SANITATION STANDARD OPERATING PROCEDURES

Objectives

After completion of this module, the participant will be able to:

1. Explain the meaning and significance of the following terms:
   a. Sanitation SOP
   b. Responsible person
   c. Regulatory control action
   d. Pre-operational sanitation procedures
   e. Operational sanitation procedures
   f. Sanitation SOP Implementation & Monitoring
   g. Sanitation SOP Maintenance
   h. Sanitation SOP Corrective Actions
   i. Sanitation SOP Recordkeeping
2. Select from a list the 4 regulatory requirements for Sanitation SOPs.
3. State the steps taken by IPP to verify Sanitation SOP implementation and monitoring, maintenance, recordkeeping, and corrective actions.
4. Identify the required corrective actions the establishment must take and record for noncompliances involving direct contamination or adulteration of product.
5. List the record retention, authentication, data integrity, and daily documentation requirements for Sanitation SOP records.
6. Discuss the enforcement action that could be taken when FSIS observes a noncompliance during a pre-operational or operational sanitation inspection.
7. Given Sanitation SOP corrective and preventive measure examples, determine those that meet the regulatory requirements of 9 CFR 416.15(b).
8. Given an example Sanitation SOP, determine regulatory compliance with 9 CFR 416.12.

References:

1. 9 CFR 416.11-416.17
2. FSIS Directive 5000.1, Verifying an Establishment’s Food Safety System
3. FSIS Directive 5000.4, Performing the Pre-Operational Sanitation Standard Operating Procedures Verification Task
4. FSIS Directive 5000.5, Verification of Less Than Daily Sanitation Procedures in Processing Operations
5. FSIS Directive 4791.11, Lockout/Tagout Safety Procedures

General Rules

§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 (Sanitation SOPs) are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product. 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 written in the Sanitation SOPs. The establishment must maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective action taken. When the establishment or FSIS determines that the Sanitation SOPs may have failed to prevent direct contamination or adulteration of product, the establishment must implement corrective actions that include the appropriate disposition of product, restore sanitary conditions, and develop measures to prevent recurrence.

Development of Sanitation SOPs

§416.12 Development of Sanitation SOPs

(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 Sanitation SOPs that clearly describe procedures the establishment will implement to prevent direct contamination or adulteration of product. The establishment and inspection personnel should understand that there are not separate Sanitation SOPs for different operations or different shifts. The Sanitation SOPs 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 Sanitation SOP 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 Sanitation SOPs as written and will maintain the Sanitation SOPs in accordance with the requirements of this part.

Inspection Verification for the Sanitation SOP Design

All USDA-FSIS inspected establishments must have written Sanitation SOPs that meet the development (basic design) requirements listed in §416.12 before a Grant of Inspection is given. The FLS, or designee, will ensure that new establishments have written Sanitation SOPs in place prior to recommending approval for a Grant of Inspection to the District Office. IPP will address basic design noncompliance while performing Sanitation SOP verification tasks.

To effectively verify compliance with the Sanitation SOP regulations, IPP are to understand the Sanitation SOP regulations (§416.11 - §416.16), be familiar with the establishment's current written Sanitation SOPs, and perform the verification tasks as described in FSIS Directive 5000.1 and FSIS Directive 5000.4.

NOTE: If IPP find that an establishment has not developed written Sanitation SOPs, they should contact their supervisor immediately.

WORKSHOP #1- Identifying the Basic Elements of the SSOPs

Objective: Carefully read the sample Sanitation SOP below. Evaluate the Sanitation SOP for compliance with §416.11 and §416.12. After you have evaluated the Sanitation SOP, answer the questions listed in the worksheet.

BEEF SLAUGHTER ESTABLISHMENT M41777—Sanitation SOP

Owner – Joe Green

This Sanitation SOP is for Beef Slaughter Establishment M41777 and becomes effective on January 28, 2013

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 1/25/13)
Joe Green

Modification Log

1. *(signature and date of Joe Green, 12/11/13)*
2. *(signature and date of Joe Green, 6/17/14)*

WORKSHOP #1- Identifying the Basic Elements of the SSOPs

For Training Purposes Only

Objective: Verification of compliance with the basic development of SSOPs

PHIS Task: Pre-operational & Operational SSOP Record Review task			
Relevant Regulatory Question	**Yes**	**No**	**Student's comments**
Does the establishment 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)]			
Do the establishment's SSOPs identify which of the procedures are pre-operational procedures? [§416.12 (c)]			
Do the establishment's pre-operational SSOP procedures address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils? [§416.12 (c)]			
Do the establishment's SSOPs specify the frequency with which the establishment will conduct each procedure? [§416.12(d)]			
Do the establishment's SSOPs identify the establishment employee or employees responsible for implementing and maintaining specified procedures? [§416.12 (d)]			
Does the establishment have records that identify the documentation and the implementation and monitoring of the SSOPs on a daily basis and any corrective actions taken? [§416.16 (a)]			
Did the individual with overall authority on-site or a higher level official of the establishment sign and date the Sanitation SOP's (1) Upon initial implementation, or (2) Upon modification [§416.12 (b)]			
Are there any failures to comply?			

Sanitation SOP Verification Tasks

The following table lists four tasks used to verify compliance with Sanitation SOP requirements.

