

CHAPTER I - SANITATION

I. Introduction

The FMIA and PPIA both establish that a meat or poultry product is adulterated if it has “been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.”

Insanitary conditions may be isolated (e.g., damaged box, product residue in containers from previous day’s production) and only affect a limited area of an establishment and that will not affect the sanitary condition of other product or equipment. In such cases, inspection program personnel are to document the noncompliance, take the appropriate enforcement action (e.g., tag product or equipment), and verify that the situation is addressed.

In other instances, the insanitary conditions may be such that the product produced in the establishment may have become contaminated with filth or otherwise rendered injurious to health. For example, if an inspector finds gross rodent infestation in an establishment, the product prepared, packed, or held under these conditions may have become contaminated with filth, and inspection program personnel may need to immediately withhold the marks of inspection and contact the District Office.

There are so many ways that insanitary conditions can cause product to be adulterated that they cannot all be listed. Instead, this directive explains the intent of the sanitation regulations and gives examples of some of the ways inspection program personnel can determine whether a meat or poultry establishment is operating under insanitary conditions.

Inspected establishments must meet two sets of regulations concerning sanitation: The Sanitation Standard Operating Procedures (Sanitation SOP) requirements and the Sanitation Performance Standards (SPS). Under the Sanitation SOP requirements, each establishment must develop, implement, and maintain written procedures for the actions it takes daily, before and during operations, to prevent product from being directly contaminated and adulterated. An establishment’s Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. The SPS regulations cover all of the other aspects of plant sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems. Keep in mind that these two sets of regulations overlap somewhat in the plant activities they cover. Also, some establishments may address certain sanitation problems within their HACCP plans.

II. Sanitation Performance Standards

A. What are the general regulatory requirements for the SPS?

Section 416.1 states: *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 FSIS regulations in 9 CFR 416.2 to 416.5 set forth more specific performance standards that each official establishment must meet to prevent the creation of insanitary conditions that could cause the adulteration of meat and poultry products. These regulations provide the sanitation standards the establishment must meet for the Federal mark of inspection to be applied to its products. Some of the SPS address conditions within or around the establishment (e.g., ventilation, lighting, facility and equipment construction, and maintenance of the grounds). Other SPS address establishment operations and so may be met by an establishment through its Sanitation SOP (e.g., sanitizing of food contact surfaces) or its HACCP plan (e.g., water reuse).

B. What is the relationship between the SPS and the Sanitation SOPs?

The SPS regulations and the Sanitation SOP regulations are set out in separate sections of 9 CFR part 416. Compliance with both, however, is necessary if an establishment is to prevent the creation of insanitary conditions that can cause the adulteration of product. The SPS regulations define generally what the establishment's sanitation efforts must accomplish to maintain the facilities and environment in a sanitary condition. The Sanitation SOP regulations define specifically what the establishment must accomplish to prevent direct contamination of product. Establishment management may choose to address some of the SPS requirements in their written Sanitation SOP or even within their HACCP plan.

III. CSI Verification Activities for Sanitation Performance Standards

A. In general, how do CSIs verify the Sanitation Performance Standards?

As scheduled by the PBIS, CSIs verify that establishments are complying with the SPS (9 CFR 416.2 – 416.5) and the Sanitation SOPs (9 CFR 416.11 – 416.16).

CSIs may directly observe conditions in the establishment or review records to verify that the establishment is complying with the sanitation regulatory requirements.

9 CFR 416.4(c) requires that an establishment have “documentation substantiating the safety of a chemical’s use in a food processing environment,” 9 CFR 416.2(g) states: “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.” The other SPS regulations do not require that an establishment maintain records of the procedures that it uses to meet these performance standards. Establishments may incorporate SPS procedures as part of its Sanitation SOPs, in which case they would have to meet the relevant recordkeeping requirements for Sanitation SOPs.

If an establishment’s procedures, or the prerequisite programs that it uses to meet the SPS, are referenced in the hazard analysis, HACCP plan, or Sanitation SOP, the records associated with the procedures are required to be available to FSIS.

Most of the time the CSIs will verify compliance with the SPS regulatory requirements by directly observing the conditions in the establishment.

