Date
Replace bad seals on north door of Cooler #1	January 29	
Installation of ceiling Fans in Coolers #1 & #2	February 3	

Note: These scheduled improvements will be verified by the CSI using the 06D01 procedure on the anticipated completion date as an unscheduled procedure, if an 06D01 is not scheduled. The regulations that pertain to these improvements are found in 9 CFR 416.1- 416.6 of the Sanitation Performance Standards. All four verification procedures will be performed daily until further notice.

Using the Verification Plan for Est. 00038M, answer the following questions:

1.) What is the purpose of the Verification Plan?

2.) How are the results of the completed 01B01, 01B02, 01C01, and 01C02 verification procedures recorded on the Daily Procedure Schedule?

3.) On February 3, the establishment has completed the installation of all of the ceiling fans in both product coolers. What ISP code is used to record the result of this verification procedure on the Daily Procedure Schedule?

4.) Are there any consequences for the establishment if they fail to meet the conditions of their proposed actions?

WORKSHOP VII- SSOP Summary

A. You are a Consumer Safety Inspector (CSI) performing procedure 01C02 in the evisceration department of a poultry plant during slaughter operations. You observe numerous loops of small intestines wrapping themselves around the food contact surfaces of the drawing spoons of an eviscerating machine. There are two spoons that have visible smears of feces on their food contact surfaces. You also observe that the eviscerating machine's rinse system is not working at the present time. The rinse system is designed to clean the food contact surfaces of each spoon before it is used again.

   1.) Do you need to gather additional information in order to assess this situation?

   If Yes, what information would assist you with your assessment?

   If No, explain your thought process.

   2.) Based on your observations, and any additional information that you have gathered, is there SSOP noncompliance?

   3.) If there is an SSOP noncompliance, what regulation(s) would be pertinent?

   4.) Would you issue an NR? If so, what is the appropriate ISP procedure code and trend indicator you would use to document the noncompliance?

B. As you are proceeding through the carcass cooler on your way to the fabrication department, you observe heavily beaded condensation forming on the underside of two carcass rails, their support structures, and the concrete ceiling in the vicinity. There are at least 20 carcass sides hanging below the underside of each rail. You see condensation dripping from the underside of one of the rails onto at least three carcass sides.

   Answer the following questions.

1.) Do you need to gather additional information in order to assess this situation ?

If Yes, what information would assist you with your assessment?

If No, explain your thought process.

2.) Based on your observations, and any additional information that you have gathered, is there SSOP noncompliance?

3.) If there is an SSOP noncompliance, what regulation(s) would be pertinent?

4.) Would you issue an NR? If so, what is the appropriate ISP procedure code and trend indicator you would use to document the noncompliance?

C. Yesterday you performed ISP procedure 01C02 in the Second Processing Department and you saw a department supervisor holding two white plastic shovels in his hands. You know that in this facility plant management considers white plastic shovels as product contact equipment. Each shovel had a QC Hold tag attached to its respective handles. The supervisor explained to you that a QC technician had found both product shovels on the floor of the icehouse anteroom. You are aware that the anteroom is a high traffic area of the Further Processing Department. The QC technician had tagged the shovels and notified the supervisor about the situation. The supervisor then gave both shovels to a production employee and instructed the employee to take the shovels to the designated equipment wash area. Soon afterward, the supervisor verbally reassured you that he had the situation under control because he had checked on the shovels and they were being washed. He also advised you that he had determined that no product had been affected and that he planned to reeducate all ice house personnel in the proper handling of white shovels.

Today your PBIS procedure schedule indicates that you should perform the 01C01 procedure. You review the company's operational sanitation SSOP records from the day before and you determine that the incident regarding the white shovels was not documented.

1.) Is this a regulatory noncompliance, and if so, what regulations are pertinent to the situation?

2.) Would you issue an NR?

D. **FSIS finding:** Boxes of frozen trim are fed into a flaking machine prior to the grinder. These boxes come down a non-product contact conveyor to a table next to the flaker. When the plant employee had a problem with the frozen product coming out of one box, he inverted the box and banged it on the table to loosen it. He then picked up the block of meat and prepared to feed it into the flaker. You initiated immediate regulatory control action due to the cross contamination of the product and the product contact surface. You then verbally notified plant management. You issued an NR using the 01C02/SSOP procedure code with the Monitoring trend indicator.

Company's corrective action: The block of meat that had been in contact with the table was discarded. The surfaces of the table that had come into contact with that block of meat were cleaned and sanitized. The employee was counseled not to let product come into contact with the table since only the outside of the boxes is allowed to contact the table. He was also counseled not to touch the block of meat with his hands, and he should only to handle the cardboard.

Do these corrective actions meet the regulatory requirements?

If not, what requirements were not met?

E. **FSIS finding:** As you enter the formulation kitchen, you observe a pallet containing boxes of raw frozen product located by the door. One of the boxes on the top row of the pallet has been damaged and the cover is torn open. Upon closer inspection, you observe that several pieces of wood are present inside the box, in direct contact with the product. You observe the box and the

pallet of product and determine that there are no company controls in place. You initiate a regulatory control action and retain the box of product. You verbally notify plant management of your findings. You then issue an NR, to address the contaminated product, using the 01C02/SSOP procedure code with the Monitoring trend indicator.

Company's corrective action: The contaminated product was placed in the inedible barrel. No other boxes on the pallet appeared to be affected. A new procedure has been instituted and employees trained to control damaged boxes both in the freezer warehouse and in the production facility.

Do these corrective actions meet the regulatory requirements?

If not, what requirements were not met?

F. You are the GS-9 IIC assigned to a small establishment that slaughters beef and processes miscellaneous beef cuts, ground beef and cooked sausages. Over the last three months, you and relief inspection personnel have issued NRs for multiple and recurring noncompliances identified for failure of the SSOP to prevent direct product contamination and failure to maintain sanitary conditions as required in the SPS. You have linked the NRs together for the same cause and your review of the records leads you to believe that there are two causes for the above NRs. The first cause is the failure to prevent rodent harborage and entry into the establishment and the second cause is a lack of adequate ventilation or airflow, resulting in condensation from overhead structures. You have issued three more NRs since the Relief Inspector's last visit for heavily beaded condensation found in multiple non-production areas. You have kept your Front Line Supervisor informed of the recurring nature of the situation and also discussed this with plant management during the weekly joint meetings.

What actions would you initiate at this time if you determine further enforcement actions are necessary?

Code of Federal Regulations

TITLE 9--ANIMALS AND ANIMAL PRODUCTS
CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 416--SANITATION

Sec. 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

Sec. 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

Sec. 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

Sec. 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

Sec. 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

Sec. 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

Sec. 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.