Sanitation Standard Operating Procedures

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. The establishment is required 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.

These written Sanitation SOPs must contain the procedures the establishment will conduct before and during operation; the frequency with which each procedure is to be conducted; the establishment employee or position responsible and be signed and dated by the individual with overall authority.

FSIS developed the Sanitation SOP model for establishments to use as a reference when developing Sanitation SOPs. The model was designed to assist establishments in applying the sanitation requirements to their operations and to meet the regulatory requirements of Part 416—Sanitation. The sanitation model is not intended to be used "as is" for industry Sanitation SOPs.

Sanitation SOPs will vary from one establishment to another because each facility will have its own processes that likely differ from that of another. An establishment must tailor the model to suit the specific circumstances of its own products, production processes and facilities. All elements of the model (e.g., frequencies, monitoring activities, corrective actions, and forms) must be modified (elements added or removed) to reflect the establishment's products, production systems and facilities.

This Sanitation SOP is for illustrative purposes only.

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A Sanitation Standard Operating Procedure Model

This document provides an overview of the Sanitation Standard Operating Procedures (Sanitation SOPs) requirements, a Sanitation SOP model[1] (Attachment 1), and the complete text of the regulations cited in the document (Attachment 2).

This information is to assist small and very small official establishments[2] in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Parts 416.11 – 416.17.[3] The Sanitation SOP model is for demonstration purposes only. The model demonstrates a way an establishment might develop Sanitation SOPs to meet the regulatory requirements of 9 CFR 416.11 – 416.17.

The text and formatting used in the model do not represent requirements that must be met. The use of headings, numbered lists, and tables (forms) are not requirements that must be met. Establishments are required to develop Sanitation SOPs specific to their facilities, production practices, and products.[4]

Sanitation SOPs (9 CFR 416—Sanitation)

Sanitation SOPs are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product (9 CFR 416.11 General Rules). The establishment is required to maintain these written procedures on file, and they must be available to Food Safety and Inspection Service (FSIS) personnel upon request.

The establishment is required to implement the procedures as written in their Sanitation SOPs. The establishment must maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs as well as 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

The establishment is required to develop written Sanitation SOPs that clearly describe procedures the establishment will implement to prevent direct contamination or adulteration of product. The Sanitation SOPs cover the entire establishment and all shifts of operation.

These written procedures[5] must:

- contain all the procedures the establishment will conduct daily, before and during operation, sufficient to prevent direct contamination or adulteration of product(s) (9 CFR 416.12(a));

[1] The model presents Sanitation SOPs for Establishment Grounds and Facilities (9 CFR 416.2), Equipment and Utensils (9 CFR 416.3), Sanitary operations (9 CFR 416.4) and Employee hygiene (9 CFR 416.5).
[2] As stated in the HACCP rule, small establishments are defined as all establishments with 10 or more employees but fewer than 500 employees. Very small establishments are defined as all establishments with fewer than 10 employees or annual sales of less than $2.5 million.
[3] The links to the CFR on pages 1, 2 and 3 take the user to Attachment 2.
[4] To ask questions or find posted Qs and As on these topics, see these external links: askFSIS Q&As and the Small Plant Help Desk.
[5] See public askFSIS Q&As on 9 CFR Part 416.12 requirements.

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- identify the procedures to be conducted prior to operations (pre-operational) and address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils (9 CFR 416.12(c));
- 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 (9 CFR 416.12(d)); and
- 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 of the regulation (9 CFR 416.12(b)).

Implementation and Monitoring the Sanitation SOPs

Establishments are required to develop written procedures that are sufficient to prevent direct contamination or adulteration of product. The establishment is also required to implement the procedures in its written Sanitation SOPs (9 CFR 416.13). The pre-operational procedures in the Sanitation SOPs are conducted before the start of operations (9 CFR 416.13(a)). All other written procedures are conducted at the frequencies specified in the Sanitation SOPs (9 CFR 416.13(b)). In addition, establishments are required to monitor daily the implementation of the procedures in the Sanitation SOPs (9 CFR 416.13(c)). If the establishment writes a procedure in its Sanitation SOP, the regulations require that it implement that procedure at the stated frequency and monitor its implementation.

Maintenance of the Sanitation SOPs

Each establishment must meet two obligations to comply with the requirements for Sanitation SOP maintenance (9 CFR 416.14). First, the establishment is required to routinely evaluate the effectiveness of all Sanitation SOPs that have been implemented in their production operations. Second, the establishment is required to revise its Sanitation SOPs as needed to maintain effectiveness and to address any changes that have occurred including changes in facilities, equipment, utensils, operations, or personnel.[6]

Establishments are not required to record the methods used to evaluate their Sanitation SOPs and determine their effectiveness. If the establishment determines the Sanitation SOPs are no longer effective and current, they must be modified, signed, and dated. This regulatory requirement encourages establishments to develop a system for the evaluation of their written Sanitation SOPs to prevent direct contamination or adulteration of product.

