

Sanitation Performance Standards

OBJECTIVES

To demonstrate mastery of Sanitation Performance Standards (SPS), the trainee will:

1. Describe the relationship between establishment sanitation and the cleanliness and wholesomeness of product.
2. Identify two sources of authority for performing sanitation inspection.
3. Define “sanitation”.
4. Define “performance standard” as it relates to sanitation.
5. Describe the relationship between SPS and Sanitation Standard Operating Procedures (SSOP).
6. Identify the task performed to verify establishment compliance with SPS.
7. List the two activities used to verify compliance with the SPS.
8. Identify when it is appropriate to cite noncompliance with 9 CFR 416.1.
9. For a given scenario, identify if there is regulatory noncompliance and the SPS regulation that was not met.
10. Describe the documents that are required by the SPS regulations.
11. Describe what differentiates SPS noncompliance from SSOP or HACCP noncompliance.
12. Describe appropriate enforcement actions when SPS regulatory requirements are not met.

INTRODUCTION

Overview

Proper and effective sanitation is vital to every step of a food manufacturing process. The wholesomeness of product is directly dependent on the sanitary practices conducted in the food production operation. Insanitary facilities and equipment, poor food handling, improper personal hygiene, and similar insanitary practices create an environment conducive to contamination of products. There are direct links between inadequate sanitation and the contamination of meat and poultry products with pathogenic bacteria.

Sanitation is broadly defined as the formulation and application of procedures that establish an environmental state that promotes cleanliness and protects public health. It has many implications when applied to the food-processing environment. A safe water supply and distribution system, unpolluted air, sound construction of facilities; effective vermin control; and proper waste handling, disposal, and treatment are critical elements of environmental sanitation. Effective environmental sanitation or cleanliness coupled with sanitary maintenance of equipment and utensils, good personal hygiene, and proper food handling practices substantially reduce the risk of direct product contamination and adulteration and are essential to the implementation of Hazard Analysis and Critical Control Point (HACCP) systems.

Inspected establishments must meet two sets of regulations concerning sanitation: The Sanitation Standard Operating Procedures (SSOP) requirements and the Sanitation Performance Standards (SPS). Compliance with both is necessary if an establishment is to prevent the creation of insanitary conditions that can cause the adulteration of product. Under the SSOP requirements, each establishment must develop, implement, and maintain written procedures for the procedures it conducts daily, before and during operations, to prevent product from **direct** contamination and adulteration. SSOP requirements are in the next training module.

Most of the SPS address conditions within and around the establishment (e.g., ventilation, lighting, facility and equipment construction, and maintenance of the grounds). A few address establishment operations and **may** be met through the establishment's SSOP (e.g., cleaning and sanitizing food contact surfaces) or its HACCP plan (e.g., water reuse). SPS are an integral part of the overall public health picture of a facility or establishment. In combination with SSOP requirements, they ensure that products are produced in a sanitary environment. **SPS carry as much regulatory weight and enforceability as any other part of FSIS's regulatory food safety system. The enforcement strategy, however, is different.**

The SPS rule requires the following businesses to operate in a sanitary environment:

- Federal and State inspected meat and poultry establishments
- Import/Export facilities
- Identification (ID) warehouses
- Custom-exempt operations

Definition of Performance Standard

Performance standards set the results to be achieved, but they do not prescribe the step-by-step procedures to produce safe meat and poultry products. Simply put, the expected result is defined in the regulation, but the methods to achieve that result are not specified. The performance standards allow establishments the flexibility to develop and employ innovative and unique sanitation procedures to achieve the desired results. Although establishments can use varying means to meet the performance standards, the required results are always the same.

Establishments must: (1) operate under sanitary conditions, (2) ensure product is not adulterated, and (3) operate in a manner that does not interfere with FSIS inspection and enforcement of the standards.

AUTHORITY

Proper sanitation is a fundamental requirement of the federal meat and poultry inspection laws that the Agency enforces. The Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) provide authority, requirements, policies, and standards related to sanitation. The law is quite clear: **meat and poultry products produced, packed, or held under insanitary conditions where they may have become contaminated with filth or may have been rendered injurious to health are deemed adulterated, without any further showing required by FSIS.**

FSIS requirements for sanitation are found in the following regulations.

- Part 307, sections 307.1-3
- Part 381, subpart G, and
- Part 416, section 416.1-416.6

Specific instructions on how to verify sanitation in an establishment are found in FSIS Directive 5000.1.

IPP RESPONSIBILITY

IPP will perform routine or directed SPS Verification tasks to determine whether establishments meet all of the SPS regulatory requirements. IPP will schedule routine sanitation verification tasks in the PHIS by selecting them from the task list and placing them on their task calendar. Directed tasks are those other than routine. IPP may schedule them when IPP observe SPS noncompliance during

the performance of other tasks or when IPP suspect noncompliance with any of the sanitation performance standards. Verification of the SPS requirements may include direct observation of conditions in the establishment and observing establishment employees or review of establishment documents.

Documentation Review

For the most part, establishments are not required to develop, generate, or maintain **daily** records that document compliance with SPS. For some of the sanitation performance standards, however, they are required to maintain and provide **specific written documents** for review. §416.4(c) requires an establishment to have “documentation substantiating the safety of a chemical’s use in a food processing environment.” §416.2(g) (1) requires an establishment to have water potability certificate. §416.2(f) requires an establishment to have a sewage disposal letter when the establishment’s system is private.

Any documentation required to meet a particular sanitation performance standard will be identified when that performance standard is discussed in this module.

- If the establishment’s SSOP contains procedures it uses to meet SPS regulations (e.g., cleaning and sanitizing of food contact surfaces), then the records associated with those procedures must meet the recordkeeping requirements for SSOPs in §416.16.
- The establishment’s hazard analysis, HACCP plan, or SSOP references, procedures or prerequisite programs it uses to meet the SPS regulations, the records associated with those procedures must be available to FSIS. Such records do not have to meet the recordkeeping requirements for SSOPs in §416.16, but must contain **ongoing** documentation that continues to substantiate the establishment’s decision in the hazard analysis, HACCP plan, or SSOP.

Direct Observations

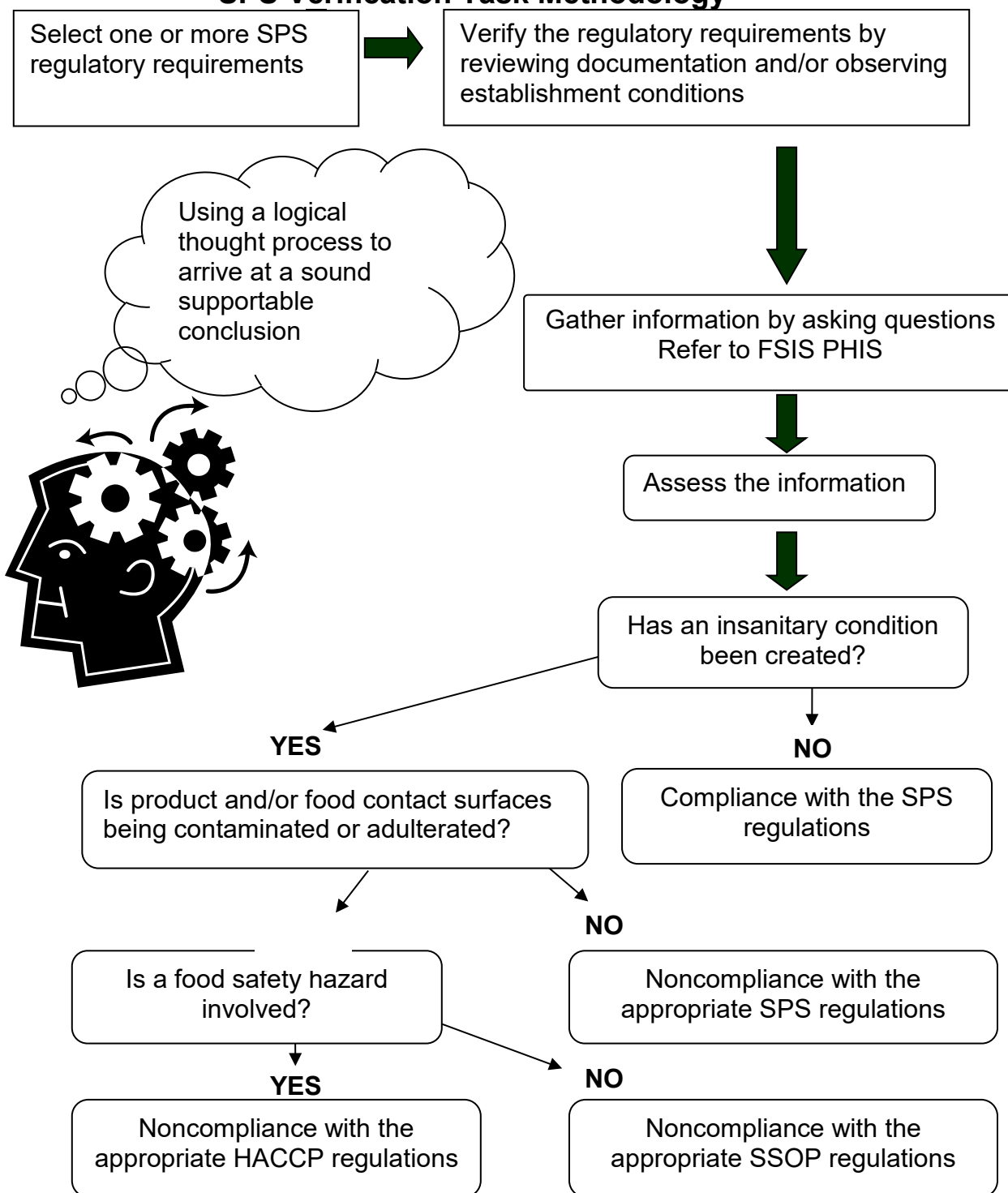
In general, IPP will verify compliance with the SPS regulations by **directly observing** the conditions in the establishment and observing establishment employees. IPP determine which sanitation performance standard or standards to verify. They choose from those listed in the regulations. When time allows, IPP are to verify multiple SPS regulatory requirements in multiple areas of the establishment each time they perform the SPS verification task. In many cases, IPP will be able to verify one or more SPS requirements while observing the establishment during other verification activities. IPP must use professional knowledge and good judgment in making the determination whether the SPS requirements are met. IPP must assess the situation in the establishment by considering what is known for a fact and what is reasonable to conclude, and then make the determination whether or not the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS from performing inspection.