Inspection Tasks	General Description
Pre-Operational Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations.
Pre-Operational Sanitation SOP Review and Observation	Use the Review and Observation verification activity **and** the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations. In PHIS, IPP should select the "Both" option on the Activity tab.
Operational Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations.
Operational Sanitation SOP Review and Observation	Use the Review and Observation verification activity **and** the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations. In PHIS, IPP should select the "Both" option on the Activity tab.

Regardless of which Sanitation SOP task is performed, IPP will verify that establishments meet all **four** of the following regulatory requirements **in addition to the design requirements §416.12:**

a. Implementation and monitoring of Sanitation SOP (§416.13);

b. Maintenance of Sanitation SOP (ensuring its effectiveness) (§416.14);

c. Sanitation SOP corrective actions (§416.15); and

d. Sanitation SOP recordkeeping (§416.16).

The Record Review Tasks: Pre-Operational and Operational

IPP use the recordkeeping verification activity to verify all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping) while performing the Pre-Operational and Operational Sanitation SOP Record Review tasks.

During the Sanitation SOP record review tasks, IPP perform the following:

1) Review the written Sanitation SOP to be familiar with the establishment's current pre-operational or operational sanitation procedures.

2) Verify that the SSOP continues to meet the design requirements of §416.12.

3) Verify that the establishment has maintained daily records that demonstrate that the establishment has implemented the pre-operational and operational procedures as written, monitored those procedures at least daily or at the specified frequency, and taken immediate or corrective action when necessary.

   For instance, IPP verify that the records indicate that the establishment conducted monitoring daily prior to the start of operations. If the establishment observed a contaminated food contact surface (residue from previous day's product) during pre-operational inspection, IPP verify that the establishment documented that the contaminated surface was re-cleaned, re-inspected and released before product passed over the surface. Similarly, if the establishment has documented the finding of contaminated product or food contact surfaces during operations, IPP verify that the documented corrective actions meet regulatory requirements.

   NOTE: In most cases, product does not contact equipment surfaces prior to the start of operations. However, if the establishment found contaminated product during pre-operational inspection, IPP will verify that the establishment has documented corrective actions that meet the requirements of §416.15(b).

4) Verify all the recordkeeping requirements of §416.16.

   For instance, IPP verify that the establishment employee responsible for the implementation and monitoring of the procedure has authenticated the records with their initials and date.

The Review and Observation Tasks: Pre-Operational and Operational

IPP use **both** the review and observation verification activity and the recordkeeping verification activity when performing the Pre-Operational and Operational Sanitation SOP Review and Observation tasks. IPP are to verify that all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping).

Each time IPP perform the review and observation tasks, they:

1) should review the written Sanitation SOP so they are familiar with the establishment's current pre-operational or operational sanitation procedures,

2) verify that the SSOP continues to meet the requirements of §416.12,

3) observe the establishment conducting its monitoring activities and implementing corrective action when they find that the pre-operational or operational procedures have failed to effectively clean and sanitize food contact surfaces,

4) inspect one or more areas and perform an organoleptic examination of some of the establishment's facilities, equipment, and utensils to assess sanitary conditions (sometimes referred to as "hands-on" inspection),

5) compare their findings with the establishment records/findings, (which may not be documented until the start of the next production day for that specific shift), and

6) verify that the establishment meets the corrective action requirement of 9 CFR 416.15 when they find that the establishment's Sanitation SOP has failed to prevent product contamination or adulteration.

Selecting Production Areas and Equipment for Pre-Op Sanitation SOP Review and Observation Verification Task (FSIS Directive 5000.4)

In both slaughter and processing establishments, IPP follow the same methodology or thought process to plan their Pre-Op Sanitation SOP verification. IPP are to select the production area(s) and equipment to examine using a risk-based approach. The area(s) and equipment selected are those that present the highest risk of becoming insanitary or causing product contamination.

The following factors indicate a higher risk to public health:

1) Equipment that will contact exposed product.

2) Equipment that will contact RTE product post-lethality.

3) Equipment that is difficult to clean.

4) Equipment that FSIS has not verified recently.

5) Equipment/area(s) with a history of noncompliance; and

6) Testing results that suggest that specific pieces of equipment may present a risk to public health.

IPP review test results and other records relevant to the food safety system weekly per FSIS Directive 5000.2. Based on information gathered from test results, establishment sanitation records or other records, establishment pre-op sanitation findings, or repetitive noncompliances, IPP are to consider whether to increase the extent of pre-op sanitation verification activities (i.e. how much equipment and how many areas).

IPP are encouraged to discuss their thought processes for making their selections on an on-going basis with their IIC or FLS. They are not expected to put their thought process in writing, nor to share it with establishment management.

Pre-Op Sanitation SOP Review and Observation Task

To perform the Pre-Op Sanitation SOP Review and Observation task, IPP should have:

- A functional flashlight.
- A pen or pencil.
- U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.
- A notepad to record their pre-operational findings.

IPP not trained in lockout/tagout (FSIS Directive 4791.11) methodology shall not perform pre-op sanitation inspection on any piece of equipment requiring lock out. If IPP select a ready-to-eat (RTE) production area for pre-operational inspection, they should start in the RTE department first to prevent introduction of microorganisms from the raw product areas.