The 06D01 procedure is used to verify compliance with the SPS requirements in one or more areas of the establishment. If the CSI determines that the establishment is meeting the sanitation regulatory requirements in a particular area of the establishment, the procedure would be documented on the procedure schedule as performed. The CSI must use professional knowledge and good judgment in making the determination whether the SPS requirements are met. The CSI must assess the situation in the establishment and then determine whether the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS from performing inspection. This means that there can be conditions in the facility that are less than perfect but that would not represent noncompliance with the SPS regulatory requirements because they are not creating insanitary conditions, adulterating product, or preventing FSIS personnel from performing inspection activities.

If the establishment is not meeting the regulatory requirements, it is the CSI's responsibility to initiate the appropriate regulatory control actions to gain regulatory compliance. The examples used in this section are to demonstrate the decisionmaking process that the CSI might use in making regulatory compliance determinations.

IV. Verification of the Grounds and Pest Control

A. What is the regulation related to grounds and pest control?

Section 416.2 (a) states: *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 FSIS program employees. Establishments must have in place a pest management program to prevent harborage and breeding of pests on the grounds and within establishment facilities. 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.*

B. How are CSIs to go about verifying the grounds provision of 416.2(a)?

Establishment situations will dictate the level of verification that must be done. Although an establishment must have a pest management program, it need not be written. If establishment management decides to have a written program, it may or may not be included in the Sanitation SOP. If the establishment has included a written pest management program as part of the Sanitation SOP, the CSI verification activities should include reviewing the Sanitation SOP, reviewing the Sanitation SOP records, and directly observing the procedures being monitored. The CSI should verify that the procedures in the Sanitation SOP are being implemented and monitored, that the establishment is documenting in the Sanitation SOP records the monitoring of the procedures, and that any necessary corrective actions are taken.

Verification is much different if the establishment has no written procedures. Since there are no recordkeeping requirements for grounds and pest control, the CSI will verify that the establishment is meeting the requirements by making observations of the outside grounds and pest control. The CSI will check the outside premises to verify that there are no breeding or harborage areas for pests. The CSI will also verify that there is no harborage or breeding of pests within the establishment by inspecting areas of the establishment for evidence of pests. Noncompliance with this regulatory requirement does not have to involve evidence of pests. The outside grounds and areas within the establishment should be evaluated to verify that no harborage or breeding area exists. If there are areas outside or inside the establishment that are providing harborage or breeding areas for pests, there is noncompliance with this requirement. When verifying this regulatory requirement, the CSI should seek answers to the following questions:

1. Are all outside areas on the official premises maintained in a manner to prevent harborage and breeding of pests?
2. Are all areas within the establishment maintained in a manner to prevent harborage and breeding of pests?
3. Does the establishment have a pest management program?
4. Does the establishment have a written pest management program as part of the Sanitation SOP?
5. If the pest management program is part of the Sanitation SOP, is the establishment monitoring this program?

C. Example of decisionmaking in judging whether there is compliance with this provision.

CSIs will have to use good judgment in making compliance determinations. The CSI must assess all of the information associated with every observation. For example, the CSI observes tall weeds around the facility. Before making a determination about regulatory compliance, the CSI should determine whether the weeds and grass permit harborage and breeding. If the weeds are scattered and do not permit harborage and breeding, there is not noncompliance. If the weeds are so dense as to permit concealment and breeding, there is noncompliance with these regulations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

D. How are CSIs to go about verifying the pest control substance provision of 416.2(a)?

The second part of this section of the regulations covers the safety, conditions of use, and the application and storage of pest control substances. The CSI will need to gain information about the safety of any such substances the establishment has on hand, the conditions of use, and how they are stored and applied when verifying compliance with these regulations. Some of the information needed could include answers to the following questions:

1. Does the establishment have documentation on file about the safety of the pest control substances?
2. Does the documentation on file include how the pest control substances are to be used?
3. Are the pest control substances being applied as per the conditions and use?

E. Example of decisionmaking in judging whether there is compliance with this provision.

This provision is very straightforward because of the potential for products being adulterated if pest control substances are misused or are not used according to the documentation on file. Therefore, if the establishment does not have documentation on file that the substances are safe and effective, and on how the substances are to be used, there is noncompliance with this provision. If the establishment is applying the substances differently than the documented uses, there is noncompliance. There is also noncompliance if the establishment is storing these substances in a manner that could result in product adulteration.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

V. Construction

A. What is the regulation related to construction?

Section 416.2 (b) states:

(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.