Establishments must identify the employees who are responsible for the implementation and maintenance of their Sanitation SOP procedures (9 CFR 416.12(d)). The establishment is required to identify the frequency with which each procedure is conducted by those employees. The establishment must sign and date the Sanitation SOPs when first created and any time modifications are made (9 CFR 416.12(b)). There are no regulatory requirements for establishment personnel to notify FSIS of any change to their SOPs.

[6] See askFSIS Q&As for information on maintenance of Sanitation SOPs.

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Corrective Actions

The regulations require establishments to take corrective actions when either the establishment or FSIS determines that the Sanitation SOPs failed to prevent direct contamination or adulteration of product (9 CFR 416.15(b)). Regardless of the type or cause of the failure, corrective actions must be taken, including appropriate disposition of product.[7]

There are three parts to corrective action, and all three of these requirements must be met and recorded each time product contamination occurs (9 CFR 416.15). One common exception to recording corrective actions individually for each incident of product contamination is when the establishment has an effective product reconditioning program in the operational Sanitation SOP. With such a reconditioning program, they do not need to document each incident of direct contamination of product individually. Inspection personnel will verify that the establishment implements these overarching procedures effectively, including the use of, effective[8] procedures to restore products to wholesome, unadulterated conditions.

The establishment is not required to notify inspection personnel when product contamination occurs. The establishment is required to implement corrective actions that will meet the requirements (9 CFR 416.15(b)). Corrective action requirements under these regulations are:

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

Re-evaluating and modifying the Sanitation SOPs and the specific procedures to which they refer is considered a corrective action. Improvements relating to the implementation of the Sanitation SOPs or the procedures to which they refer are also considered corrective actions.

Recordkeeping

The regulations require the establishment to maintain daily records (9 CFR 416.16(a)) sufficient to document the implementation and monitoring of the Sanitation SOPs as well as any corrective actions taken.[9] To meet these requirements, the establishment must have records documenting that monitoring has been conducted daily for each of the procedures specified in the Sanitation SOPs.

When Sanitation SOP monitoring frequencies are more than once per day, the monitoring activities must be documented at the specified frequencies. The regulations require that the establishment follow the specified monitoring frequency established in the Sanitation SOP. The establishment employee specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedures is required to authenticate these records with initials or signature and the date (9 CFR 416.16(a)).

Records may be maintained on a computer system provided the establishment implements

[7] See askFSIS Q&As for information on Corrective Actions.
[8] Establishments must provide supporting information when a prerequisite program becomes part of the HACCP system. See page 16 of the FSIS Compliance Guideline HACCP Systems Validation guide for how to identify support for prerequisite programs.
[9] See askFSIS Q&As for information on Recordkeeping.

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appropriate controls to ensure the integrity of the electronic data (9 CFR 416.16(b)). Records regarding the implementation of any corrective action must be kept on-site for a period of 48 hours once completed. After 48 hours, the records may be kept off-site but must be made readily available to FSIS within 24 hours of original request. Sanitation SOP records must be maintained for at least 6 months.[10] (9 CFR 416.16(c)).

[1] Electronic records may be kept on an in-house computer or remote server for the first 48 hours. The electronic records must be readily available to FSIS during the 48 hour period.

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Attachment 1

FSIS developed the Sanitation SOP model for establishments to use as a reference when developing their own Sanitation SOPs. Sanitation SOPs will vary from one establishment to another because each facility will have its own processes that likely differ from that of another. The Sanitation SOP model addresses the sanitation concerns for a fictional company. An establishment must tailor the model to suit the specific circumstances of its own products, production processes and facilities. All elements of the model (e.g., frequencies, monitoring activities, corrective actions, and forms) must be modified (elements added or removed) to reflect the establishment's actual products, production systems and facilities.

This Sanitation SOP is for illustrative purposes only.

Model – Sanitation SOP[11]

XYZ Meat Packers, Inc. is a red meat processing establishment. This plant receives beef and pork for further processing. This facility cuts, grinds, and packages product.

Owner – Signature: _____ Date: _____

Plant Manager -

Team Captains –

The Team Captains or their designees are responsible for implementing and daily monitoring of Sanitation SOPs and recording the findings and any corrective actions. The Team Captains are responsible for training and assigning specific duties to other employees and monitoring the employees' performance within the Sanitation SOPs. All records, data, checklists, and other information pertaining to the Sanitation SOPs is maintained on file and made available to inspection personnel.