When IPP determine that the establishment has failed to meet the SPS, IPP also evaluate what is known for a fact and determine if the establishment has also failed to meet the SSOP and/or HACCP requirements. If the establishment is not meeting the regulatory requirements, IPP must document how the establishment is not meeting the regulatory requirements in PHIS and initiate the appropriate regulatory control actions to gain regulatory compliance.

At times, there can be conditions in the establishment that are less than perfect but do not represent noncompliance with the SPS regulatory requirements because they are not creating insanitary conditions, adulterating product, or interfering with FSIS inspection activities.

If IPP determine that the establishment is meeting the sanitation regulatory requirements in a particular area of the establishment, IPP should document those findings of compliance in the PHIS. The SPS verification task should be documented as completed in PHIS. This does not mean that all sanitation requirements have been met in the entire establishment; it only means that the requirements verified were met in that specific area at the time the task was performed.

SPS Verification Task Methodology



SPS REGULATIONS Workshop #1

Circle the letter in front of the correct answer for each question.

1. The SPS requirements are found in 9 CFR Part:
 - a. 301.
 - b. 319.
 - c. 416.
 - d. 417.
2. Which statement best describes SPS regulations?
 - a. They contain highly prescriptive sanitation requirements.
 - b. They prescribe the step-by-step methods or means of achieving defined sanitation requirements.
 - c. They provide the establishment with minimum flexibility to be innovative in sanitary facility design, construction, and operations.
 - d. They define the expected sanitation results, but do not prescribe the methods or means to achieve those sanitation results.
3. The verification task for verifying compliance with the SPS regulations has two parts. Which of the following is **not** one of those parts?
 - a. Interviewing establishment production line employees.
 - b. Reviewing specific establishment documentation.
 - c. Directly observing conditions in the establishment.
4. The establishment must generate and maintain daily records sufficient to document compliance with the SPS regulations.
 - a. True.
 - b. False.

5. When the IPP perform the routine SPS verification task, he or she should verify:
 - a. That all of the requirements in the SPS regulations are met in the establishment.
 - b. That the requirements in at least five of SPS regulations are met in the establishment
 - c. That the requirements for the selected SPS regulations are met in one or more areas of the establishment.

SANITATION PERFORMANCE STANDARDS



The sanitation performance standards identified in §416.1-416.5 focus on specific areas or conditions in and around the establishment that **may** result in insanitary conditions that **could lead** to the adulteration of product. These regulations provide the sanitation standards the establishment must meet for the mark of inspection to be applied to its products. Insanitary means “a state, condition, or occurrence which may lead to the contamination or adulteration of edible meat or poultry product when it is exposed, processed, handled, stored, or packaged”. Noncompliance involves “insanitary conditions” that **do not** result in **direct** contamination or adulteration of product.

Note: The term “adulterated” is defined in §301.2 and §381.1.

§416.1 General Rules

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.

This regulation sets the overall requirement for all of the sanitation performance standards. Establishments **must** ensure that conditions in and around the plant **do not** lead to adulterated product.

9 CFR 416.1 is to be cited in situations where findings indicate that an

establishment systematically fails to maintain sanitary conditions, and that product adulteration may occur as a result.

§416.2 Establishment grounds and facilities

This sanitation performance standard regulation covers grounds and pest control; construction; light; ventilation; plumbing; sewage disposal; water supply and water; ice and solution reuse; and dressing rooms, lavatories, and toilets.

§416.2(a) Grounds and pest control

Proper maintenance of the grounds about an establishment is essential for ensuring good sanitation. Establishments need to keep the outside premises of the establishment clean, orderly, and free from the basic essentials of life (i.e., food, water, and a place to hide and rear young) that attract and sustain a population of insects, rodents, or birds. The objective is to keep the official premises of the establishment so well maintained that pests will seek sustenance elsewhere. The **best internal pest management program** cannot be effective when a ready supply of vermin is present just outside the establishment doors!

§416.2(a) 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 the 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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- The outside premises of the establishment are maintained in a manner that does not lead to the creation of insanitary conditions or interfere with FSIS inspection.
- Sources of product contamination or adulteration are prevented **even if** the source originates from outside the establishment's "official premises." For example, the establishment must prevent objectionable odors, smoke, flying ash, etc., even when it is coming from neighboring industries such as oil

refineries, paper pulp mills, chemical establishments, etc., from adulterating product.

Note: The “**official premises**” are the boundaries of the establishment and the limit of the IPP’s inspection responsibilities. The establishment is required to designate the official premises of the establishment. The IPP may ask for written documentation of the boundaries to facilitate inspection of the establishment.

- A pest control management program is implemented and maintained to prevent and/or eliminate pest harborage and breeding on the outside grounds **and** within the establishment.

Note: Pests can transmit several diseases to humans through food contamination.

Therefore, their presence in or around a food establishment creates an insanitary condition! Meat and poultry products should not be contaminated or adulterated through the misuse of pest control substances.

Note: Pest control substances are pesticide chemicals (insecticides, rodenticides, or avicides) used to eliminate insects, rodents, and birds, and repellents used to keep them away.

All pest control substances are safe for their intended use and applied, handled, and stored to prevent the creation of insanitary conditions that could lead to adulterated product. Pesticides, repellents, traps, and other devices must be used in a manner that will kill, capture, or repel pests that venture onto the premises or gain entrance to the establishment **without** contaminating product, product containers, or equipment.

Documentation substantiating safe use of a pest control substance in a food processing environment is available for FSIS review.

The Environmental Protection Agency (EPA) requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are followed.

FIFRA addresses the application of pesticides and the safety of chemicals.

► Safety Documentation

The regulations require that documentation substantiating the safety of a chemical’s use, including a pesticide, in a food processing environment be made available to the IPP for review [§416.4(c)]. This documentation can vary with the

nature and intended use of that chemical.

Some chemicals must meet certain requirements set forth by other Federal Agencies. For example, pesticides have to meet the requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) administered by the Environmental Protection Agency (EPA). EPA requires pesticides to be **registered** with EPA, labeled as such, and used only for their **intended purpose** in accordance with their **use instructions and safety precautions** pertinent to their use.

The documentation in this case would include proof of EPA registration and **could** include labels, application instructions, safety precautions, and other information such as records of use. IPP may see documentation in the form of a statement that the chemical was previously approved by FSIS and listed in the **old** USDA List of Proprietary Substances and Nonfood Compounds Book. IPP can accept this statement as proof that the chemical and its use are safe as long as the chemical's formulation and use has not changed since the book was printed.

► EPA Registered Label

The EPA registered pesticide label is a legal document that is numbered, indicates that the pesticide is a "restricted use" pesticide if it is, and lists the target pest, the effective concentration, the permitted conditions of use (food or nonfood areas), application methods and directions, and any safety precautions.

► Restricted Use and General Use Pesticides

The EPA classifies pesticides as "restricted use" and "general use" compounds. General use pesticides are nonresidual (contact or knockdown) pesticides that may be prepared, mixed, and used by any representative of the official establishment or its contracted pest control company. Contact or knockdown insecticides produce rapid results but must directly contact the insect to be effective.

Restricted use pesticides are residual pesticides that **may not** be purchased by the general public. They are **restricted to specific uses** and application methods. These pesticides are more hazardous and may be prepared, mixed, and used only by, or under the supervision of, certified applicators. Such persons must comply with State and EPA requirements. Residual pesticides are liquid or wetted powder insecticides that are sprayed on or applied to surfaces that insects contact. They can kill for several hours or longer after application because a toxic residue remains on the treated surface for a period of time.

Insecticide and rodenticide baits, powders and pellets are also residual pesticides.

► Pesticide Application Methods

There are several methods of applying liquid spray or aerosol insecticides.