After establishment management informs IPP that an area is ready for FSIS pre-op inspection, IPP perform the review component of Pre-Op Sanitation SOP Review and Observation verification task. They are to inspect areas in the establishment, equipment and utensils, and places on equipment that, if insanitary, would present the greatest risk of transferring pathogens or other

contaminants to product (e.g., direct food contact surfaces that are difficult to clean or may serve as microbial harborage sites). Establishments can elect to reassemble equipment after they complete their monitoring and implementation of the Sanitation SOPs. However, IPP can request that the establishment disassemble the piece of equipment so that the IPP will be able to perform their pre-op sanitation verification.

IPP perform "hands-on" inspection to verify that direct food contact surfaces are organoleptically clean. This means that the surfaces look clean, feel clean, and smell clean. IPP visually examine the food contact surfaces for product residues from previous days' operations. They feel the contact surfaces to determine if there are residues or foreign materials (e.g. grit, dust, etc.) present from previous days' operations that are not visible. IPP detect any odors in these area(s) that may indicate insanitary conditions.

If direct food contact surfaces are contaminated with residues from previous days' operations, it is likely that these conditions will harbor microorganisms and/or have a chemical residue present. The surfaces should be free of foreign material such as fat, blood, hair, rust, dust, grease, and cleaning chemicals.

IPP are to focus on food contact surfaces and not on surfaces or areas that do not directly contact product. They are to look at selected pieces of equipment rather than all equipment. When there are large numbers of simple equipment such as pans, buckets, trays, or hand tools, IPP are to select a representative sample (e.g. one or two each).

Although the focus is on food contact surfaces, IPP should remain aware of other insanitary conditions such as unclean non-food contact surfaces; condensation; peeling paint; and scaling rust from overhead fixtures in areas where products are processed, handled, or stored.

When IPP have completed their examination of the selected area(s) and equipment, IPP should compare their findings to the establishment's sanitation findings. If the written records are not yet completed, IPP may ask the establishment about its pre-operational findings and any actions taken. However, IPP must verify the recordkeeping requirements before completing the task.

When IPP observe contaminated direct food contact surfaces during the pre-op sanitation verification, they are to reject the affected equipment. The establishment has the responsibility to restore sanitary conditions (clean the contaminated food contact surface) and document the restoration of sanitary conditions under §416.16(a). **Preventive measures do not need to be developed and documented unless product has been contaminated or adulterated by the unclean surface.** IPP should not remove the USDA reject tag until the establishment has restored sanitary conditions.

In rare situations in which product has been contaminated or adulterated before the start of operations, the establishment must take corrective actions that meet the requirements in §416.15(b). Furthermore, IPP should not remove the regulatory control action until the establishment has proposed corrective actions, either verbally or in writing, that meet these requirements.

In some cases, the establishment might conduct monitoring of the implementation of the Sanitation SOP procedures before inspection personnel arrive at the establishment. In these situations, the FLS or IIC will decide how frequently IPP will directly observe the establishment conducting their monitoring procedures. The supervisor will consider several factors when making this decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from Sanitation SOP records.

Operational Sanitation SOP Review and Observation Task

IPP should select area(s) of the establishment and equipment that presents the **highest risk** for insanitary conditions or product contamination. If a RTE production area is selected, IPP should start in the RTE area to prevent introducing microorganisms from the raw product areas into the RTE area.

IPP are to have:

- a functional flashlight.
- a pen or pencil.
- U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.
- a notepad to record their operational findings.

IPP should observe the equipment, employees, and facilities to verify that product contamination is not occurring during operation. For example, employees might contact contaminated surfaces with their hands and/or clothing and return to handling product without first cleaning their hands or changing their outer clothing. If IPP observe contaminated direct food contact surfaces or contaminated product, there is Sanitation SOP noncompliance whether there is a procedure written in the establishment's Sanitation SOP to cover that situation or not.

IPP should inspect direct food contact surfaces of equipment, facilities, and utensils. Although the task focuses on verifying product and food contact surfaces are not contaminated during operation, IPP should be aware of other potential sources of product contamination such as condensation, peeling paint, dead-end pipes and scaling rust from overhead fixtures where products are processed, handled, or stored can contaminate products.

When possible, IPP should also observe the establishment conducting its monitoring activity. Some establishments conduct the monitoring of operational

sanitation at a frequency of once or twice daily. Therefore it might be difficult for the IPP to observe this activity

When IPP have completed their assessment of the sanitation in one or more areas of the establishment, they should compare their findings with the establishment's sanitation findings. If the records are not complete at the time, IPP might ask the establishment if it has conducted monitoring and what observations were made. However, IPP must verify the recordkeeping requirements prior to completion of the task.

IPP should be aware that there are times the responsible establishment employee might not be able to propose permanent preventive measures immediately. However, in these situations, the establishment should propose a tentative preventative measure of what they will do until they determine a permanent solution.

