

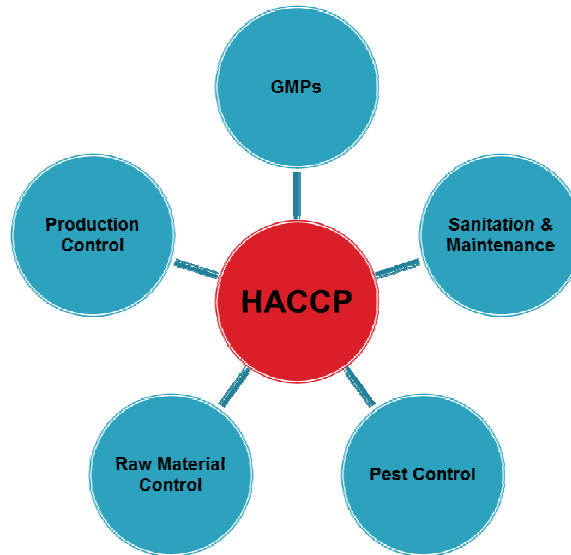


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Opening remarks

Highlight what we will cover and how it will be covered



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During this week we will be discussing HACCP, and all of prerequisites that are needed to support HACCP. We are going to start with Sanitation Performance Standards (SPS) which can basically be covered in GMP.



SANITATION PERFORMANCE STANDARDS (SPS)

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During this session of training we are going to discuss Sanitation Standard Operating Procedures (SSOPs), Sanitation Performance Standards (SPS), and Good Manufacturing Practices (GMPs).

All of these play an important role in Pathogen Reduction and are prerequisite programs for Hazard Analysis Critical Control Point (HACCP). In general these programs cover sanitation, both pre-operational and operational, throughout the entire establishment.

All of these programs, SSOP, SPS, GMP, and HACCP when implemented properly will ensure that the establishment is producing a safe unadulterated product for consumers.

The United States Department of Agriculture, Food Safety Inspection Service regulations §CFR 416.1-17 addresses the requirements of SPS and SSOPs were implemented on January 25, 2000. Following the outline of the regulations we will begin with SPS.

Performance standards define the results to be achieved by sanitation, but not the specific means to achieve those results.

Establishments have flexibility to determine what is appropriate and sufficient in maintaining sanitary conditions and preventing the adulteration of product; therefore, they can meet the sanitation performance standards in different ways.

General Rules

CFR 416.1



- ▶ **Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.**

The key wording in this slide is **must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions.**

As we go through these regulations, we will provide some examples .

Establishment Grounds and Facilities CFR 416.2



▶ Grounds and Pest Control

- **The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with government inspection program employees.**

Page 1

The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by Inspection program employees.

Example, weeds, storage of old or unused equipment. Although this is outside, it could attract pest and rodents and provide them harborages.

Establishment Grounds and Facilities CFR 416.2



▶ Grounds and Pest Control

- Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities.

Page 1

Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities.

The program needs to identify the what is done, by who, and have records to demonstrate the implementation

Establishment Grounds and Facilities CFR 416.2



▶ Grounds and Pest Control

- **Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.**

Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

Example: Poison can not be used within the facility or where packaging material or ingredients are stored. Residuals used for crack/crevasse and then sealed.

Establishment Grounds and Facilities CFR 416.2



▶ Construction

- Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

Page 1
416.2

(b) *Construction.*

(1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

Establishment Grounds and Facilities CFR 416.2



▶ Construction

- Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

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Page 2
416.2

(b) *Construction.*

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

Example- Rust resistant materials, floors sloped so there is no standing water, good repair

Establishment Grounds and Facilities CFR 416.2



▶ Construction

- Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

Page 2

(b) *Construction.*

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

Examples- This means outside doors, including dock doors, must be properly sealed. No gaps, basically if you see day light it is not adequately sealed.

Establishment Grounds and Facilities CFR 416.2



▶ Construction

- **Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.**

Page 2

Construction

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

Establishment Grounds and Facilities CFR 416.2



▶ Lighting

- Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

Page 2

(c) *Light.*

Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

Establishment Grounds and Facilities CFR 416.2



▶ Ventilation

- Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

Page 2

(d) *Ventilation.*

Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

Examples:

Condensation comes under this requirement, but may also come under SSOP if product or equipment is contaminated or will like result in contamination

Establishment Grounds and Facilities CFR 416.2



▶ Plumbing

- Sufficient quantities of water available
- Proper conveyance of sewage/liquid waste
- Prevent adulteration of product, water supplies, equipment, and utensils. And prevent insanitary conditions throughout establishment.