- **General surface treatment**—Applying a liquid spray insecticide to hit the individual insect or treat specific surfaces such as floor-wall junctions or baseboards
- **Spot Treatment**—A variation of general surface treatment in which a residual insecticide is applied in a small secluded site (e.g., electrical panels, motor housings, and legs of lockers) that precludes any opportunity for transfer of the insecticide to employees, their clothing, hand tools, or any other transfer vehicle that may result in product contamination.
- **Crack and Crevice Treatment**—A more restrictive method of general surface treatment that involves delivering small amounts of insecticide deep into cracks where insects enter the building or crevices where insects may hide throughout the establishment. **The application of residual insecticides** in edible product areas, including areas where exposed edible product is stored, such as a cooler, or its packaging material is stored is usually limited to **crack and crevice** treatment. The cracks should be effectively sealed to prevent further insect traffic after the insecticide becomes ineffective.
- **Space Treatment**—The dispersal of insecticides into the air of a specific space/room by foggers, misters, or aerosol devices. Residual insecticides cannot be used for space treatment of edible product areas, including areas where exposed edible product, the equipment used to produce it, or its packaging material is stored and areas such as welfare facilities where employees may transfer the insecticide to product.
- **Void Treatment**—A variation of space treatment where an insecticide is dispersed into a void (such as a hollow wall) by foggers, misters, or aerosol devices.

► Verifying Compliance with this Regulation

First, IPP need to determine if the establishment has incorporated procedures into its SSOP that meet the regulatory requirements for this section of the

sanitation regulations. For example, an establishment may include its pest management program in the SSOP. When the establishment has included procedures for controlling pests and for the safety, conditions of use, application, and storage of pest control substances in the SSOP, management must implement and monitor such procedures and document the monitoring results including any corrective actions taken on the SSOP records. In such cases, IPP determine compliance with the regulatory requirements while performing the SSOP verification tasks.

If the pest management program is not in the establishment's SSOP, then IPP need to determine whether or not it is in a written format. The pest management program **does not** have to be written, but if it is, the establishment should follow these written procedures. The verification methodology is different when the pest management program **is not** part of the establishment's SSOP or when the establishment **does not** have written pest control.

Outside premises and pest control program verification

IPP should examine and assess the outside premises of the establishment and the establishment's pest control system in one or more places within the establishment. IPP should **verify** the outside grounds are maintained in a sanitary manner, there are no areas where pest can breed, live, or hide outside or inside the establishment, and there is no evidence of pest infestation outside or inside the establishment.

1. IPP May Gather Information by Seeking the Answer to the Following Questions:

Are all outside areas on the official premises maintained in a manner to prevent harborage and breeding of pests?

Are all areas within the establishment maintained in a manner to prevent harborage and breeding of pests?

Does the establishment have a pest management program?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for objectionable odors and flying dust, smoke, and ash in the air outside the establishment.

Note: Meat and poultry products may be exposed to airborne contaminants that can enter the establishment through necessary openings such as loading and receiving docks, employee and visitor entrances and exits, etc.

- Look for accumulations of trash, debris, board piles, scrap metal, old equipment, or other refuse lying around outside the establishment or useful materials and equipment stored in direct contact with the ground outside the establishment for several days.
- Look for tall or overgrown vegetation.

Note: Accumulations of rubbish, equipment stored on the ground, and tall weeds and dense grass are potential homes and hiding places for rodents and other vermin.

- Look for accumulations of hog hair, bones, viscera, paunch contents, feathers, manure, and other inedible materials in inedible operating and storage rooms and outside the establishment on shipping docks, near dumpsters, or in live-bird areas, driveways, pens, alleys, etc.

Note: These organic waste products contain most of the contaminants, disease-producing, and spoilage microorganisms from establishment production processes. If not handled properly, they can produce objectionable odors, serve as fly-breeding materials, and attract rodents and other vermin.

- Look for low areas with standing water outside the establishment.

Note: Surface and run-off water are usually heavily contaminated. Stagnant water in pools or puddles can emit offensive odors, serve as a breeding place for insects, and a source of water for rodents and other vermin.

- Look for conditions inside and outside that interfere with inspection, e.g., inaccessible storage rooms or buildings on the official premises; no passageways or aisles between rows of supplies, boxes, and ingredients; or rows of supplies, boxes, and ingredients stored too close to the wall or stored in a manner that the entire floor-wall junction is not visible for detecting pest activity in dry storage areas, etc.
- Look for indications that the establishment has a pest management program in place, e.g., an outside pest extermination firm has serviced the establishment, rodent bait stations and glue boards are used in the dry storage and inedible areas, holes are sealed around pipes and electrical

conduits that enter the establishment, or establishment employees inspect incoming supplies for the presence of insects, etc.

- Look for evidence of pest activity “around” and “within” the establishment.

Note: Evidence of rodent activity might be visual observation, sound, droppings, runways and rub marks, nests and burrows, and gnaw marks, while evidence of insect activity might be visual observation, egg capsules, and excrement.

“Around” the establishment would include outside premises and outside buildings within the official premises but not connected to the production facility. “Within” the establishment would include processing areas, inedible product areas, and nonprocessing areas.

Processing areas are production rooms or production-related areas such as dry ingredient storage areas, spice rooms, coolers, packaging material and container dry storage areas, or any other areas where meat and poultry product is accessible. **Nonprocessing areas** are electrical rooms, boiler rooms, maintenance rooms, welfare facilities, business offices, or similar places.

Evidence of pest activity in a processing area requires further investigation to determine if products, ingredients, or packaging materials have been adulterated or contaminated.

2. Assess the Information.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the outside premises of the establishment or the establishment’s pest control system that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(a) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- There is an accumulation of pipes, scrap metal, and old equipment lying on the ground outside the establishment.
- A large inedible product dumpster outside the establishment is emitting an objectionable odor.
- There are several low areas with standing/stagnant water in them outside the establishment.
- Several rows of palletized packaging boxes are stored so close to the wall that there is no access to view the floor-wall juncture to detect pest activity.
- There is evidence of pest activity (e.g., rodent droppings) in a **nonprocessing** area of the establishment (e.g., maintenance room or boiler room).

Pest control substance use, handling, and storage verification

IPP should observe and assess the use, handling, and storage of pest control substances in one or more areas of the establishment and review establishment documentation that supports the safety of their use in the food processing area or outside the establishment. IPP should **verify** that pesticide sprays, gases (fumigants), powders, pellets, or baits and repellents are handled, stored, and used in a manner that does not create insanitary conditions or adulterate product and that documentation describing the safe use of the chemical is on file in the establishment.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Does the establishment have documentation on file about the safety of the pest control substances?

Does the documentation on file include how the pest control substances are to be used?

Are the pest control substances being applied as per the conditions of use?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for pesticides used around the outside of the establishment or in the establishment that are not EPA-registered.
- Look for “restricted use” (residual) pesticides being prepared, mixed, or applied by a person who is not a certified applicator or under the supervision of certified applicator.
- Look for pesticides and repellents used in a manner that is inconsistent with their label instructions, safety precautions, or conditions of use identified in the use documentation on file.

Note: Some application methods do not allow operations to be conducted during treatment. Other methods allow the establishment to be in operation when treated but require exposed product to be removed from the treatment area or be effectively covered. Some methods of applying pesticides require the establishment to thoroughly wash and rinse food-contact surfaces of equipment and utensils before reusing them.

- Look for evidence of the use of **residual** insecticides in processing areas or areas such as locker rooms, lunchrooms, restrooms, halls, and the inspection office that are frequently used by employees whose primary work duties are in edible food areas.

Note: If the establishment keeps pesticide use records on file, IPP could compare these records to the documented application methods and precautions in the documentation that is on file at the establishment.

If a residual insecticide is used in an area like a locker room, it could be transferred to employees, their work clothing, or other materials and objects that

may contact product and indirectly contaminate it. Floor-wall junctions in areas with natural barriers such lockers, tables, cabinets, guard rails, and vending machines may be **spot**-treated with a residual pesticide if they **will not** be contacted by employees' shoes or other objects that could lead to secondary transfer of the insecticide to product

False or drop ceilings in processing areas or employee welfare areas cannot be spot/void treated with a residual pesticide unless the establishment can ensure that there is no opportunity for the pesticide spray or vapor to drift onto food-contact surfaces or other objects or materials below that may be contacted by employees whose primary work duties are in edible food areas.

- Look for pest control substances stored directly above or adjacent to (commingled with) food ingredients or product-packaging materials.
Note: Pesticides are toxic chemicals and if stored in this manner they could be mistaken as food additives or soil packaging materials if they happen to leak or are spilled.
- Look for clear identification (common name of the compound) on containers used to **store** amounts of pest control substances that have been removed from their **original** fully labeled (bulk) container.
- Look for documents, e.g., Safety Data Sheets (SDS), letter of guaranty, previous USDA acceptance, etc., that support the safety of pest control substances applied in the food-processing environment or around the establishment and how they are to be used in the establishment.

2. Assess the Information Gathered by IPP.

When the establishment has no documentation on file to support the safety of a pest control substance that is used in or outside the establishment, there is noncompliance with §416.4(c).

When IPP find one of the other conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any misuse, mishandling, or improper storage of pest control substances, there is noncompliance with the requirements of §416.2(a) and IPP

should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- The establishment's pest extermination company is applying an insecticide in a manner that is inconsistent with the instructions on the label.
- A two-gallon container of insecticide is stored on a rack next to bags of flour in the ingredient dry storage area.

§416.2(b) Construction

An establishment's construction, layout (placement of rooms and equipment) and product flow can have a significant impact on daily sanitation operations and the goal of minimizing or eliminating product contamination.

The performance standards for construction provide establishments, regardless of size, flexibility to design facilities and equipment in the manner to maintain a sanitary environment for food production.