(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.

(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.

(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.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(b), the CSI should assess the construction of the facility in one or more areas. To do this, the CSI needs to seek answers to questions like the following:

1. Are the buildings, including their structures, rooms, and compartments, kept in good repair, and are they of sufficient size to allow for processing, handling, and storage of product?

2. Are the walls, floors, and ceilings cleaned and sanitized as necessary?
3. Are the structures, rooms, and compartments kept in good repair?
4. Are the rooms and compartments of sufficient size to allow for processing, handling, and storage of product?
5. Are the walls, floors, ceilings, doors, windows, and other outside openings constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice?
6. Are edible products and inedible products processed, handled, and stored in a manner that prevents product adulteration and the creation of insanitary conditions? Are they processed, handled, and stored separately? If not, is there an opportunity for cross-contamination?

C. Example of decisionmaking in judging whether there is noncompliance with this provision.

The CSI must realize that it is the establishment's responsibility to maintain the facilities in a manner that will not adulterate product or create insanitary conditions. When the CSI is conducting verification procedure 06D01, he or she may observe situations in the establishment in which compliance is not evident. The CSI must evaluate all the information associated with the observation before making a compliance decision. The CSI must remember that the standard used for this requirement is the SPS regulations. The CSI is to assess the condition observed in light of the regulatory requirement and decide whether regulatory requirements have been met.

For example, the CSI observes an area in the establishment that appears to be of insufficient size to allow for storing of product in a manner that prevents insanitary conditions and consequent product adulteration. The CSI should assess the entire situation. If the establishment is able to maintain this area in a sanitary condition, the establishment is in compliance with the regulation. If there is not adequate space in the area to permit the area to be maintained in a sanitary manner, there is noncompliance with this provision. For example, if the floors and walls cannot be cleaned regularly because of the overcrowded conditions, there is noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

VI. Lighting

A. What is the regulation related to lighting?

Section 416.2 (c) states: *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.*

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(c), the CSI should assess the lighting in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the intensity and quality of lighting adequate for the establishment to determine that the products being processed, handled, stored, or examined are unadulterated, and that sanitary conditions are maintained?
2. Are the intensity and quality of lighting adequate for the establishment to determine that equipment and utensils are appropriately cleaned?
3. Are the intensity and quality of lighting adequate in the hand-washing areas, dressing and locker rooms, and toilets for the establishment to determine that sanitary conditions are maintained?

C. Example of decisionmaking in judging whether there is compliance with this provision.

Since this section of the regulation does not set specific amounts of lighting required, the CSI cannot go to an area of the establishment with a light meter and make a compliance determination. When the CSI is verifying this requirement performing the 06D01 procedure, he or she will have to use good judgment and a sound decisionmaking process to determine compliance. The CSI may observe an area of the establishment that appears to have inadequate lighting. He or she must assess the condition in that area to determine whether the lighting is adequate for the establishment to ensure that sanitary conditions are maintained, and that product is not adulterated. If this is the case, there is compliance with this provision. If the lighting is not adequate to ensure that sanitary conditions are maintained and that product is not adulterated, there is noncompliance with this provision. For example, if the lighting is not adequate to enable establishment employees to determine whether a substance on product is fecal material, the lighting is inadequate, and there is noncompliance.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

VII. Ventilation

A. What is the regulation on ventilation?

Section 416.2 (d) states: *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.*

B. How may CSIs go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(d), the CSI should assess the ventilation in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Is the ventilation adequate to control objectionable odors and vapors that could adulterate product or mask the odor of spoiled or otherwise adulterated product?
2. Is the ventilation adequate to control condensation?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes fog or smoke in the cooked meats cooler. When entering the cooler, it appeared that the ventilation was not adequate to control vapors. The CSI assesses the situation and determines that the establishment has placed 10 trays of warm product in the area. The CSI observes that the vapor in the room dissipates before forming any moisture on the ceiling. In this situation, there is not noncompliance. If the vapor coming from the warm product does form moisture on the ceiling, creating an insanitary condition, there is noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

VIII. Plumbing and Sewage

A. What are the regulations related to plumbing and sewage?

Section 416.2 (e) states: *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;

(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.