Page 2

(e) *Plumbing.*

Plumbing systems must be installed and maintained to:

- (1) Carry sufficient quantities of water to required locations throughout the establishment;
- (2) Properly convey sewage and liquid disposable waste from the establishment;
- (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

Establishment Grounds and Facilities CFR 416.2



▶ Plumbing

- Adequate floor drainage
- Prevent back-flow conditions or backup of sewer gases

Page 2

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases.

Establishment Grounds and Facilities CFR 416.2



▶ Sewage disposal

- Disposed into a system separate from all other drainage lines or disposed of through means sufficient to prevent backup of sewage into product areas where product is processed, handled or stored.

Page 2

(f) *Sewage disposal.*

Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored.

When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

Establishment Grounds and Facilities CFR 416.2



▶ Water supply

- **Must comply with the National Primary Drinking Water regulations (40 CFR part 141)**
<http://www.epa.gov/safewater/contaminants/index.html#primary>
- **Municipal – a water report by the State or local health agency certifying or testing the potability**
- **Private well - certification renewed semi-annually**

Page 2 and 3

(g) *Water supply and water, ice, and solution reuse.*

(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.).

(2) If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

Establishment Grounds and Facilities CFR 416.2



- ▶ **Dressing rooms, lavatories, toilets**
 - **Rooms must be sufficient size, in sanitary condition and in good repair. Separate from processing**
 - **Lavatories - provided with hot/cold water, soap and towels**
 - **Refuse containers constructed and maintained in a sanitary condition**

Page 3

416.2

(h) *Dressing rooms, lavatories, and toilets.*

(1) Dressing rooms, toilet rooms, and urinals must be sufficient in number; ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

Equipment and Utensils

CFR 416.3



- ▶ **Equipment and utensils must allow for thorough cleaning and not lead to product adulteration**
- ▶ **FSIS inspection program employees are not to be prevented from performing duties**
- ▶ **Inedible receptacles - not to create insanitary conditions or used to store edible product in, and be properly marked**

Bottom of page 3 and top of page 4
416.3

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

Sanitary Operations

CFR 416.4



- ▶ All food-contact surfaces must be cleaned and sanitized as frequently as necessary
- ▶ Non-food contact surfaces must be cleaned as frequently as necessary
- ▶ Cleaning compounds, sanitizing agents and chemicals must be safe for use intended

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416.4

§ 416.4 Sanitary operations.

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

Sanitary Operations

CFR 416.4



- ▶ **Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments. (include sanitary dressing procedures)**

Page 4
416.4

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

Employee Hygiene

CFR 416.5



- ▶ Cleanliness
- ▶ Clothing
- ▶ Disease control

Page 4

416.5

§ 416.5 Employee hygiene.

(a) *Cleanliness.*

All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) *Clothing.*

Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) *Disease control.*

Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

Tagging equipment, rooms, or utensils CFR 416.6



- ▶ When a government inspector finds that equipment, room, utensil, or compartment are insanitary or if used will cause product to become adulterated, they will attach a tag to the equipment, room, utensil, or compartment as well as any product that may be involved.

Page 5

§ 416.6 Tagging insanitary equipment, utensils, rooms or compartments.

Establishment employees should be doing this too!!!! If establishment takes this action then inspection personnel observe that they have taken appropriate corrective action. If not, then government inspectors must take action.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a ‘U.S. Rejected’ tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a ‘U.S. Rejected’ tag.



SSOP

(Sanitation Standard Operating Procedures)

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SSOP's is your sanitation program that contains procedures, monitoring, and recordkeeping necessary to implement the program. It is a pre-requisite for HACCP.

You will learn during this training that the SSOP plays a major role protecting product from being contaminated with *Listeria monocytogenes* and other organisms.



SSOP Features

- ▶ **General rules (416.11)**
- ▶ **Development of Sanitation SOP (416.12)**
- ▶ **Sanitation SOP implementation (416.13)**
- ▶ **Maintenance or effectiveness (416.14)**
- ▶ **Corrective Actions (416.15)**
- ▶ **Recordkeeping (416.16)**

SSOP General Rules

CFR 416.11



- ▶ **Each establishment shall develop, implement, and maintain written standard operating procedures for sanitation**

Page 5

§ 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).