§416.2(b)(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's Responsibilities

The establishment has the responsibility to ensure that:

- Buildings, including the rooms, compartments, coolers, and freezers are of such materials, construction, and finish (surface) that permit thorough cleaning to prevent insanitary conditions and product adulteration during processing, handling and storage.
- Rooms, compartments, coolers, freezers, and structures are large enough to allow orderly processing, handling, and storage of product. Inadequate room size and poor placement of equipment may result in congested operations that can lead to insanitary conditions.
- The structure of the establishment, its rooms, compartments, coolers, and freezers remains in good repair. Neglected or deteriorating facilities can defeat even the best sanitation program and lead to insanitary conditions or the adulteration of product.

Note: Floors subject to wet cleaning operations that are not watertight, i.e., have cracks, crevices, or holes, allow biological material and moisture to accumulate. Organic materials (e.g., protein and fat residue) and moisture caught or stuck in cracks or holes in the floor coupled with a prolonged drying time are all important factors in microbial growth.

Walls with rough or uneven surfaces where product is handled are difficult to clean because they may have recesses or depressions where protein and fat residue and foreign materials can collect. Likewise, junctions at floors and walls in production areas that have crevices, open cracks, or separations can allow water, dust, debris, and product residue to collect.

Although ceilings seldom contact product, they are a potential source of product contamination if foreign material or moisture drops onto equipment and exposed products. Therefore, they should be maintained in good repair and free of potential overhead contaminants such as scaling paint or plaster and leaks.

► Verifying Compliance with This Regulation

IPP should examine and assess the design and construction of rooms, compartments, and structures in one or more areas of the establishment where product is processed, handled, and stored. IPP should **verify** that the room, compartment, or structure (door, partition, or post) is made with materials that can be cleaned, is of sufficient size, and is maintained in good repair.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions:

Are the rooms and compartments of sufficient size to allow for processing, handling, and storage of product?

Are the structures, rooms, and compartments kept in good repair?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for doors or doorways too small to permit product transferred on rails or in hand-trucks to pass through without contacting the door jamb.
- Look for carcass rails without enough passageway space to prevent exposed product from contacting walls, refrigeration units, columns, or other fixed parts of the building.
- Look for inadequate space and capacity in work rooms, freezers, and coolers causing congested installation of equipment and storage of product, poor product clearance from objects, trash dumpsters stored next to exposed product or food-contact surfaces, etc.
- Look for breaks, cracks, and holes in the floors, walls, and ceilings of production areas and employee welfare facilities.
- Look for junctions at floors, walls, and ceilings in production areas and employee welfare facilities with open crevices, cracks, or separations.
- Look for flaking or peeling paint or plaster on ceilings where product is processed, handled, or stored.
- Look for leaks in the ceilings of production areas and employee welfare facilities when it is raining.
- Look for plastic strips in poor repair on doors through which exposed product passes.

2. Assess the Information gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good

judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the design, construction, and maintenance of any room, compartment, or structure in the establishment that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(b)(1) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- Flaking or peeling paint on the walls or ceilings of edible product areas.
- Two holes in the glass board of a wall in an edible product area permitting moisture to penetrate the wood behind it.
- Open gaps in the drop ceiling of the spice room because two fiberglass plastic ceiling panels have warped and are no longer seated correctly on metal cross straps.
- An exposed gap/separation at the wall-floor juncture in the equipment and utensil washroom because two brick tiles that cover it are gone.

§416.2(b)(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Floors, walls, and ceilings in areas where product is processed, handled, or stored are made of durable, easily cleanable, and moisture-resistant materials. Materials that are absorbent like wood, plaster board, and porous panels and tiles are difficult to keep clean.
- Floors, walls, and ceilings are cleaned at a frequency sufficient to prevent insanitary conditions and product adulteration.

Note: In order to be susceptible to thorough cleaning, the basic building materials used in the floors, walls, and ceilings of production and storage areas should be easy to clean, rigid, smooth, impervious to moisture, and resistant to wear and corrosion.

► Verifying Compliance with This Regulation

IPP should examine and assess the materials used to build and the cleanliness of the floor, walls, and ceiling of one or more rooms, compartments, and structures in the establishment. IPP should **verify** that the materials used in the construction of the floor, wall, and ceiling are durable and nonabsorbent. IPP should also **verify** that the floor, wall, and ceiling have been cleaned and sanitized as needed to prevent insanitary conditions.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Are the walls, floors, and ceilings made of materials that are durable and impervious to moisture?

Are the walls, floors, and ceilings cleaned and sanitized as necessary?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for the accumulation of dried or encrusted product residue from previous days' production, dust, or debris on floors and walls where product is processed, handled, and stored.
- Look for floors, walls, and ceilings made with materials that are absorbent in areas that are wet-cleaned.

- Look for dust, dirt, and debris on ceilings and window ledges where product is processed, handled and stored.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the construction and cleanliness of the floor, walls, or ceiling of a room, compartment, or structure in the establishment that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(b)(2) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- There is an accumulation of dust on the ceiling around air vents in the fresh sausage packaging room.
- There are fat particles and hog hair from the previous days' production on the wall behind the dehairing machine.

§416.2(b)(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- The design and construction of the plant creates a barrier that prevents the entry of pests from the outside. Some places where pests can gain entry into the establishment include gaps or separations in exterior wall-floor, wall ceiling, and doorjamb junctures, gaps around service entries (e.g., pipes and electrical conduits) through exterior walls, floors, and ceilings, etc.
- Breaks in the construction such as holes or cracks in exterior walls are promptly repaired.
- Doors that open to the outside and windows are protected against the entrance of pests or equipped with suitable devices (screens, fans, seals, etc.) to keep them out.

► Verifying Compliance with This Regulation

IPP should examine and assess the design, construction and maintenance of the establishment's exterior walls, floors, ceilings, outside doors, and other outside openings in one or more areas of the establishment. IPP should **verify** that the outer walls, ceilings, and floors prevent the entrance of pests. IPP should also **verify** that outside openings such as doors and windows are equipped with suitable devices or barriers to keep insects, birds, and rodents out.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

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?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for broken areas, holes, cracks, and separations in the exterior walls of the establishment.
- Look for open or broken windows without devices or barriers to prevent the entrance of pests.

- Look for outside doors with gaps around the jambs that remain open (ajar) or do not close tightly, or are in poor repair (e.g., have holes in them).
- Look for gaps around pipes and electrical conduits entering the building.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the effectiveness of a floor, wall, ceiling, door, or establishment opening's construction or maintenance in excluding pests that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(b)(3) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- There are open gaps or cracks around several outside doors and pipes entering the establishment.
- A window without a screen has a broken windowpane.
- There is a crack in the exterior block wall of the ingredient storage room.

§416.2(b)(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's Responsibilities

The establishment has the responsibility to ensure that areas where edible products are processed, handled, and stored are **adequately** separated from those areas like inedible product departments that could cross-contaminate food products with disease-causing microorganisms, chemicals, filth, or other extraneous and deleterious materials.

Note: Establishments can process, handle, or store edible and inedible product in the same room as long as they are separated by time or space in a manner that prevents adulteration of the edible product or the creation of insanitary conditions.

► Verifying Compliance with This Regulation

IPP should examine and assess the handling and storage of inedible product. IPP should verify inedible products are adequately separated from edible products.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Are edible products and inedible products processed, handled, and stored in a manner that prevents product adulteration and the creation of insanitary conditions?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for inedible product containers commingled with edible product in coolers.
- Look for inedible product contacting edible product.
- Look for inadequate separation between the handling of inedible and condemned products and edible product.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the handling and storage of inedible product that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(b)(4) and IPP should document that noncompliance on an NR. If the conditions that IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- Inedible containers with byproducts to be used as animal or pet food are commingled with containers that have edible offal in them in a cooler.
- The denaturing or decharacterizing and packing of inedible byproducts and the handling and packing of edible offal are in a room too small to keep employees and products separated.

§416.2(c) Light

Adequate lighting is essential to maintain a sanitary environment for slaughter and processing operations. Without adequate lighting, insanitary conditions are difficult to see and correct. Similarly, contaminants cannot be easily avoided or removed if they cannot be seen.

§416.2(c) 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's Responsibilities

The establishment has the responsibility to provide good quality lighting of sufficient intensity in production related areas, equipment and utensil washrooms or wash areas, hand washing areas, and welfare facilities to ensure that sanitary conditions are maintained and that product is not adulterated.

The establishment will determine which intensities and qualities of light are appropriate in different processing environments. The lighting needs to be intense enough to allow **both** establishment and inspection personnel to determine that sanitary conditions are maintained and product is not adulterated.

Note: FSIS has reserved specific lighting requirements of 200 footcandles of shadow-free light with a color rendering index of 85 in all poultry establishments (except establishments under traditional inspection) at the postmortem inspection stations and at reinspection (prechill and postchill) stations (§381.36). A minimum of 50 footcandles of shadow-free light is required at the inspection surfaces of the head, viscera, and carcass on cattle and swine slaughter lines [§307.2(m)(1)]. Since these lighting requirements are not covered under the SPS regulation, they are verified using the Inspection & Reprocessing Stations requirements.

► Verifying Compliance with This Regulation

IPP should examine and assess the quality and intensity of the lighting in production related areas, equipment and utensil washrooms or wash areas, hand washing areas, or employee welfare rooms in the establishment. IPP should **verify** that the quality and intensity of the lighting is adequate to ensure sanitary processing conditions are maintained and to examine product.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

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?

Are the intensity and quality of lighting adequate for the establishment to determine that equipment and utensils are appropriately cleaned?