Frequencies for Performing the Sanitation SOP Verification Tasks

IPP are to perform pre-operational and operational Sanitation SOP verification tasks at frequencies scheduled by PHIS or an adjusted frequency based on relevant information (e.g. a developing trend of noncompliance). IPP are to:

1. perform two pre-operational Sanitation SOP verifications per week at each establishment in an assignment, including one Pre-Op SSOP Review and Observation and one Pre-Op SSOP Record Review task. These two pre-operational tasks are to be performed at an approximately equal amount;

2. perform one operational Sanitation SOP verification task at each establishment in an assignment during each shift – either an Operational SSOP Review and Observation or Operational SSOP Records Review task. These two operational tasks are to be performed at an approximately equal amount; and

3. perform "inspector directed" Sanitation SOP verification tasks as warranted by conditions observed at the establishment. For example: During the performance of other verification tasks unrelated to sanitation, if inspection personnel observe insanitary conditions, they are to perform an Operational SSOP Review and Observation verification task. IPP are also to perform Sanitation SOP tasks as directed by their supervisor.

In patrol assignments, there are times when inspection personnel cannot perform the Pre-Op SSOP Review and Observation task in each establishment once per week due to simultaneous start times or having more than five establishments on the patrol. In such cases, IPP are to use good judgment and their knowledge of the establishments' compliance histories with sanitation requirements to decide where and when to do Pre-Op Sanitation SOP verification tasks.

When an establishment operates on Saturdays, Sundays, and holidays, IPP are to conduct pre-operational and operational sanitation tasks in the same manner and frequency as they do during the week. Whenever IPP performed a task on reimbursable overtime, IPP are to check the appropriate box on the task's Activity tab to document this fact.

We will now cover each of the Sanitation SOP regulatory requirements in more detail.

IMPLEMENTATION AND MONITORING

§416.13 Implementation (Monitoring) Requirement

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 Sanitation SOPs. If the establishment writes a procedure in its Sanitation SOP, 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

IPP should verify that the establishment is meeting these regulatory requirements by performing the recordkeeping, and the review and observation task.

When verifying the implementation requirement while performing the pre-operational Sanitation SOP task, IPP 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 verifying the implementation requirement while performing the operational Sanitation SOP task, IPP are verifying that the establishment is implementing the procedures that will be conducted during operations.

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

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

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

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

- Does the Sanitation SOP contain monitoring frequencies?

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

3. Environmental Sampling

There are no regulatory requirements to include environmental sampling in an establishment's Sanitation SOP. However, if environmental sampling is included in the Sanitation SOP, IPP should verify that the establishment is following those procedures. IPP should observe the establishment collecting samples, review sample results, and verify that the corrective actions specified in the Sanitation SOP are taken when necessary. The verification should be completed as part of the Sanitation SOP review & observation task. If the establishment is conducting environmental testing but the procedures are not included in the Sanitation SOP, IPP will review the establishment's testing results weekly as described in FSIS Directive 5000.2. Information gathered from such testing results should be used in the IPP's thought process for selecting the areas and equipment examined and the extent of inspection (i.e., how much equipment and several areas) during the Operational Sanitation SOP review and observation task in establishments that process meat and poultry products.

Examples of Implementation and Monitoring Noncompliance:

An establishment has a Sanitation SOP 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 food contact surfaces. These procedures will be conducted daily prior to operation. QA personnel will monitor all equipment with food contact surfaces for acceptability daily prior to operations.

  -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 IPP finds a contaminated food contact surface during pre-op inspection, there is noncompliance with §416.13(a)

- 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. QA personnel will monitor the product reconditioning procedure twice a day.

  -If the IPP finds that product is not promptly removed from the floor and properly reconditioned, there is noncompliance with §416.13(b).

  -If the establishment is not monitoring the product reconditioning procedure twice during the day, there is noncompliance with §416.13(c).

- A production employee will observe all overheads in product storage areas and remove condensation as necessary during operation. QA personnel will monitor the procedure designed to prevent condensation from contaminating product.

  -If the IPP finds condensate dripping on product, there is noncompliance with §416.13(b).

  -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 procedure designed to control condensation daily, there is noncompliance with §416.13(c)

WORKSHOP #2: Monitoring

Objective: Given a scenario, identify any noncompliance, the relevant regulations, and the actions you would take in response to your findings.

In-plant scenario
You are performing a Pre-Operational Sanitation SOP Review and Observation task. 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 perform the review portion of the task by going back to the band saw and opening the door to the cabinet. You observe that the rest of the saw blade, as well as the inside of the cabinet, has meat and fat particles, and bone dust, adhering to the direct and indirect food contact surfaces.

1.) Based on your observations, list your concerns?

2.) List the actions that you would take?

3.) Is there a Sanitation SOP noncompliance? If yes, describe the noncompliance(s) and the relevant regulation(s).

4.) Would you issue an NR? If so, what specific language would you include in the noncompliance description?

MAINTENANCE

§416.14 Maintenance Requirement

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

Before federally inspected meat or poultry establishments are permitted to operate, they must develop Sanitation SOPs 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 Sanitation SOPs 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 Sanitation SOPs once they are implemented.

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

Although establishments must identify the members of their management team who will be responsible for implementation and evaluation of their Sanitation SOPs, they are not required to identify the method the individuals employ to perform the evaluations. The regulation only requires that establishments perform an evaluation of the effectiveness of their Sanitation SOPs; it does not dictate how establishments should perform this evaluation. The establishment must sign and date the Sanitation SOPs any time modifications are made. However, there is no regulatory requirement that the establishment personnel should notify FSIS inspection personnel of the change.