SSOP Development

CFR 416.12



- ▶ Each establishment shall develop, implement, and maintain written standard operating procedures for sanitation
- ▶ Shall describe all procedures conducted daily before and during operation
- ▶ Shall be signed and dated initially and when modified

Page 5

§ 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.

SSOP Development

CFR 416.12



- ▶ **Pre-Operational procedures conducted prior to operations shall be identified as such and shall :**
 - **Address cleaning of food contact surfaces of facilities, equipment, and utensils**

 - **Specify the frequency with which each procedure is to be conducted and identify employees responsible**

Page 5

(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).

SSOP Implementation

CFR 416.13



- ▶ **Each Official Establishment Shall**
 - **Conduct pre-operational procedures before start of operations**
 - **Conduct all other procedures (operational) at frequencies specified**
 - **Monitor daily the implementation of procedures in the SSOPs**

Page 5

§ 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.

Maintenance and Effectiveness CFR 416.14



- ▶ **Establishment shall routinely evaluate the effectiveness of the SSOPs and procedures therein**
- ▶ **The establishment shall revise both as necessary to keep them effective and current.**

Page 5

§ 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.

Corrective Action

CFR 416.15



- ▶ **Corrective action must be taken when either the establishment or government inspectors determine that the establishment's SSOPs have failed to prevent direct contamination or adulteration of product.**

Page 5

§ 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).

Corrective Actions

CFR 416.15



▶ Must include procedures to ensure:

- **Appropriate disposition of product**
- **Restore sanitary conditions**
- **Prevent recurrence of direct product contamination and adulteration**

Page 5

(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.

There has been a change in this area. FSIS recently issued, January 6, instructions to their field personnel stating that preventive actions no longer must be taken or documented on pre-operational sanitation unless product has been contaminated. Even if FSIS inspectors find the unacceptable equipment.

Recordkeeping

CFR 416.16



- ▶ The establishment shall maintain daily records sufficient to document:
 - Implementation and monitoring of SSOPs
 - Any corrective action taken
 - Employees must initial and date records

- ▶ Record retention

Page 6

§ 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 accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site, provided such records can be made available to FSIS within 24 hours of request.

Government Inspection Role CFR 416.17



- ▶ **Government inspection personnel shall verify the adequacy and effectiveness of the SSOP's, verification may include:**
 - **Reviewing the SSOP's**
 - **Reviewing the daily records**

Page 6

416.17

Government inspection personnel shall verify the adequacy and effectiveness of the SSOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

Reviewing the SSOP's

Reviewing the daily records documenting the implementation of the SSOP's and the procedures specified therein and any corrective actions taken or required to be taken

Government Inspection Role CFR 416.17



- ▶ **Government inspection personnel shall verify the adequacy and effectiveness of the SSOP's, verification may include:**
 - **Direct observation of the implementation**
 - **Direct observation or testing to assess the sanitary conditions in the establishment**

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Page 6

Government inspection personnel shall verify the adequacy and effectiveness of the SSOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

Direct observation of the implementation of the SSOP's and the procedures specified therein and any corrective actions taken or required to be taken

Direct observation or testing to assess the sanitary conditions in the establishment

Government Inspection Role CFR 416.17



- ▶ **Verify the initial adequacy of SSOP, or when modifications are made by asking these questions:**
 - **Does the establishment have a written SSOP that describes the procedures the establishment conducts daily to prevent direct contamination of product?**
 - **Does the SSOP identify which of the procedures are pre-operational procedures?**

Page 6

416.17

To verify the initial adequacy of the establishments SSOP, or when modifications are made, there are several questions that should be asked. These questions include:

Does the establishment have a written SSOP that describes the procedures the establishment conducts daily to prevent direct contamination of product?

Does the SSOP identify which of the procedures are pre-operational procedures?

Government Inspection Role CFR 416.17



- Does the SSOP identify which of the procedures are operational procedures?
- Does the SSOP address (at a minimum) the cleaning of food contact surfaces of facilities, equipment and utensils?

Page 6 and 7

Does the SSOP identify which of the procedures are operational procedures?

Does the SSOP address (at a minimum) the cleaning of food contact surfaces of facilities, equipment and utensils?