Section 416.2 (f) states: *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.*

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(e) and (f), the CSI should assess the plumbing in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are sufficient quantities of water provided throughout the establishment?
2. Does the plumbing system properly convey sewage and disposable waste from the establishment?
3. Does the plumbing system provide adequate floor drainage?
4. Is the plumbing installed to prevent back-flow conditions and cross-connections between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing?
5. Is the plumbing installed to prevent the backup of sewer gases?
6. Is the sewage disposed into a sewage system separate from all other drainage lines or other means to prevent backup of sewage into areas where product is processed, handled, or stored?
7. If the sewage disposal system is a private system requiring approval by a State or local health authority, is the letter of approval available to FSIS upon request?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI is in the area of the plant where several water-cooking units are being drained simultaneously. There is a gutter drain that the water is drained into, and the end of a cleanup hose is submerged in the gutter drain. The CSI thinks there is noncompliance with this provision but decides to evaluate the situation further. The CSI finds a vacuum breaker at the cleanup station to prevent back siphonage. The CSI determines there is not noncompliance. If there had been nothing to prevent back siphonage, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

IX. Water Supply and Water, Ice, and Solution Reuse

A. What is the regulation related to water supply?

Section 416.2 (g) states: (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.). 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.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(g), the CSI should check the water in the facility in one or more areas.

While in these areas, the CSI needs to seek answers to questions like the following:

1. Does the establishment have documentation that the water in the establishment complies with the EPA's National Primary Drinking Water Regulations?
2. Is there adequate water pressure, at a suitable temperature, in all areas where required, for example, for processing product; for cleaning rooms and equipment, utensils, and packaging materials; for employee sanitary facilities?

4. If the establishment uses a municipal water supply, does it have a water report issued under the authority of the State or local health agency certifying or attesting to the potability of the water supply?

5. If the establishment uses a private well for its water supply, does the establishment have on file documentation certifying the potability of the water supply that is renewed semi-annually?

C. What is the regulation related to reuse of water, ice, and solutions for RTE product?

Section 416.2(g)(2) states: *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.*

D. How are CSIs to go about verifying this regulation?

The CSI should determine whether the establishment is reusing water, ice, or solutions (such as brine, liquid smoke, or propylene glycol) to chill or cook RTE product.

If the establishment is reusing water, ice, or solutions to cook or chill RTE products, the CSI needs to seek answers to these type of questions:

1. Are water, ice, and solutions that are reused maintained free of pathogenic organisms and fecal coliform organisms?
2. Is other physical, chemical, and microbiological contamination reduced to prevent adulteration of product?
3. Did the establishment consider water, ice, and solution reuse in the hazard analysis?
4. If the establishment considered water, ice, and solution reuse in the hazard analysis and found a food safety hazard reasonably likely to occur, is there a CCP in the HACCP plan to address this hazard?

E. What is the regulation related to reuse of water, ice, and solutions for raw product?

Section 416.2(g) states: *(3) Water, ice, and solutions 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.*

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

F. How are CSIs to go about verifying this regulation?

CSIs should review sections of the establishment's Sanitation SOP or HACCP plan that address water supply and water, ice, and solution reuse before considering the actual establishment condition. They should assess program effectiveness pertaining to water supply and water, ice, and solution reuse through observing actual establishment conditions and considering the following:

1. Is the potable water supply from a municipal source? If not, does the certification or other documentation on file evidence that the establishment's potable water supply meets the EPA's primary potability requirements for sources of drinking water?

2. Is there an adequate supply of potable water in the establishment?

3. Are the ice-making equipment, rooms, and augers maintained in good repair and sanitary condition?

4. Is water, ice, and solutions reuse accomplished properly and according to 9 CFR 416.2?

NOTE: The regulations state that water may be reused "for the same purpose." This means that water used to wash or otherwise process raw product may be reused to wash or otherwise process raw product, even at a different point in processing, provided that "measures are taken to reduce physical, chemical, or microbiological contamination." For example, an establishment could reuse poultry chiller water in a scalding tank. Furthermore, water used to process RTE product could be reused to wash or process raw product. But water used to

process raw product may not be reused to process RTE product. For example, an establishment could not reuse poultry chiller water for cooking or cooling packaged RTE product.