Are the intensity and quality of lighting adequate in the handwashing areas, dressing and locker rooms, and toilets for the establishment and FSIS inspection personnel to determine that sanitary conditions are maintained?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for inadequate lighting at the work surface in areas where product is processed, handled, stored, or examined.
- Look for inadequate lighting in employee welfare areas.
- Look for inadequate lighting in areas where equipment and utensils are cleaned and inspected for cleanliness.
- Look for lighting that distorts the color of the surface of the product.

2. Assess the Information Gathered by IPP.

If the lighting is inadequate for IPP to determine whether insanitary conditions exist, there is noncompliance with these regulatory requirements.

Note: IPP should realize that there might be less than perfect situations that do not constitute noncompliance. If one light is inoperable, but its absence does not cause the intensity or quality of the lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether or not the product is adulterated, there is no noncompliance.

Scenario

*You find two inoperable sets of lights over two blenders **ready for use** in the north corner of the sausage kitchen that make the lighting inadequate for you to verify that food-contact surfaces are sanitary during pre-op sanitation inspection. At this point, you do not know if there is an insanitary condition, but there is noncompliance with the requirements of §416.2(c). You take official control of the blenders by placing a U.S. reject tag on them. After the establishment repairs the lights, you inspect the blenders and find residue from the previous day's production on the mixing arms inside the hoppers. The inadequate lighting may*

*have contributed to the establishment's failure to clean the food-contact surfaces of the blenders and the pre-op sanitation monitor's failure to see the product residue in the blenders. You should document **all** of the noncompliance conditions (including the inadequate lighting) on **one** NR using the Pre-Operational Sanitation SOP Review and Observation task.*

Examples of the failure to meet the requirements of this regulation are:

- There is low lighting in the gizzard-peeling area that prevents an establishment worker from inspecting the product.
- The lighting at the boneless meat re-inspection area is not adequate to determine the wholesomeness of the beef trimmings.

§416.2(d) Ventilation

A good ventilation system is important to the production of wholesome meat and poultry products. Unless the quality of air entering the establishment is controlled and the quality of the air in the establishment is maintained, products may become contaminated by dust, odors, smoke, fumes, and condensate. A poor ventilation system can serve as a vehicle for disseminating microorganisms.

§416.2(d) 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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that the ventilation system:

- Provides enough ventilation for all areas of the establishment, including processing, packaging, and welfare rooms to control condensation to the extent necessary to prevent creation of insanitary conditions and the adulteration of product.
- Promptly exhausts objectionable vapors (e.g., ammonia), fumes (e.g., from gas forklifts), and odors (e.g., from hide cellars, grease traps, toilet rooms, and inedible tank rooms) to the outside so they don't accumulate and enter edible areas where they can be absorbed by exposed product.
- Provides air from the outside that is **free** of odors from livestock pens and inedible areas, dust, fumes, and other airborne contaminants that can

contaminate product. If air is exhausted from the establishment, air from somewhere else will replace it.

Note: The Agency does not expect the establishment to completely eliminate all odors, vapors, and condensation. However, establishments must control the airborne contaminants such as odors, vapors and condensate (mists) to prevent adulteration of the environment that can lead to creation of insanitary conditions or the adulteration of product.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's ventilation system where products are processed, handled, or stored and in employee welfare rooms. IPP should **verify** that the establishment's ventilation is adequately controlling the formation of vapors (including steam) and condensate, and promptly removing objectionable vapors and odors that could create insanitary conditions or adulterate product from the establishment.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

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

Is the ventilation adequate to control condensation?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for a build-up of condensation in rooms where product is processed, handled, or stored.

Note: Condensate is free moisture formed on a surface or in the air when there is too much water vapor for the air to hold. Condensate is formed only when the temperature of the air or surface is below the dew point of the surrounding atmosphere. When condensate forms in air, it becomes fog. When condensate forms on a surface, it wets it, and if the condition persists, the moisture accumulates to the point of forming droplets that fall from a horizontal surface or run down a vertical or inclined surface. Some areas where condensate is likely to form include ceilings above cooking vessels and poultry chill vats, the ceiling around refrigeration units, or on the bottom of refrigeration units in processing areas.

- Look for a build-up of condensation on the ceilings of coolers and freezers or the bottom of refrigeration units in these areas.
- Look for objectionable vapors and odors, e.g., ammonia and diesel fumes, in areas where product is processed, handled, or stored.
- Look for air intakes in areas where product is processed, handled, or stored, bringing in air contaminated with dust, smoke, and odors.
- Look for airflow carrying contaminants from an area in the establishment being remodeled to a product area in the establishment.
- Look for airflow carrying foul odors from toilet rooms entering areas where product is processed, handled, or stored.
- Look for air flowing from raw product areas to ready-to-eat product areas.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's ventilation that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(d) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

You observe condensation that has formed on the underside of the stainless steel lid covering a large kettle during cooking. The cooking kettles, including the lids, are cleaned, sanitized, and monitored as part of the establishment's written SSOP. In this case, the condensation has no affect on product safety, sanitary conditions, or inspection. In regards to condensation, you need to keep in mind that some forms of condensation are unavoidable and acceptable as long as the establishment controls the condensation to ensure that it does not create an insanitary condition or adulterate product.

Scenario

*You observe beaded condensation on the ceiling directly above carcasses stored in the carcass holding cooler. You look for evidence that the condensate has dripped from the ceiling, e.g., drops on the floor between carcasses. You do not see any dripping condensate or find any evidence for you to conclude that condensate has contacted the carcasses. At this point, there is noncompliance with §416.2(d) because an insanitary condition exists that **could lead** to product contamination or adulteration and you would document this noncompliance on an NR.*

If the condensate had built up enough to be dripping onto the carcasses and the establishment could demonstrate there were no food safety hazards associated with the contamination, you would document this under the appropriate SSOP task.

Examples of the failure to meet the requirements of this regulation are:

- There is air from an area where raw product is handled flowing into an area where ready-to-eat product is handled.
- A foul odor emanating from a restroom is entering an area where product is processed and handled.
- Diesel fumes from parked trucks are being drawn into the receiving coolers.
- Beaded condensate is on the bottom of a refrigeration unit (not equipped with a drip pan) in an area where product is processed, handled, or stored.

§416.2(e) Plumbing

Plumbing is a particularly important consideration in food establishments. Because plumbing systems transport water to and from establishments, problems with the plumbing system can easily lead to product contamination or adulteration. Plumbing impacts the establishment's water supply, drainage, and sewage disposal systems.

Plumbing systems must be installed and maintained to:

416.2(e)(1) Carry sufficient quantities of water to required locations throughout the establishment;

► Establishment's Responsibilities

The establishment has the responsibility to ensure that the plumbing system provides enough potable water for sufficient cleaning of equipment and utensils, facilities, hands, outside areas, etc., to prevent product adulteration or creation of insanitary conditions.

Note: An adequate supply of water is critical in sanitation programs and establishment operations. Reduced water pressures, resulting from improperly sized and maintained pipelines, may adversely affect various washing operations and cleaning equipment that depend upon specific water pressure and volume to perform their intended functions.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's potable water supply system in one or more areas of the establishment. IPP should **verify** that the system can provide water in quantities sufficient for all operating needs.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Are sufficient quantities of water provided throughout the establishment?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for inadequate amounts of water in areas of the establishment that require wet cleaning operations.
- Look for inadequate amounts of water for flushing inedible materials (e.g., feathers and viscera) down the troughs in poultry slaughter operations.
- Look for inadequate amounts of water for scalding birds in poultry slaughter operations.
- Look for the absence of hot and cold water outlets in areas that require wet cleaning operations, e.g., near livestock pens, grease catch basins or traps, and outside inedible material removal areas.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's potable water supply system that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(e)(1) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, the establishment is in compliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- The water flow rate for removing inedible poultry viscera from the production room is inadequate, allowing the viscera to pile up in the trough.

- There are no water outlets in an area of the official premises that requires the removal of fat, grease, blood, meat juices, feathers, manure, etc.

§416.2(e)(2) Properly convey sewage and liquid disposable waste from the establishment;

► Establishment's Responsibilities

The establishment has the responsibility to ensure that sewage lines, drainage lines, and floor drains are of sufficient size to permit prompt removal of sewage (from toilet bowls and urinals) and liquid waste or waste water (e.g., water that contains blood, fat, animal fecal material, or product residues) from the processing environment and official premises.

► Verifying Compliance with This Regulation

IPP should examine and assess the waste disposal system in one or more areas in or outside the establishment. IPP should **verify** that the drainage system is designed to promptly remove waste materials from the establishment.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Does the plumbing system properly convey sewage and disposable waste from the establishment?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for blocked or clogged floor drain inlets and drain lines.

Note: Frequently blocked or clogged drains may be too small to accommodate the amount of waste material being removed.

- Look for accumulations of water in the bottom of ice storage compartments.
- Look for catch basins or traps for recovering grease located near edible product departments and in areas where edible products are received and shipped.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the

information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements.

IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's waste (solid and liquid) disposal system that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(e)(2) and IPP should document that noncompliance on a NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- There is a clogged drain in a production area allowing waste water to backup onto the floor.
- An ice storage compartment allows the water from melted ice to collect in the bottom.
- A grease trap located on the official premises is giving off a foul odor.

§416.2(e)(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

► Establishment's Responsibilities

The establishment has the responsibility to ensure that its plumbing system distributes a potable water supply throughout the establishment in quantities sufficient for all operating needs and the drainage and sewage lines permit the rapid removal of waste from the establishment without adulterating product or creating insanitary conditions.