It is also a responsibility of the establishments to revise their Sanitation SOPs 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 Sanitation SOP. However, the methodologies used to evaluate their

Sanitation SOPs and to determine their effectiveness do not need to be recorded. If the establishment determines the Sanitation SOPs are no longer effective and current, the Sanitation SOPs must be revised.

2. Inspection Verification

FSIS is responsible for verifying the establishment meets the maintenance regulatory requirements. IPP should verify this requirement while performing the Pre-Operational and Operational Sanitation SOP tasks. When verifying this requirement, IPP must understand that IPP should review the establishment's Sanitation SOP records and NRs over a period of time to determine whether this requirement is met. Just because IPP find an unclean food contact surface while performing the review and observation task for pre-operational sanitation does not mean that the establishment needs to evaluate the effectiveness of the Sanitation SOPs.

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

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

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

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

- Does the establishment routinely review the Sanitation SOP records to determine if there are trends occurring indicating that the Sanitation SOP needs revising?

NOTE: In addition to determining if the establishment has met the maintenance requirement, information gathered from reviewing the establishment's Sanitation SOP records and NRs may be used in the thought process for selecting the

areas and equipment examined and the extent of inspection (i.e., how much equipment and how many areas) during the Pre-Operational Review and Observation task in establishments that process meat and poultry products. For instance, IPP could determine from the Sanitation SOP records and NRs which processing areas or rooms and equipment are typically found to be unclean and if noncompliances are increasing during pre-op verification.

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

Example of Maintenance Compliance

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 Sanitation SOP. Data used in this evaluation may consist of the different Sanitation SOP 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 direct food contact zones addressed by the Sanitation SOP. They will identify instances within these documents where the implementation of the Sanitation SOP 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 Sanitation SOP.

Example Noncompliance with the Maintenance Regulatory Requirement

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

CORRECTIVE ACTION

§416.15 Corrective Action Requirement

(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 **Sanitation SOPs 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 product contamination occurs. The corrective actions also include appropriate disposition of product.

NOTE: Most of the time product will not be involved during pre-operational sanitation monitoring. When the establishment finds direct food contact surfaces that are unclean during its monitoring of pre-operational sanitation and cleans the surfaces before product passes over that surface, this is compliance. In these situations, FSIS believes the establishment's Sanitation SOP has worked as intended. Implementing and documenting preventative measures are not required.

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(b). The establishment should take full responsibility for the corrective actions meeting the three requirements of the regulation. 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.

Reconditioning Product

Although there is no regulatory requirement, establishments may have a procedure in its Sanitation SOPs for reconditioning product that incidentally comes in contact with a non-food contact surface (such as the floor). The procedure usually consists of the following steps; an establishment employee 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. This procedure is used for 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 reconditioning procedure in its Sanitation SOP, it would be required to take and document corrective actions that meet the requirements of §416.15 each time product falls on the floor.

2. Inspection Verification

IPP should verify this regulatory requirement when performing the Sanitation SOP verification tasks. Every time the establishment implements corrective actions due to product contamination, IPP should verify that the regulatory requirements in §416.15 are met. IPP can verify this requirement by performing any of the verification tasks. When performing the Pre-Operational Sanitation SOP Record Review task, IPP should request the daily pre-operational sanitation records that they want to review. IPP should review the monitoring records to determine if the establishment documented occasions in which product was contaminated. If there is documentation showing the establishment had found product contamination during pre-operational monitoring, there should also be documentation of the corrective actions taken for these situations. IPP should review these corrective actions and compare them to the regulatory requirements to verify that they have been met. Did the establishment have adequate documentation to demonstrate appropriate disposition of the affected product? 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?

When performing the Operational Sanitation SOP Record Review task, IPP should request from the establishment the daily operational sanitation records that they want to review. IPP should review the monitoring records to determine if there were instances of direct food contact surfaces or product being contaminated. If there is documentation showing the establishment had found a contaminated food contact surface that had contacted product or product contamination during the operational monitoring, there should also be

documentation of the corrective actions taken for these situations. IPP should review these corrective actions and compare them to the regulatory requirements to verify that they have been met. Did the establishment have adequate documentation to demonstrate appropriate disposition of the affected product? 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?

When IPP are performing the Pre-Operational Sanitation SOP Review and Observation task and find direct food contact surfaces that are contaminated, IPP should take a regulatory control action on the piece or pieces of equipment. There is an insanitary condition which is noncompliance with §416.13(a). In most cases product is not coming into contact with equipment surfaces during pre-operational sanitation inspection. The establishment must clean the surface (re-establish sanitary conditions) and document the restoration of sanitary conditions according to §416.16(a). FSIS would expect the establishment to consider how to make appropriate improvements in the execution of its pre-operational procedures because the establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions as stated in §416.1. However, establishing and documenting preventive measures **are not** required.

If IPP are observing the establishment performing the monitoring as part of the Pre-Operational Sanitation SOP Review and Observation task and the monitor finds a contaminated food contact surface, this provides an opportunity for IPP to observe the establishment implementing actions to restore sanitary conditions.

When IPP are performing the Operational Sanitation SOP Review and Observation task and find direct food contact surfaces or product that is contaminated, IPP should take a regulatory control action of that equipment or product. IPP should keep that control action in place until the establishment has given IPP 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 establishment proposes corrective actions that will meet these requirements. This also provides IPP the opportunity to verify that the establishment implements the corrective actions that they proposed. IPP should also verify that the corrective actions they document are the same as those they implemented.