X. Dressing Rooms and Lavatories

A. What is the regulation related to dressing rooms and lavatories?

Section 416.2 (h) states: *(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.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(h), the CSI should assess the dressing rooms, toilet rooms, and urinal rooms. The CSI should also assess the lavatories in one or more areas of the establishment. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the dressing rooms, toilet rooms, and urinals sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair?
2. Are dressing rooms, toilet rooms, and urinals separate from the rooms and compartments in which products are processed, stored, or handled?
3. Are there lavatories with running hot and cold water, soap, and towels placed in or near toilet and urinal rooms and other places in the establishment as necessary?
4. Are refuse receptacles constructed and maintained in a sanitary manner?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI is in an area of the establishment where edible product is being handled. There are several employees working in this rather large room. The CSI observes that there is only one lavatory close by. The CSI thinks that there

may be noncompliance with this requirement but decides to evaluate the situation further before making a compliance determination. The CSI observes that the employees are handling product, and when employees' hands are contaminated, they go to the lavatory and wash their hands. The CSI determines that in this situation, there is not noncompliance. If the employees were not washing their hands because the lavatory was not appropriately located in this area, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

XI. Equipment and Utensils

A. What is the regulation related to equipment and utensils?

Section 416.3 states: *(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 or 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.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.3, the CSI should assess the equipment and utensils in one or more areas of the establishment. While in these areas, the CSI should also verify that the receptacles used for storing inedible material meet the regulatory requirements. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the equipment and utensils used for processing and otherwise handling edible product or ingredients of material and construction that facilitates thorough cleaning?

2. Are equipment or utensils constructed, located, or operated in a manner that prevents inspection program personnel from inspecting the sanitary condition of the equipment or utensils?

3. Are receptacles used for storing inedible material constructed of materials that can be maintained in a sanitary manner?

4. Are receptacles used for storing inedible products marked conspicuously and distinctively to identify permitted uses?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes a closed system that had not been disassembled for cleaning. The CSI does not believe that there is noncompliance with this provision but decides to assess the situation further before making a compliance determination. By looking into the matter, he or she determines that this system is cleaned-in-place, and that there are inspection openings at every change of direction to allow for verification of the effectiveness of the sanitation procedures. The CSI inspects the system through the openings and finds that the closed system is being adequately cleaned. There is compliance with this provision. If the closed system did not permit inspection or was creating insanitary conditions, there would be noncompliance with this provision. The CSI should keep in mind that the establishment may choose to meet the requirements of 9 CFR 416.3 through its Sanitation SOP or through other activities it conducts to comply with the SPS regulations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

XII. Sanitary Operations

A. What is the regulation related to sanitary operations?

Section 416.4 states: *(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. [In most cases the documentation will be "Material Safety Data Sheets."]

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

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.4, the CSI should assess how the equipment and utensils in one or more areas of the establishment are cleaned and handled. The CSI should assess whether products are protected from adulteration during processing, handling, storage, loading, and unloading, and during transportation. The CSI should also assess use, handling, and storage of cleaning compounds, sanitizing agents, processing aids, and other chemicals in the establishment. The CSI needs to seek answers to questions like the following:

1. Are all food-contact surfaces of facilities, equipment, and utensils cleaned and sanitized as frequently as necessary to prevent insanitary conditions and the adulteration of product?

NOTE: Many establishments will comply with the requirements of Section 416.4(a) through Sanitation SOP activities.

2. Are non-food contact surfaces of facilities, equipment, and utensils used in the operation of the establishment cleaned and sanitized as necessary to prevent the creation of insanitary conditions and the adulteration of product?

3. Are the cleaning compounds, sanitizing agents, processing aids, and other chemicals used by the establishment safe and effective under the conditions of use?

4. Does the establishment have documentation substantiating the safety of a chemical's use in a food processing environment?

5. Does the establishment protect product from adulteration during processing, handling, storage, loading and unloading, and transportation from official establishments?