Note: All plumbing should be sized, installed, and maintained in accordance with applicable State and local plumbing laws, ordinances, and regulations. If the plumbing system is not properly designed, installed, or maintained, contamination of the water supply, product, equipment, or utensils can occur or be created from conditions like cross-connections, backflow, flooding, drain system stoppage, and overhead leakage.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's plumbing system in one or more areas of the establishment. IPP should **verify** that the establishment's plumbing system is designed, installed, and maintained to prevent product contamination and adulteration.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Does the plumbing system's design, installation, and maintenance prevent adulteration of product, contamination of water supplies, equipment and utensils, and the creation of insanitary conditions in the establishment?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for dead-end pipes attached to the water supply system.

Note: Short lengths of capped pipes are considered to be dead ends. For instance, a tee with one opening plugged is not a dead-end pipe, but any length of capped pipe extending from the tee is a dead-end pipe. A dead-end pipe may serve as a reservoir for stagnant water where microorganisms can grow.

- Look for leaking wastewater drainage and sewage lines in production areas and employee welfare rooms.

- Look for potable water that has an off odor, color, or taste, or contains rust and scale.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements.

IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's plumbing system that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(e)(3) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- A dead-end pipe is attached to a potable water supply line.
- A waste water drainage pipe that is a few feet above the floor and runs along the wall of the cutting and boning room has a small leak at an elbow.

§416.2(e)(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;

► Establishment's Responsibilities

The establishment has the responsibility to ensure that all parts of floors where waste water is discharged onto the floor, wet cleaning operations are conducted, or where floors are frequently hosed down are well drained to prevent accumulation of waste and the spread of contaminants during operations.

Note: Establishment wastewater usually contains contaminants such as disease-producing and spoilage microorganisms. Therefore, contaminated fluids like wastewater that accumulates on the floor or flows across a floor for long distances can create insanitary conditions. For instance, the accumulation of liquid and suspended solid waste can create objectionable odors in working areas, make proper cleaning impossible, and be tracked through production areas by employees, increasing the likelihood of product contamination.

► Verifying Compliance with This Regulation

IPP should examine and assess drainage in one or more areas with wet cleaning operations or where wastewater is discharged on the production floor during operations. IPP should **verify** that the floor is well drained and the drainage of wastewater does not create insanitary conditions or adulterate product.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Does the plumbing system provide adequate floor drainage?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for floors with areas including low spots in traffic areas where solid waste or wastewater pools or collects because the floor is not sloped or pitched toward the drain.
- Look for wastewater discharged from soaking and cooking vats, tripe scalders, chilling tanks, or other large vessels **during operations** that travels across the floor in traffic areas before entering a drain.
- Look for drainage lines that allow waste water from handwashing facilities and meat wash sinks that discharge water onto floors of product handling or storage areas

- Look for drainage lines from drip pans of overhead refrigeration units that discharge water onto the floor.
- Look for wastewater from poultry transfer belts with continuous washing systems that flow across the floor carrying organic waste to other areas of the room before entering a drain.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to establishment drainage that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(e)(4) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- Water from drip pan drainage lines is flowing across the floor to the floor drain located in the middle of the cooler.
- Liquid and suspended solids (wastewater) are accumulating in a low area of the production room floor where employees walk.

§416.2(e)(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

► Establishment's Responsibilities

The establishment has the responsibility to ensure that its water distribution system is free of possible pollution or contamination sources such as backflow and cross-connections between non-potable water, wastewater, or sewage lines and potable water lines.

Note: Maintaining the integrity of the water supply system within the establishment is critical to product safety. A chief concern is the possibility of contamination of the water distribution system within the establishment, and that the water becomes a vehicle for the transmission of disease-causing organisms.

► Types of Cross-Connections

A cross-connection is an **actual or potential** link between the potable water supply and a source of contamination (sewage, foreign materials, chemicals, etc.). A direct (or permanent) cross-connection is one where a potable water line has actually been plumbed (solid-pipe connection) to a non-potable water (e.g., recirculated process water, untreated river water, or wastewater) line. An indirect (or temporary) cross-connection is one in which the end of a water faucet or outflow end of the line terminates below the flood level of the sink, kettle, vat, etc. Contamination or pollution occurs when the pressure differentials between the water supply and another system (reuse water, non-potable water, etc.), via a connection, are sufficient to transfer contaminants or pollutants into the potable supply. Temporary reversal of pressures or momentary vacuums in the water supplies can be unpredictable.

► Backflow

Backflow is the flow of water or other liquids that is opposite to the expected or intended direction. Backflow is undesirable; however, a potable water system protected with backflow preventing devices can remain safe. **Backpressure** (a pushing force) and **back-siphonage** (a vacuum pulling force) are two forms of backflow.

Backpressure is a concern in establishments with two or more piping systems. Backpressure occurs when both systems (potable and non-potable water) are under pressure but the non-potable system has greater pressure than the potable system, which pushes the contaminated water into the potable water

supply. For backpressure to occur, a **direct** (solid pipe) connection between the two water systems has to exist.

Back-siphonage occurs when the pressure in the potable system drops below zero (or has negative pressure), which draws or pulls (siphons) the contaminated water into the potable water supply. Back-siphonage can occur with an indirect (submerged inlets) or direct (solid-pipe) cross-connection.

► Potable Water Supply Protection from Cross-Connections

Once a cross-connection exists, a ruptured water main, a sudden large water withdrawal, or any situation that causes a **pressure differential**, with the potable system having the lower pressure or negative pressure, can result in the reverse flow of fluid (backpressure or back-siphonage) and contamination of the entire water distribution system and potable water supply. Hence, direct cross-connections between potable and non-potable water lines must not exist and equipment installations where submerged water inlets are unavoidable must be equipped with mechanical anti-backflow devices (vacuum breakers) to protect the potable water supply from contamination.

A vacuum breaker admits atmospheric pressure to a piping system between the source of the pollution and the origin of the vacuum, preventing back-siphonage. To be effective, the vacuum breaker should be installed between the last cutoff valve and the submerged water line.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's water distribution system in one or more areas of the establishment. IPP should **verify** that there are no cross-connections between potable water lines and other piping systems to prevent backflow to the water supply system.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Is the plumbing installed to prevent backflow conditions and cross-connections between piping systems that discharge wastewater or sewage and piping systems that carry water for product manufacturing?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for direct cross-connections between potable water lines and non-potable water lines, waste water lines, or sanitary (toilet and urinal) lines.

Note: Non-potable water (e.g., untreated water from a river or lake or water from an untested source such as a private well) may be used in establishments for limited purposes. Cross-connections are hard to recognize or discover because of their location. For IPP to determine if there are possible cross-connections between the potable water supply and the non-potable water supply, IPP may ask the establishment for assistance in distinguishing potable water lines from non-potable lines.

- Look for direct cross-connections between lines carrying water or solutions for reuse and lines carrying potable water.
- Look for water lines with submerged inlets in processing equipment not equipped with mechanical vacuum breakers to prevent back-siphonage.

Note: Submerged inlets are created when the outflow end of a potable water line is covered with water or other liquid. The water or liquid **may not** be potable. When IPP identify a submerged potable water inlet on a piece of equipment, IPP should ask the establishment to show IPP the location of the vacuum breaker.

- Look for cleanup hoses with ends or nozzles submerged in sinks, defrost tanks, cleaning solution tanks, clogged drains, puddles of water on floor, etc., not equipped with mechanical vacuum breakers.

Note: When IPP identify a submerged hose end in a drain, tank, sink, etc., IPP should ask the establishment to show the location of the vacuum breaker.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's water distribution system that is creating an insanitary condition, there is noncompliance with the requirements of §416.2(e)(5) and IPP should document that noncompliance on

an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- A water hose not equipped with a vacuum breaker to prevent back-siphonage has its nozzle submerged in the evisceration trough drain.
- There is a cross-connection with a shut off valve between the potable water supply and the non-potable water supply.

§416.2(e)(6) Prevent the backup of sewer gases.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that foul odors (sewer gases) from sink and floor drains do not enter the establishment.

► Verifying Compliance with This Regulation

IPP should examine and assess sink and floor drains in one or more areas in the establishment. IPP should **verify** that the drain is not allowing sewer gases to enter the establishment.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Is the plumbing installed to prevent the backup of sewer gases?

To assist IPP in answering this question, look for drains in the establishment that are emitting sewer gases.

Note: The floor drainage system is usually sealed off so that sewer gases do not enter the establishment by equipping drains, including blood drains, with a deep seal trap and a vent to the outside. The effectiveness of the trap depends upon enough water remaining to constitute a seal. As water flows through the trap and down the drainpipe, a suction is created that will pull the water out of the trap and break the seal unless the suction is broken by venting the drain pipe to the outside air. The seal can also be broken by evaporation of trapped water. Therefore, drains installed in areas where there is seldom any wet cleanup are more likely to emit foul odors because the water in the trap has evaporated.

2. Assess the Information Gathered by IPP.

When IPP find a drain in the establishment emitting sewer gases, it is creating an insanitary condition, and there is noncompliance with the requirements of 416.2(e)(6). For example, if IPP found a floor drain in a cooler allowing the release of sewer gases, IPP should document this noncompliance on an NR.