If IPP are observing the establishment performing the monitoring as part of the Operational Sanitation SOP Review and Observation task and the monitor finds a food contact surface or product contaminated, this provides an opportunity for IPP to observe the establishment implementing the corrective actions. IPP can observe the establishment taking actions that restore sanitary conditions. IPP

can observe the establishment to verify that they make appropriate disposition of product. If they put preventive measures in place immediately, IPP can verify these preventive measures.

NOTE: IPP 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 IPP 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 IPP that they will have a meeting with top management. This should be documented on the Sanitation SOP records. After the meeting, when the preventive measures have been decided, the establishment needs to document those preventive measures in the Sanitation SOP records.

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 establishment 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 establishment records. You should keep notes of your findings while performing this verification task so that you can accurately document them on the NR.

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

- When FSIS or the establishment determines that the Sanitation SOPs 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?

- When FSIS or the establishment determines that the Sanitation SOPs 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 Sanitation SOPs fail to prevent the direct contamination or other adulteration of product during

operation, does the establishment implement corrective actions that prevent recurrence?

- Do the corrective actions include the reevaluation and modification of the Sanitation SOPs or improvements in the execution of the procedures when trends are occurring?

NOTE: If the establishment is monitoring the pre-operational sanitation procedures, finding unclean food contact surfaces, and taking actions to restore sanitary conditions, and IPP **are not** finding direct food contact surfaces unacceptable, the establishment is in compliance with the regulations. Now, IPP should focus on whether the establishment is making improvements to the execution of its pre-operational sanitation procedures sufficient to prevent the creation of insanitary conditions and preventing direct contamination or adulteration of product. The requirement for preventive measures only applies when the Sanitation SOP fails to prevent direct contamination or adulteration of product. However, when IPP find unclean food contact surfaces during pre-operational sanitation inspection or direct contamination or adulteration of product during operations, IPP should take a regulatory control action. The regulatory control action should not be relinquished until the establishment has cleaned the food contact surface or taken corrective actions in §416.15 for contaminated product including proposing an **acceptable** preventive measure. The IPP should not accept the same preventive measures previously proposed by the establishment, if those preventative measures were ineffective in preventing recurrence.

NOTE: If the establishment finds direct contamination or adulteration of product and takes appropriate corrective actions as per §416.15(b), then there is no need to initiate a regulatory control action or document an NR. These corrective actions include restoring sanitary conditions, making appropriate disposition of product, and implementing measures to prevent recurrence. If the establishment finds a contaminated food contact surface during preoperational sanitation inspection and cleans and sanitizes the surface before product goes across that surface, then there is no need to initiate a regulatory control action or document an NR.

Examples of Noncompliance

- You are performing an Operational Sanitation SOP review and observation task on Friday morning. At 8:00 a.m., you observe an entry on the operational sanitation monitoring record. At 7:30 a.m., the monitor documented that he observed rail dust from the overhead rails on carcasses hanging in the cooler #1. You decide that this may be a good opportunity to verify the corrective action requirement by actually observing the establishment's corrective actions. You proceed to cooler #1. You observe two employees examining carcasses on the rail in the hallway outside of cooler #1. You remain in the area and observe the establishment's reconditioning of a few carcasses. After examining and trimming the contamination off the carcasses, the employees placed the trimmed carcasses in cooler #2. You notice an establishment hold tag on the door to cooler #1. You open the door to the cooler and see that there are no carcasses stored in the cooler. Monday morning you review the establishment's corrective action record. You find the following information documented. "Establishment employees examined all carcasses in cooler #1 and trimmed any visible contamination off the affected carcasses. We moved the carcasses that were not contaminated and the trimmed carcasses to cooler #2". In the preventive measure section, you find the following documented. "We cleaned the rails over the weekend".

  This is noncompliance with §416.15(b) because the establishment did not implement measures that would prevent product contamination from recurring.

- In another example, you are performing the Operational Sanitation SOP record review task 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 #3: Corrective Actions

Objective: To verify and evaluate the establishment's corrective actions

PHIS Task: Routine Operational SSOP Review & Observation Task

A. **FSIS finding**: In the second processing department, you observed two establishment employees pick up five poultry carcasses off the floor and place them onto the moving sizing belt which is a food contact surface. The contaminated carcasses were placed on top of 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 NR for a monitoring noncompliance using an Operational Sanitation SOP Review and Observation task.

Establishment'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 Sanitation SOP monitoring checks will be performed for the next two months to assure that the training for sizing belt personnel is effective.

1) Did the establishment restore sanitary conditions? If yes, please briefly describe what the establishment did.

2) Did the establishment put measures in place to prevent recurrence of direct contamination or adulteration of product? If yes, please list.

3) Did the establishment appropriately disposition the product?

4) Do these corrective actions meet the regulatory requirements? If not, what regulation should be cited on the NR?

B. **FSIS finding**: The Sanitation SOP 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 Operational Sanitation SOP Review and Observation task and you note that several pieces of meat have fallen on the floor. All pieces of product were picked up immediately by an establishment employee and placed in the bottom of the meat wash sink. You continue to observe and 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 for monitoring noncompliance.

Establishment'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 Sanitation SOP 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.