6. If the establishment uses extended clean-up procedures, are these procedures included in the Sanitation SOP?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes several vats of meat in the raw product storage area that are not covered. There are several other vats of meat stored in this area that are covered. The CSI thinks that there might be noncompliance with this provision but decides to evaluate the situation further before making a compliance determination. The CSI looks at the overhead in the area and does not observe any conditions that would constitute insanitation or that would cause product

adulteration. The CSI observes an employee come into the area and take a vat of product out of this area. The CSI follows the employee to determine whether the product needs to be protected while being transferred to another area. The CSI finds no conditions that would require the product to be covered during transit. Therefore, the CSI determines that there is not noncompliance with this provision. If the CSI had observed that there was a condition in the establishment that could adulterate product during storage or handling, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

XIII. Employee Hygiene

A. What is the regulation related to employee hygiene?

Section 416.5 states: *(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.

NOTE: The regulations pertaining to employee hygiene apply to FSIS personnel as well as to plant personnel. As representatives of a public health agency, it is imperative that inspection program personnel lead through example and follow all provisions in 9 CFR 416.3 and 416.5 during the performance of their official duties within federally inspected meat and poultry product establishments. Inspection program personnel must adhere to establishments' special requirements as well. In this manner, FSIS personnel can aid in maintaining the sanitary conditions inside the facilities to which they are assigned.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.5, the CSI should assess employee hygiene in one or more areas of the establishment. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the persons in contact with product, food-contact surfaces, and product-packaging materials adhering to hygienic practices?
2. Are aprons, frocks, and other outer clothing worn by persons who handle product made of material that is disposable or readily cleaned?
3. Are clean garments worn at the start of the day and changed during the day as often as necessary?

NOTE: These regulations do not require establishment employees to wear frocks or smocks, but require outer clothing to be of material that is disposable or readily cleanable.

4. Are persons who appear to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination excluded from any operations that could result in product adulteration and the creation of insanitary conditions?

NOTE: If inspection program personnel have questions about an employee having an infectious disease, he or she should discuss this with plant management. Inspection program personnel are not trained to diagnose infectious diseases.

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes an employee preparing to start to work in the raw product area. The employee puts on an apron. The CSI observes that the apron is dirty from the previous day's production. The CSI thinks that there is noncompliance with this provision but decides to evaluate this situation further before making a compliance determination. He observes the employee go to the washroom and clean the apron thoroughly before starting to work. The CSI determines that there is not noncompliance with this provision. If the employee does not clean the apron appropriately before going to work, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

XIV. Sanitation SOPs

A. What are the written Sanitation SOP Procedures?

The establishment has the responsibility to develop, implement, and maintain written Sanitation SOPs. The basic regulatory requirements are described in 9 CFR 416.12. At the time inspection is granted, the establishment must have a Sanitation SOP that meets these requirements. The CSI performs the 01A01 procedure to verify that the written procedures meet the basic regulatory requirements. The CSI determines when it is necessary to perform the 01A01

procedure. There are four Sanitation SOP regulatory requirements. The four requirements are: implementation and monitoring, maintenance, recordkeeping, and corrective action. If the CSI determines that the Sanitation SOP does not meet the regulatory requirements specified in 9 CFR 416.12, he or she should contact the DO for direction.

XV. Inspection Procedures

A. What are the inspection procedures for the Sanitation SOPs?

There are two Sanitation SOP procedures for pre-operational sanitation verification (01B01/01B02) and two Sanitation SOP procedures for operational sanitation verification (01C01/01C02). The CSI performs these procedures to verify that the establishment is meeting the Sanitation SOP regulatory requirements. Those requirements are:

1. Implementation and monitoring of Sanitation SOP (416.13);
2. Maintenance of Sanitation SOP (ensuring its effectiveness) (416.14);
3. Sanitation SOP corrective actions (416.15); and
4. Sanitation SOP recordkeeping (416.16)

B. How do CSIs conduct the 01B01 procedures?

The 01B01 Sanitation SOP procedure is the pre-operational recordkeeping procedure. This recordkeeping procedure instructs the CSI to verify the daily documentation of the establishment's implementation and monitoring of the Sanitation SOP procedures and required corrective actions.

When the CSI performs the 01B01 procedure, he or she should review the Sanitation SOP and the establishment's pre-operational Sanitation SOP records to verify that the establishment is meeting the regulatory requirements for pre-operational sanitation.