§416.2(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's Responsibilities

The establishment has the responsibility to ensure that:

- Sewage from sanitary (toilet bowl and urinal) drainage lines is disposed of in a manner that prevents the backup of fluid and suspended waste containing human waste onto processing area floors.
- An approval letter from a State or local health authority is filed on-site and available to FSIS upon request when its sewage disposal system is a private system that must be approved.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's sewage system. IPP should **verify** that sewage from toilets and urinals is removed from the establishment in drainage lines that are separate from hand washing lavatory, floor, and equipment drainage lines or disposed of in different manner that prevents the backup of sewage onto processing area floors.

IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

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?

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?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for drainage lines from toilets or urinals connected to other drainage lines in the establishment.
- Look for an approval letter on file if the establishment has a private system to dispose of sewage that must be approved by a State or local health authority.
- Look for drainage lines from toilets or urinals that drain into grease catch basins or traps.

Examples of the failure to meet the requirements for this regulation are:

- The establishment has no documentation on file from a State or local health authority for approval of a **private** sewer system when approval is required.
- The establishment's toilet bowls and urinals drain into the establishment's grease recovery catch basin.

SPS REGULATIONS WORKSHOP #2

Multiple Choice Questions

1. The SPS regulations:
 - a. Require establishments to develop, implement, and maintain written procedures it conducts daily, before and during operations, to prevent product from direct contamination and adulteration.
 - b. Address areas or conditions in and around the establishment that may result in insanitary conditions that could lead to the adulteration of product.
 - c. Cover the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that directly contact product.
2. The grounds and pest control performance standard requires the establishment to:
 - a. Store useful materials and equipment in an orderly manner on elevated racks at least 12 inches high outside the establishment.
 - b. Have a pest management program in place to prevent the harborage and breeding of pests on the grounds and within the establishment.
 - c. Provide concrete paving extending at least 20 feet from the building, at loading docks, livestock chutes, or other areas where vehicles or loaded and unloaded.

3. Which of the following statements regarding the grounds and pest control performance standard is **true**?
- a. The establishment does not have to prevent potential sources of product contamination or adulteration if the source originates from conditions outside the official premises of the establishment.
 - b. The establishment's pest management program must be a written document.
 - c. Documents supporting the safe and effective use of a pest control substance must be available for FSIS review.
 - d. Pest control substances used on the official premises must be approved by FSIS prior to use.
4. Which of the following statements is **not** found in the performance standard for construction?
- a. Doors and doorjambs that may contact product must be clad with a rust-resistant metal, e.g., stainless steel, with tightly soldered or welded seams, and the juncture of the doorjamb sealed with an effective sealing compound.
 - b. Establishment buildings, including their structures, rooms, and compartments, must be of sound construction and in good repair.
 - c. Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin.
 - d. Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture.

5. The lighting performance standard requires the establishment to:
- a. Provide a minimum of 50 foot candles of shadow-free light in areas where food is processed, handled, stored, and examined.
 - b. Cover light bulbs, fixtures, skylights, or other glass suspended over exposed food in any stage of preparation with a non-shattering protective shield, or provide safety-type light bulbs.
 - c. Provide lighting intense enough to allow both establishment and inspection personnel to determine if sanitary conditions are maintained and that product is not adulterated in areas where food is processed, handled, stored, and examined.
 - d. Provide a minimum of 30 foot candles of shadow-free light in areas where food is processed, handled, stored, and examined so that both establishment and inspection personnel can determine if sanitary conditions are maintained and that product is not adulterated.
6. The ventilation performance standard requires the establishment to:
- a. Prevent all odors and vapors in production areas.
 - b. Control odors, vapors, and condensation to prevent product adulteration.
 - c. Prevent the formation of any condensation inside the establishment.
- 7 Which statement is **not** found in the performance standard for plumbing?
- a. The establishment's plumbing system must provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning.
 - b. The establishment's plumbing system must prevent sewer gases from entering the establishment.
 - c. Hot and cold water outlets must be equipped with functioning mechanical anti-backflow devices.
 - d. The establishment's plumbing system must properly convey sewage and liquid disposable waste from the establishment.

Matching Question

Match the statement in the left column with the correct term in the right column.

- | | |
|--|--|
| _____ The dispersal of insecticides into the air of a specific space/room by foggers, misters or aerosol devices. | A. Official Premises |
| _____ A short length of capped pipe extending from a tee. | B. Space Treatment |
| _____ An actual or potential link between the potable water supply and a source of contamination (sewage, waste water, etc.). | C. Backflow |
| _____ The boundaries of the establishment and the limit of the IPP's inspection responsibilities. | D. Processing Areas (Pesticide Application) |
| _____ Production rooms or production-related areas such as dry ingredient storage area, spice room, cooler, packaging material and container dry storage area, or any other area where meat and poultry product is accessible. | E. Cross-Connection |
| _____ Electrical rooms, boiler rooms, maintenance rooms, welfare facilities, business offices, or similar places. | F. Dead-End Pipe |
| _____ Flow of water or other liquids that is opposite to the expected or intended direction. | G. Surface Treatment |
| _____ Admits atmospheric pressure to a piping system between the source of the pollution and the origin of the vacuum, thus preventing back-siphonage. | H. Nonprocessing Areas (Pesticide Application) |
| _____ Applying a liquid spray insecticide to hit the individual insect or treat a specific surface such as a floor-wall junction | I. Vacuum Breaker |

Fill-in the Blank Questions

Refer to the module to fill in the blanks.

1. Pest control substances used must be _____ and _____ under the conditions of use and not be _____ or _____ in a manner that will result in the adulteration of product or the creation of insanitary conditions.
2. Establishments can process, handle, or store edible and inedible product in the same room as long as they are separated by _____ or _____ in a manner that prevents adulteration of the edible product.
3. Sewage must be disposed into a _____ separate from all other _____ or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored.
4. _____ installations where submerged water inlets are unavoidable must be equipped with _____ to protect the water supply from contamination.

416.2(g) Water supply and water, ice, and solution reuse

Water is used to clean facilities and equipment in meat and poultry establishments. In many operations, water is used as an ingredient in product formulations. Water, unless it comes from a safe supply, may serve as a source of contamination of product, equipment, utensils, and hands.

§416.2(g)(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Running water is distributed under adequate pressure and at a sufficient temperature to areas of the establishment that require a water supply.
- Its water supply meets the potability standards in the National Primary Drinking Water Regulations issued by the EPA. If the establishment uses a municipal water supply, documentation attesting to the water supply meeting National Primary Drinking Water Regulations needs to be filed on-site and available to FSIS upon request. In the absence of such documentation, a water potability certificate or report from a State or local health agency or other responsible entity certifying potability filed on-site and available to FSIS upon request will be sufficient. There is not a mandatory renewal period for the potability certificate from a municipal source.
- A water potability certificate or report from a State or local health agency or other responsible entity certifying potability is filed on-site and available to FSIS upon request when its water supply comes from a private well. The potability certificate or report must be renewed semi-annually.
- Documentation stating that any water used to make ice being supplied to the establishment meets the National Primary Drinking Water regulations or a water report from a State or local health agency or other responsible entity certifying that the ice being supplied is made from potable water is filed on-site and available to FSIS upon request when the establishment uses ice from a different water source in the preparation of product.
- Ice to be used in direct contact with product or food equipment is handled in a sanitary manner.

Note: A water report (laboratory analysis) provided by the State or local health agency or other responsible entity certifying potability on file is acceptable in lieu of documentation stating that the establishment's water supply meets the National Primary Drinking Water requirements. A laboratory report that properly attests to the water supply as being potable **may state that the water is potable or indicate the absence of coliform bacteria.** "Potable" simply means drinkable or safe for human consumption or food processing.

The National Primary Drinking Water Regulations were promulgated under the authority of a 1986 law known as The Safe Drinking Water Act. Public or

municipal water supply systems (classified by EPA as "Community Water Systems") are the major source of water for meat and poultry establishments. Some meat and poultry establishments use private wells for their water supply. EPA classifies private industrial well water supplies as "Noncommunity Water Systems" and does not require testing for potability. FSIS, however, requires water from a private well to be tested and certified as potable semi-annually. Generally, state and local governments **do not** test private wells for potability. Private laboratories will test the well water and provide establishments with potability certificates.

Water from any source **not tested for potability or certified** as meeting the National Primary Drinking Water requirements is automatically considered to be a nonpotable supply.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's water supply in one or more areas of the establishment. IPP should **verify** that the water is at an adequate pressure and temperature for its intended purpose and that ice is made and handled in a sanitary manner. IPP should also **verify** that documentation stating that the water in the establishment complies with the EPA's National Primary Drinking Water regulations or the required water potability certificates are on file and available to IPP upon request.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Does the establishment have documentation that the water in the establishment complies with the EPA's National Primary Drinking Water Regulations?

OR

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?

Is there adequate water pressure, at a suitable temperature, in all areas where required, for example, for processing product; for cleaning rooms, equipment, and utensils; and for employee sanitary facilities? 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?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for water supplies with inadequate pressures and/or temperatures to accomplish thorough cleanup, e.g., remove fat, oil, meat juices, blood, manure, etc., from the surface being cleaned.
- Look for water spray washing equipment with insufficient pressure to thoroughly wash carcasses.
- Look for documentation on file that states the water used in the establishment meets EPA's National Primary Drinking Water regulations when its water comes from a municipal source.
- Look for a water potability certificate or report on file when there is no documentation attesting to the fact that the establishment's water meets EPA's National Primary Drinking Water regulations when its water comes from a municipal source.
- Look for a current water potability certificate or report on file when the water used in the establishment comes from a private well.