Government Inspection Role CFR 416.17



- Does the SSOP specify the frequency with which the establishment will conduct each procedure?
- Does the SSOP identify the establishment employees responsible for implementing and maintaining specified procedures?

Page 7

Does the SSOP specify the frequency with which the establishment will conduct each procedure?

Does the SSOP identify the establishment employees responsible for implementing and maintaining specified procedures?

Government Inspection Role CFR 416.17



- Does the establishment identify records that are used daily to document the implementation and monitoring of the SSOP and corrective actions when taken?
- Has an individual with overall authority on-site or higher level official signed and dated the SSOP?
-

Page 7

Does the establishment identify records that are used daily to document the implementation and monitoring of the SSOP and corrective actions when taken?

Has an individual with overall authority on-site or higher level official signed and dated the SSOP?

Government Inspection Role CFR 416.17



- ▶ **Documentation problems**
- ▶ **Request corrective action**
- ▶ **Determine if program is adequate**

Page 7

If there any problems identified during the review of the SSOP, then government inspectors must document those problems and request a corrective action from establishment management. Once the SSOP has been found to be adequate, then government inspectors must monitor the daily implementation of the program.

Government Inspection Role CFR 416.17



- ▶ Monitor the daily implementation

- ▶ On-going verification
 - Direct observation
 - Records review

Page 7

The on-going verification can be accomplished different ways. This training recommends that the approach to on-going verification is divided into two categories; direct observation and records review.

Government Inspection Role CFR 416.17



- ▶ **Direct observation:**
 - **Hands-on review of facilities, equipment, and utensils or**

 - **By observing the establishment employees conducting their monitoring of sanitation, taking corrective action, and recordkeeping.**

Page 7

Direct observation is accomplished by conducting either a hands-on review of facilities, equipment, and utensils or by observing the establishment employees conducting their monitoring of sanitation, taking corrective action, and recordkeeping. It is highly recommended that a mixture of both direct observation methodologies is used to verify that the establishment is following their program.

Inspectors should be taking with them a flashlight and a sufficient number of the tags when conducting either of these procedures.

If inspectors are conducting a hands-on review of the facilities, equipment, and utensils, they should be allowing the establishment to conduct their own monitoring prior to starting the hands-on review. Inspectors should be comparing what they identify during their hands-on to what the establishment identified during their monitoring.

If inspectors identify problems that affect product or product contact surfaces that were not identified by establishment personnel, they must take an enforcement action on product and/or equipment. Documentation needs to include the fact that the establishment failed to identify the problems during their monitoring. Request corrective action which should include how the establishment is going to correct the monitoring.

Government Inspection Role CFR 416.17



- ▶ **Records review**
 - **Daily**
 - **Establishment is conducting procedures identified in the SSOP, documenting results, and are taking appropriate corrective actions**
- ▶ **Document failures**
- ▶ **Document to demonstrate government verification is completed daily**

Page 7

The records review portion of verification must occur daily. To conduct this review the inspector must review records that demonstrate the establishment is conducting procedures identified in the SSOP, documenting results, and are taking appropriate corrective actions sufficient to address all parts of 416.15. If the establishment is failing to complete these tasks then the inspector must document this failure and request corrective actions from the establishment.

It is recommended that during a standard work week, that inspectors conduct hands-on direct observation at least 2 times and that records are reviewed daily. If problems are identified by inspectors every time they conduct the hands-on direct observations, that they increase the frequency as needed to ensure that products are being produced that are safe from contamination.

Inspectors must document in some way that they are conducting these reviews even if there are not any problems identified. If inspectors continue to identify problems they may request assistance from supervisors or request an investigation.

Government Oversight



- ▶ **Organizational structure and staffing to ensure uniform implementation**
- ▶ **Control and supervision over official activities of employees and establishments**
- ▶ **Assignment of competent inspection personnel**

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One of the areas that FSIS looks at during an audit is government oversight.

Does the government structure allow for oversight of inspection throughout the country.

How are new requirements distributed to the field inspection personnel

Is staffing adequate for each and every shift producing product for the U. S.

How often are reviews conducted by supervisors

How are inspection personnel trained

Government Oversight



- ▶ Authority and responsibility to enforce U. S. requirements
- ▶ Adequate administrative and technical support to operate the inspection system

Government must enforce US requirements

Adequate administrative and technical support. Does the government have a regular training program. Does the government have a way ensure that requirements are implemented the same throughout the country.



Questions



Thank you