The CSI should review the Sanitation SOP to become knowledgeable about the procedures in it. The CSI should review the daily pre-operational Sanitation SOP records to verify that the establishment is following the pre-operational procedures, that the monitoring activities are conducted at the specified frequency, that the corrective action requirements are met, and that records are being authenticated by the establishment employee responsible for implementation and monitoring of the Sanitation SOP. This is a recordkeeping procedure and the CSI should be reviewing pre-operational records only to determine if the establishment is meeting the regulatory requirements.

C. How do CSIs conduct the 01C01 procedures?

When the CSI performs the 01C01 procedure, he or she should review the establishment's operational sanitation records to verify that the regulatory requirements for operational sanitation are met.

The CSI should review the Sanitation SOP to become knowledgeable with the procedures in it. The CSI should review the Sanitation SOP operational records to verify that the establishment is following the operational procedures in the Sanitation SOP, that the monitoring activities are conducted at the specified frequency, that the corrective action requirements are met, and that records are being authenticated by the establishment employee responsible for implementation and monitoring of the Sanitation SOP.

D. What are CSIs to do when performing the 01B02 procedure?

The 01B02 Sanitation SOP procedure is a review and observation procedure for verifying pre-operational sanitation. When performing the review and observation procedure, the CSI will verify all four requirements: implementation and monitoring, maintenance, corrective actions, and recordkeeping.

The CSI should review the Sanitation SOP to ensure that he or she is knowledgeable about the current written procedures.

NOTE: The CSI needs to understand the procedures in the Sanitation SOP that the establishment is implementing to prevent direct contamination or other adulteration of product. The CSI should become familiar with any monitoring procedures and frequencies that may be included in the Sanitation SOP. Without this knowledge the CSI will not be able to verify regulatory compliance.

If the CSI is to perform the 01B02 procedure and has reviewed the Sanitation SOP, he or she should verify the pre-operational sanitation requirements by inspecting direct contact surfaces in one or more areas of the establishment, observing the establishment perform the monitoring procedures, and comparing his or her findings with what the establishment has documented.

NOTE: When the CSI is performing the 01B02 procedure, he or she should inspect direct contact surfaces and observe the establishment conduct its monitoring procedures when possible.

It is possible that the CSI might be performing his or her review and observation procedure at the same time the establishment is monitoring their pre-operational procedures. This provides an excellent opportunity for the CSI to perform the observation part of this procedure. In some cases, the establishment might conduct its monitoring of the implementation of the Sanitation SOP procedures before inspection program personnel arrive at the establishment. In these situations, the CSI should seek direction from supervisory personnel as to how frequently he or she should directly observe the establishment conduct monitoring. The supervisor should consider several factors when making this

decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from Sanitation SOP records.

NOTE: On Saturdays, Sundays, and Holidays, CSIs are to conduct pre-operational sanitation procedures in the same manner and frequency as they do during the week.

E. What are CSIs to do when performing the 01C02 procedures?

The CSI should perform the 01C02 procedure the same way as he or she conducts the 01B02, except this procedure is conducted during operations. Again, the CSI should review the Sanitation SOP to become familiar with all the procedures in the Sanitation SOP.

The CSI should verify that the establishment is meeting the Sanitation SOP regulatory requirements for operational sanitation by:

1. inspecting one or more areas of the establishment to ensure procedures are effective in preventing direct contamination or other adulteration of product,
2. observing the establishment perform the monitoring procedures, and
3. comparing the findings to what the establishment has documented.

It might be difficult for the CSI to observe the establishment conducting its monitoring because 9 CFR 416.13 requires that the establishment monitor the procedures in the Sanitation SOP daily. The CSI might not be available to observe that activity when it is occurring.

XVI. Implementation and Monitoring

A. What is the implementation and monitoring regulation?

Section 416.13 states: (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.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.13, the CSI should seek answers to the following type of questions:

1. Is the establishment implementing the pre-operational procedures in the Sanitation SOP prior to the start of operations?
2. Are direct contamination or adulteration of product or unclean direct product contact surfaces observed by FSIS or the establishment?
3. Is the establishment conducting the procedures in the Sanitation SOP as specified?
4. Does the Sanitation SOP contain monitoring frequencies?
5. If the Sanitation SOP does not contain monitoring frequencies, is the establishment monitoring the implementation of the procedures in the Sanitation SOP daily?