Pre-operational Sanitation – Equipment and Facility Cleaning Objective

All equipment is disassembled, cleaned, and sanitized before starting production

Establishment sanitary procedure for cleaning and sanitizing equipment

a. Product debris is removed from all equipment.
b. Equipment is rinsed with water to remove remaining debris.
c. An approved cleaner is applied to equipment and properly cleaned.
d. The equipment is reassembled.
e. Equipment is sanitized with approved sanitizer and rinsed with potable water if appropriate.

Implementing, Monitoring and Recordkeeping

Team Captains perform daily organoleptic sanitation examination after pre-operational equipment cleaning and just before sanitizing and before operations

[11]This information is to assist small and very small establishments in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Parts 416.11 – 416.17. The Sanitation SOP model is for demonstration purposes only. Establishments are required to develop Sanitation SOPs specific to their facilities, production practices, and products.

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begin. The results are recorded on the establishment's Pre-operational Sanitation Form. If found to be acceptable, the appropriate line is checked on the form. If found unacceptable, actions taken to restore sanitary conditions is documented on the Pre-operational Sanitation Form.

Corrective Actions

When the Team Captains determine that the equipment does not pass organoleptic examination, the cleaning procedure and inspections are repeated. The Team Captains monitor the cleaning of the equipment and retrain employees if necessary. Corrective actions are recorded on the establishment's Corrective Action Log.

Cleaning of Facilities including floors, walls, and ceilings

Cleaning procedures

1. Debris is swept up and discarded.
2. Facilities are rinsed with potable water.
3. Facilities are cleaned with approved cleaner.
4. Facilities are rinsed with potable water.

Cleaning of floors, ceilings, and walls is done at the end of each production day and when needed to maintain sanitary conditions.

Establishment monitoring

The Team Captain performs daily organoleptic examination before operations begin. Results are recorded on the establishment's Pre-operational Sanitation Form.

Corrective action

When the Team Captain finds that the facilities do not pass organoleptic examination, the cleaning procedures and inspections are repeated. The Team Captain examines the cleaning of the facilities and retrains employees as needed. Corrective actions to prevent direct product contamination or adulteration are recorded on a Corrective Action Log.

Operational Sanitation—Equipment and Facility Cleaning Objective

Processing is performed under sanitary conditions to prevent direct and cross-contamination of the product

Sanitary procedures for processing

1. Employees clean and sanitize hands, gloves, knives, other hand tools, cutting boards, etc., as necessary during processing to prevent the creation of insanitary conditions and the contamination of products.
2. All equipment tables and other product contact surfaces are cleaned and sanitized throughout the day as needed to maintain sanitary conditions and protect the product.

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3. Outer garments such as aprons, boots, and gloves are hung in designated areas when employees leave processing areas. Outer garments are maintained in a clean and sanitary manner and are changed at least daily and more often if necessary.
4. At the midday break: major solids are physically removed from floors, equipment, and food contact surfaces. Equipment is disassembled as required for adequate cleaning. All surfaces are rinsed with cold water. Equipment is sanitized with approved sanitizer and rinsed with potable water as appropriate.
5. At the end of the shift: major solids are physically removed from floors, equipment, and food contact surfaces. Equipment is disassembled as required for adequate cleaning. All surfaces are rinsed with cold water.
6. Administrative personnel wear smocks and waterproof boots when in processing areas. Smocks are laundered in-house as needed. Maintenance workers wear gray uniforms and waterproof boots. Maintenance uniforms are laundered in-house as needed.
7. Prevention of cross-contamination: clothing and personal belongings are not stored in production areas. Workers do not eat food, chew gum, drink beverages, or use tobacco in production areas. Workers sanitize their boots in boot baths. Waste is removed from processing areas every four hours during production. Coolers are cleaned weekly or more often if needed. Cooler evaporators are cleaned every six months or more often if needed.
8. Allergen control: allergen free products are processed first, followed by products containing allergens.
9. Condensation: drip or condensate does not contaminate food or packaging materials. The finished product cooler is monitored twice a day. Condensation is removed in a sanitary manner.
10. Packaging materials are protected from contamination during storage and use.
11. Cleaning compounds, sanitizers and lubricants used in processing and packaging areas are food-grade. Non-food-grade chemicals and lubricants are stored separately outside processing and packaging areas.
12. Product reconditioning: an employee removes product from the floor in a timely manner, trim contaminants from the product surface area, wash the product at a product wash station, and examines it before returning it to production. This procedure is used for occasional instances of product contamination.
13. Employee health: employees are instructed to report to their supervisor any health condition that might result in food contamination.