5) Did the establishment restore sanitary conditions? If yes, please briefly describe what the establishment did.

6) Did the establishment put measures in place to prevent recurrence of direct contamination or adulteration of product? If yes, please list.

7) Did the establishment appropriately disposition the product?

8) Do these corrective actions meet the regulatory requirements? If not, what regulation should be cited on the NR?

RECORDKEEPING

§416.16 Recordkeeping Requirement

(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 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(a) requires the establishment to maintain **daily** records sufficient to document the implementation and monitoring of the Sanitation SOPs 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 Sanitation SOPs. If the establishment has specified a monitoring frequency in the Sanitation SOP 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 Sanitation SOPs as being responsible for the implementation and monitoring of the procedures shall authenticate these records with initials or signature and the date.

There must also be a written record of any corrective actions required by §416.15. These records must be maintained daily.

Note: The establishment has until the beginning of the same shift the next business day to complete SSOP 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.

§416.16(c) states that 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

IPP should perform the Pre-Operational Sanitation SOP Record Review task when verifying compliance with the pre-operational sanitation recordkeeping requirements and Operational Sanitation SOP Record Review task when verifying compliance with the operational sanitation recordkeeping requirements. IPP should verify that these daily records contain:

- Documentation of the monitoring of the Sanitation SOPs;
- Documentation of any corrective actions taken; and
- Authentication (initials or signature of responsible person and the date).

IPP should also verify that:

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

Some of the questions that IPP need to consider when evaluating the establishment's records are listed below. As in all the other evaluations of the establishment's Sanitation SOP system, IPP will need to be very familiar with exactly what the Sanitation SOP says in relation to the records they are keeping. In addition to knowing what is in the Sanitation SOP, IPP will also need to understand the regulatory aspect of recordkeeping.

- Are the Sanitation SOP records available to FSIS upon request?
- Are the records completed prior to the start of the same shift the next operating day?
- Are the records completed in the manner specified in the Sanitation SOP?
- Are the records' entries legible?

- Was all monitoring done and recorded at the prescribed frequency?
- Are the records initialed or signed and dated?

WORKSHOP #4: Recordkeeping

Objective: Verification of compliance with Recordkeeping

PHIS Task: Operational SSOP Record Review task

A. You elect to perform Operational Sanitation SOP Record Review task in the QC office at the beginning of your shift. You ask the QC manager for the Sanitation SOP records from yesterday. The QC manager tells you that the records are completed but 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?

Documentation and Enforcement

After completing a SSOP verification task, IPP are to use PHIS to document findings of compliance or noncompliance.

If the establishment is in compliance with all Sanitation SOP regulatory requirements, IPP will mark the regulations that were verified and check the "Inspection Completed" box.

When IPP determine that an establishment does not meet one of the regulatory requirements in 9 CFR §416.11 through §416.16, IPP should immediately notify the establishment's management about the Sanitation SOP noncompliance and take a regulatory control action, if one is necessary. IPP will need to document the findings of the Sanitation SOP noncompliance on a Noncompliance Record (NR), FSIS Form 5400-4.

When IPP become aware that an establishment was required to take corrective actions per 9 CFR 416.15, IPP must verify that the establishment met the requirement and document in PHIS that they verified the requirements.

When IPP observe contamination of product or direct food contact surfaces during an Operational Sanitation SOP verification task, they are to take a regulatory control action on the affected equipment or product. IPP are to remove the regulatory control action only after the establishment has taken corrective actions that 1) ensure appropriate disposition of products, and 2) restore sanitary conditions, and at least proposed 3) prevent recurrence of direct contamination or adulteration of products.

When IPP observe contamination of direct food contact surfaces during a Pre-Operational Sanitation SOP verification task, they are to take a regulatory control action on the affected equipment. During pre-operational sanitation, there should be no affected product. IPP are to remove the regulatory control action only after the establishment has restored sanitary conditions

If the establishment has found the contaminated contact surface or product and taken the corrective actions required, there is no noncompliance. IPP are to verify that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces.

When IPP observe Sanitation SOP noncompliance that does not result in contamination of product or food contact surfaces (e.g. failure to initial records), they are not to take a regulatory control action.

If IPP observe **both** Sanitation SOP and SPS noncompliance while performing a Sanitation SOP verification task, they document both noncompliances on a single

Sanitation SOP NR by recording a result of noncompliance for each applicable regulatory citation.

***EXAMPLE**: While performing the Pre-Op Sanitation SOP Review and Observation verification task in the fabrication department, IPP observe product residue and grease on several meat hooks, in addition to fat particles and hog hair from the previous days' production on the wall behind the dehairing machine. IPP are to document each noncompliance and cite §416.13(a) and §416.2(b) under the Pre-Op Sanitation SOP Review and Observation verification task and record the result on a single NR.*

If IPP observe **only** SPS noncompliance while performing a Pre-Op Sanitation SOP verification task, record the noncompliance under the task being performed at the time of the observation. In this example, the noncompliance would be documented under a Pre-Op Sanitation SOP task even though the regulatory citation is an SPS regulation.

NOTE: If IPP determine that a Sanitation SOP noncompliance represents a systematic or repetitive failure by the establishment to prevent product contamination or maintain sanitary conditions, they are to document noncompliance with 9 CFR 416.1 in addition to the applicable Sanitation SOP regulation.