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

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

XVII. Maintenance

A. What is the maintenance regulation?

Section 416.14 states: *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.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.14, the CSI will seek answers to questions of the following type:

1. Has the establishment routinely evaluated the effectiveness of the Sanitation SOPs in preventing direct contamination or adulteration of product? Is the establishment doing environmental testing or taking other steps to assess whether its Sanitation SOPs are effective?

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

NOTE: Construction and removal of walls, ceilings, and floors may cause harborage sites for *L. monocytogenes* to be dislodged from otherwise protected areas. The CSI should ask whether the establishment has stepped up its on-going verification activity to ensure that the current Sanitation SOP or other procedures are adequate to find insanitary conditions.

3. Does the establishment routinely review the Sanitation SOP records to determine if there are trends occurring showing the Sanitation SOP needs revising?

C. What is an example of noncompliance?

- 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.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

XIII. Corrective Actions

A. What is the regulation on corrective actions?

Section 416.15 states: (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.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

In every situation where it is necessary for an establishment to take correction actions that are to meet the requirements of 9 CFR 416.15, CSIs are to verify the establishment's compliance with 9 CFR 416.15, by seeking answers to the following:

1. If there is direct contamination or other adulteration of product, does the establishment implement corrective actions that restore sanitary conditions, prevent recurrence, and make appropriate disposition decisions regarding any product that may be contaminated?

NOTE: CSIs are to take the appropriate control action (see Chapter IV) when there is direct product contamination or other adulteration of product. CSIs are not to release product or equipment affected by the control action and are not to "close out" the NR until they have verified that the establishment has restored sanitary conditions, has completed the proper product disposition, and has implemented preventive measures (see 9 CFR 416.15).

2. Do the corrective actions include the reevaluation and modification of the Sanitation SOPs or improvements in the execution of the procedures when necessary?

NOTE: In situations not involving direct contact surfaces that may cause adulterated or contaminated product, if the establishment is monitoring the pre-operational sanitation procedures, finding noncompliance, and taking the corrective actions required in 9 CFR 416.15, the CSI should focus on whether the overall implementation of the Sanitation SOP is effective in preventing direct contamination or other adulteration of product. The CSI should not focus on the fact that the preventive measures being used are the same as previous preventive measures used by the establishment.

When the CSI finds direct contact surfaces unclean or direct contamination or adulteration of product, he or she should take a regulatory control action. That regulatory control action should not be relinquished until the establishment has proposed an acceptable preventive measure.

There is no noncompliance if the establishment finds such conditions and takes the appropriate corrective actions. These corrective actions include restoring sanitary conditions, making appropriate disposition of product, and implementing measures to prevent recurrence. This thought process would not pertain to situations in which product became contaminated. Since the Sanitation SOP must contain procedures to prevent direct contamination or adulteration of product, FSIS would expect the establishment to have procedures in place to prevent the contamination of product.

C. What are some examples of noncompliance?

- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to ensure appropriate disposition of product.
- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to restore sanitary conditions.
- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to prevent recurrence of direct contamination or adulteration of product. This may lead to a trend of repeated noncompliances.

CSIs will document noncompliance in a manner that accords with Chapter IV of this document.

XIX. Recordkeeping

A. What is the regulation on recordkeeping?

Section 416.16 states: (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.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.16, the CSI should seek answers to the following type of questions:

1. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken?

2. Is an establishment employee responsible for the implementation and monitoring of the procedures in the Sanitation SOPs and authenticating the records with his or her initials and date?

3. If records are being maintained on computers, are there controls to ensure the integrity of the electronic data?

4. Are Sanitation SOP records being maintained for at least 6 months and available to FSIS?

5. Are Sanitation SOP records kept off-site 48 hours after completion? If so, are they available to FSIS within 24 hours of request?

6. Do the Sanitation SOP records accurately reflect the sanitary conditions of the establishment?

7. Are the Sanitation SOP records available for FSIS at the start of the same shift the following day?

CSIs will document noncompliance in a manner that accords with Chapter IV of this document.