Monitoring and Recordkeeping

The Team Captains are responsible for ensuring that employees' hygiene practices, sanitary handling procedures, and cleaning procedures are maintained. The Team Captains monitor the sanitation procedures during the day. Results are recorded on the establishment's Operational Sanitation Form daily.

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Corrective Action

The Team Captains identify sanitation problems, stop production if necessary, and notify processing employees to take appropriate action to correct sanitation problems. If necessary, processing employees are retrained, and corrective actions are recorded on a Corrective Action Log.

Establishment Grounds and Facilities

Grounds and Pest Control

Each day, after operations have ended, the Team Captain directs an employee to examine:

1. The area around the building for trash, debris, and garbage. All items found are disposed of in an appropriate waste container;
2. The area around the building for evidence of rodents, flies, and birds (nesting/feeding);
3. The rodent glue traps to ensure they are free of captured rodents and are properly placed and maintained; and,
4. The use and storage of pest control substances to ensure they are used according to manufacturer's instructions and stored securely and away food production and storage areas.

Facilities

Each Wednesday, during operations, the Team Captain examines:

5. The structure, rooms, and compartments to verify they are of sound construction and in good repair;
6. The walls, floors, and ceilings to verify they are impervious to moisture and can be cleaned and sanitized;
7. The walls, floors, ceilings, doors, windows, and other outside openings to verify they prevent the entrance of vermin (flies, birds, rats, and mice);
8. The room where edible product is processed, handled, or stored to verify the room and edible product is separate from inedible product storage;
9. The lighting in the product handling and storage rooms, equipment and utensil cleaning area, the hand washing area, the locker room, and the toilet to ensure there is sufficient lighting;
10. The ventilation to verify it controls odors, vapors, and condensation;
11. The plumbing system to verify sufficient city supplied water is available where needed in the building, and all floor and sink drains, and the toilet and shower basin remove waste from the building as intended (no backflow or standing water).
12. The supply of running water to verify there is sufficient pressure and temperature in

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the processing room, the cleaning room, hand washing sinks, toilet, and shower.

13. The locker room, toilet and sinks to verify they are maintained in a sanitary condition and in good repair

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Pre-operational Sanitation Form		
Area and Equipment Results	**Accept**	**Reject**
Equipment disassembled, cleaned, and sanitized before starting production		
Cleaning of facilities including floors, walls, and ceilings		

Notes

Date: ____/____/_____ Initials _____ (passes examination)

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Employees clean and sanitize equipment					
Food contact areas cleaned and sanitized as necessary					
Outer garments handled appropriately					
Food contact and equipment cleanup					
Administrative personnel in food processing departments					
Prevention of cross-contamination					
Allergen Control					
Condensation					
Packaging materials					
Cleaning compounds					
Employee health					
Product reconditioning					
Notes **Date: ____/____/_____ Initials _____**					

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Corrective Action Log			
Sanitary Procedures Found Unacceptable (Recorded on the Operational Sanitation Form)	✓		✓
Employees clean and sanitize equipment		Allergen Control	
Food contact areas cleaned and sanitized as necessary		Condensation	
Outer garments handled appropriately		Packaging materials	
Food contact and equipment cleanup		Cleaning compounds	
Administrative personnel in food processing departments		Employee health	
Prevention of cross-contamination		Product reconditioning	
Measures taken to ensure the appropriate disposition of any contaminated product			
Measures taken to restore sanitary conditions			
Measures taken to prevent recurrence, including appropriate re-evaluation and modification of the Sanitation SOP			
Notes **Date: ____/____/_____ Initials _____**			

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	M A/R	T A/R	W A/R	T A/R	F A/R
Trash, Debris, and Garbage					
Evidence of Rodents, Flies, and Birds					
Rodent Glue Traps					
Use and Storage of Pest Control Substances					
Initials					

Notes

Date: ____/____/_____ Initials _____ (passes examination)

Establishment Facilities	
Results	**Accept or Reject**
Construction and Repair	
Walls, Floors and Ceilings	
Openings to the Outside	
Edible and Inedible Product	
Lighting	
Ventilation	
Plumbing	
Water Supply	
Locker Room and Toilet	

Notes

Date: ____/____/_____ Initials _____ (passes examination)

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Attachment 2

Code of Federal Regulations

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

PART 416--SANITATION[12]

Sec. 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 of the regulation.

Sec. 416.12 Development of Sanitation SOPs.

- 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).
- 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.
- 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.
- 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).

Sec. 416.13 Implementation of SOPs.

(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.

Sec. 416.14 Maintenance of Sanitation SOPs.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and the

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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 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.

Sec. 416.16 Recordkeeping requirements.

(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.

Sec. 416.17 Agency verification.

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

(a) Reviewing the Sanitation SOPs;

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

(c) Direct observation of the implementation of the Sanitation SOPs 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.

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