

08 Sanitation Standard Operating Procedures (SSOP)

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.

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).

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.

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.

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.

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**.

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.

IPP will verify that establishments meet **all four** of the following regulatory requirements during the performance of each SSOP task:

- a. Implementation and monitoring
- b. Maintenance
- c. Corrective actions
- d. Recordkeeping

The following table lists the 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.

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 §416.1.
- 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.

- 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.

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

- 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.

Note: Recommend having a good flashlight to check dark areas or inside pipes/equipment.

Pre-Op Sanitation SOP Review and Observation Task

- 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.
- 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).
- 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 by placing a reject tag;
 - **Notify** the establishment, and
 - **Document** the noncompliance on NR.
- 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 U.S. Rejected tag until the establishment has restored sanitary conditions.

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.
- IPP should observe the equipment, employees, and facilities to verify that product contamination is not occurring during operation.
- 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.
- 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.

- 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.

WORKSHOP #1- Identifying the Basic Elements of the SSOPs
Examples of Pre-Op and Operations SSOPs *Training Purposes Only*

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, 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, 12/11/2018)*
- 2. (signature and date of Joe Green, 6/17/2019)*

WORKSHOP #1- Identifying the Basic Elements

Objective: Verification of compliance with the basic development of SSOPs
For Training Purposes Only

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?			