Application of the Rules of Practice

The Rules of Practice regulations describe the enforcement actions that can be taken if establishments do not meet regulatory requirements. Sections 500.3 and 500.4 of the Rules of Practice regulations describe the enforcement actions that can be imposed on an establishment when the Sanitation SOP 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 Sanitation SOP does not prevent contaminated or adulterated product from being produced and shipped, IPP 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 IPP should take an immediate withholding action. When contaminated or adulterated product has been produced and shipped, IPP are not required to notify the establishment in advance that IPP are taking the withholding action. FSIS will provide the establishment written notification later. An NR is written documentation of the noncompliance. The District Office will review the circumstances and advise the FLS or IIC on how to proceed when further enforcement actions are necessary.

2. Failure to meet the design regulatory requirements

   Before inspection is granted, the establishment must have developed a written Sanitation SOP that meets the requirements of §416.11-416.12. However, if an existing establishment modifies its Sanitation SOP or fails to maintain the Sanitation SOP such that it no longer meets the basic design requirements, IPP should notify the establishment about the noncompliance and contact their supervisor regarding possible enforcement 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 Sanitation SOP failures

   This means that IPP must have adequate documentation to support the determination that the Sanitation SOPs have repeatedly not been implemented and maintained to be effective in preventing direct contamination or adulteration of product. It is not necessary for IPP to determine that contaminated or adulterated product has been shipped to impose the enforcement actions described in §500.4. It is necessary that IPP have adequate documentation to demonstrate that the establishment is unable to prevent repeated failures of the Sanitation SOPs. There are two reasons why Sanitation SOP failures can occur. (1) Either the Sanitation SOP is not designed adequately to prevent contamination or adulteration of product, or (2) the Sanitation SOPs are not properly implemented.

   IPP must associate the Sanitation SOP failures to the same cause identified within the NRs generated at the establishment. For this reason, accurate documentation is very important. Each associated NR should reference the previous NR number, the NR date, and list the specific preventive measures that were not implemented or were ineffective in preventing the recurrence of the Sanitation SOP failures.

   When IPP determine there is adequate documentation to support an

enforcement action as specified in §500.4, IPP should contact the District Office, via supervisory channels, and request the assistance of an EIAO for the issuance of a Notice of Intended Enforcement action (NOIE). There is no specific number of NRs required for the issuance of an NOIE, but their documentation should support their requested enforcement action. Based on the EIAO's recommendations, the District Office will issue the Notice of Intended Enforcement action to the establishment.

Noncompliance Documentation Summary Exercise

Read each scenario. Identify the appropriate PHIS task under which the noncompliance(s) would be documented and the noncompliant regulations.

1. Before the start of operations, two inoperable sets of lights over the blender prevent you from being able to verify that food contact surfaces are sanitary. The quality of the lighting is not of sufficient intensity to conduct inspection activities. These are the only lights in the blender area. You reject the area until the establishment repairs the lights. Then you observe product residue from previous days' production on the mixing arms of the blender. You reject the blender until sanitary conditions are restored.

2. During operations, you observe condensation dripping on carcasses in the carcass cooler. You reject the cooler, retain affected carcasses, and notify establishment management. The establishment is able to demonstrate there is no food safety hazard associated with the contamination.

3. While performing the Pre-Operational Review and Observation task, you observe a rough, uneven weld with crevices that connects one of the agitating paddles to the shaft of a vertical mixer ready for use in the sausage room. Upon further examination, you also find an accumulation of product residue stuck in the crevices in the weld. You reject the mixer and notify management. The establishment is able to demonstrate there is no food safety hazard associated with the contamination.

4. While passing through the fabrication department to perform an SPS task, you observe 5 specks of a black substance on a piece of meat on the cutting table and 20 more specks on the table surface. Further inspection revealed a very heavy accumulation of grease and dust on an overhead pipe. You reject the area, retain the product, and notify management. The establishment is able to demonstrate there is no food safety hazard associated with the black substance.

5. While performing a routine Operational SSOP Review and Observation task in the carcass cooler, you observe a rail with an accumulation of rust on it. Beef sides are stored directly under the rusted area on the rail. You examine the hock and round area of several sides of beef. You find numerous black specks on four sides of beef.

6. While performing a HACCP verification task, you observe an employee prepare a pickle solution by adding salt from 50 pound bags to a vat of water. You note that he did not strip the outer layer of the bag before placing the bag over the edge of the vat, and you decide to examine the solution. You find extraneous material (lint, dust, debris, etc.) floating on top of the pickle solution. You reject the pickle solution tank and notify management.

7. While passing through a processing area to conduct a HACCP verification task, you observe an employee lift cartons of frozen beef trimmings from the floor, open them, and touch exposed surfaces of the beef trimmings without washing his hands. You retain the product and notify management. The establishment is able to demonstrate that there is no food safety hazard associated with the contamination. After management proposes adequate corrective actions, you remove the tag, and verify corrective actions.

8. Before operations, you observe an employee using a pesticide to fog the processing area. The processing area also has equipment with food contact surfaces and packaging materials that are exposed to the pesticide. You determine the pesticide used and examine the label which states the pesticide is not approved for use in food processing areas. You immediately notify establishment management and verify their corrective actions.

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.