2. Assess the Information Gathered by IPP.

If IPP **do not** find documentation on file that states the water used in the establishment meets EPA's National Primary Drinking Water regulations or a water potability certificate or report when the water comes from a municipal source or a current water potability certificate or report when the establishment's water supply comes from a private well or the documentation or certificate is not available upon request, it would represent noncompliance with §416.2(g)(1).

When IPP find one of the other conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's water or ice supply that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(g)(1) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements for this regulation are:

- Water at a sufficient temperature is not available at any of the water outlets in a room where product is processed, handled, and stored.
- The establishment cannot produce documentation that its municipal water supply complies with the National Primary Drinking Water regulations or a potability certificate.
- The establishment's current water potability certificate for its private well is two years old.

§416.2(g)(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.

§416.2(g)(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 has come into contact with raw product may not be used on ready-to-eat product.

► Establishment's Responsibilities

Water reuse is an important consideration because meat and poultry operations require large amounts of potable water. Control of pathogens in water used in processing is essential for ensuring that meat and poultry products do not become adulterated. Technologies are available that effectively recondition water so that it is safe to **reuse** in a number of processing operations.

The establishment has the responsibility to ensure that:

- Product is not adulterated by reused water, ice, or solutions and the sanitary conditions are not compromised.
- Water, ice, or a solution used to chill or cook ready-to-eat product is free of pathogenic organisms and fecal coliform organisms and has been handled to reduce physical, chemical, and microbiological contaminants before being reused for the same purpose. Ready-to-eat product is a product that can be eaten by the consuming public with little or no further processing. Examples include franks, bologna, ham, and cooked corned beef.
- Water, ice, or a solution used to chill or wash a raw product has been handled to reduce physical, chemical, and microbiological contaminants before being reused for the same purpose. Raw product (e.g., uncooked meat and poultry, vegetables, and ingredients) may be contaminated with pathogenic microorganisms and fecal coliforms, so reuse water must have those contaminants reduced. For example, an establishment that re-circulates water in a chill tank for raw poultry might add chlorine to the water to reduce the number of pathogens.
- Water, ice, or solutions that have been used on raw product are not used on ready-to-eat product. To minimize the possibility of **cross-contamination** between different types of products (ready-to-eat and raw) or processes, water can be reused only for the same purpose.

Note: The requirement that water be reused only "**for the same purpose**" means that water used to chill, wash, or otherwise process raw product may be reused to chill, wash, or otherwise process **raw product even at a different step in the process** provided that "measures" are taken to reduce physical, chemical, and microbial contamination. For example, the establishment may reuse reconditioned chiller water from the final bird washer in the scalding tank. In addition, water used to process ready-to-eat product (e.g., fully cooked corned beef) could be reused to wash or process raw product (e.g., blanch pinto beans).

Water used to process raw product **may not** be reused to process ready-to-eat product.

For instance, the establishment could not reuse poultry chiller water for cooking or chilling ready-to-eat product (e.g., fully cooked poultry rolls). The likelihood of hazards occurring as a result of the establishment's water reuse system should be addressed in the establishment's hazard analysis. If hazards are likely to occur when the material (e.g., brine, ice, water, or other solution) is reused, water treatments or reconditioning controls such as filtering, screening, the addition of chlorine, etc., that are designed to eliminate and reduce them will be incorporated into the establishment's HACCP plan.

► **Verifying Compliance with This Regulation**

IPP should examine and assess the reuse of water, ice, or solutions that contact edible product. IPP should **verify** that the reuse is for the same purpose, that measures have been taken to reduce physical, chemical, and microbiological contaminants, and that water, ice, or solutions reused on ready-to-eat product are free of pathogenic organisms and fecal coliforms.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Are water, ice, and solutions that are reused, maintained free of pathogenic organisms and fecal coliform organisms?

Is other physical, chemical, and microbiological contamination reduced to prevent adulteration of product?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for water, ice, and solution reuse in the establishment's hazard analysis.
- Look for a Critical Control Point (CCP) and the procedures for handling water, ice, and solutions for reuse in the HACCP plan if the establishment found a food safety hazard reasonably likely to occur with water, ice, or solution reuse.
- Look for microbiological or chemical analyses (e.g., chlorine or other additive concentration) documentation that indicate that the reused water, ice, or solution used on ready-to-eat product is free of pathogens.

- Look for reused water, ice, or a solution that was not filtered, screened, or chlorinated, to reduce physical, chemical, and microbiological contaminants.
- Look for water, ice, or a solution that was used to chill or wash raw product reused on a ready-to-eat product.
- Look for equipment (pipelines, storage tanks) used in handling of reused water that is not designed, constructed, installed, or located to facilitate cleaning or prevent contamination.

Note: Water storage tanks should be enclosed and not exposed to the outside elements (dust, dirt, insects, or debris). Pipelines should not have dead-ends where water can stagnate.

2. Assess the Information Gathered by IPP.

If the establishment found a food safety hazard reasonably likely to occur with water, ice, or solution reuse and does not have a CCP in the HACCP plan, then there is noncompliance with the requirements of Part 417 of the regulations. IPP would document this noncompliance on an NR using the Hazard Analysis Verification task and appropriate HACCP regulations.

When IPP find one of the other conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to water, ice, or solution reuse on ready-to-eat product that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(g)(2). If IPP find any condition relating to water, ice, or solution reuse on raw product that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(g)(3). IPP should document noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with

the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the regulatory requirements for the reuse of water, ice, and solutions that contacts edible product are:

- Reusing a brine solution to chill bologna without filtering, screening, or treating it to reduce physical, chemical, and microbiological contaminants.
- Reusing water from raw vegetable rinsing operations to chill cooked hot dogs.

§416.2(g)(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.

► Establishment's Responsibilities

Some establishments recondition their water through an advanced wastewater treatment facility, either on-site or under contract.

The establishment has the responsibility to ensure that:

- Its reconditioned water has never contained human waste (water from toilet bowls and urinals).
- Its reconditioned water meets the requirements of §416.2(g)(1).
- Its reconditioned water is only used **on** raw product (e.g., to wash the surface of carcasses on the kill floor) and in edible and inedible production areas (e.g., to wash equipment and floors) throughout the facility but not **in** product formulations.
- Products, facilities, and equipment that have contacted reconditioned water undergo a separate final rinse with potable, nonreconditioned water.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's use of reconditioned water in one or more areas of the establishment. IPP should **verify** that reconditioned water meets the requirements in §416.2(g)(1) and is used only on raw products and not in product formulations, and that any facility, piece of equipment, or product that has contacted reconditioned water is rinsed with potable, nonreconditioned water.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Is reconditioned water properly applied?

Does the establishment's reconditioned water supply meet the EPA's National Primary Drinking Water regulatory requirements as indicated by a certificate or other documentation on file?

Are equipment, facilities, and raw product rinsed with potable, nonreconditioned water after contacting the reconditioned water?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for documentation attesting to the fact that the reconditioned water meets EPA's National Primary Drinking Water regulations.
- Look for products formulated with reconditioned water.
- Look for equipment, floors, or raw product washed with reconditioned water that do not receive a separate final rinse with potable, nonreconditioned water.

2. Assess the Information Gathered by IPP.

If IPP **do not** find documentation on file that states the reconditioned water used in the establishment meets EPA's National Primary Drinking Water regulations or the documentation is not available upon request, it would represent noncompliance with §416.2(g)(4).

When IPP find one of the other conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should

use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's reconditioned water that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(g)(4) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- The establishment does not rinse the kill room floors with potable water after washing them with reconditioned water.
- The establishment used reconditioned water to formulate a pickle solution that was pumped into hams.

§416.2(g)(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.

► Establishment's Responsibilities

The establishment can use non-potable water or reuse water for any purpose in edible or inedible product areas provided it ensures that the water:

- Has never contained human waste. Establishment must not reuse water from toilet and urinal lines.
- Has been conditioned (treated) to be **free of pathogenic organisms**. Reuse water must be free of pathogenic organisms to prevent their introduction into and spread throughout the establishment.
- **Does not** contact edible product. Reuse water might contain coliform bacteria, chemicals, or physical contaminants, so it cannot contact edible product.

► Verifying Compliance with This Regulation

IPP should examine and assess the establishment's use of nonpotable water in one or more areas of the establishment. IPP should **verify** that non-potable water used in edible and inedible product areas is free of pathogens and does not come into contact with edible product.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Is the nonpotable water maintained free of pathogenic organisms?

Does the non-potable water used in edible product departments come in contact with edible product?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for microbiological or chemical analyses (e.g., chlorine or other additive concentration) documentation that indicate that the reused water is free of pathogens.
- Look for non-potable water (e.g., from a river or lake) used in edible or inedible product areas that might not be free of pathogenic organisms.
- Look for non-potable water contacting edible product or product components.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should

use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's pathogen free nonpotable water use that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(g)(5) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements for this regulation are:

- Reusing chemically treated water from employee restrooms to clean antemortem pens.
- Reusing water that has never contained human waste, is free of pathogens, but has not been subject to measures that reduce physical, chemical, and microbial contamination to rinse raw vegetables to be used in meat food products.

§416.2(g)(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that water that might contain pathogens, chemicals, or physical contaminants is not used where edible product is handled or stored. A non-potable water supply or reuse water that does not

meet the use conditions of paragraphs §416.2(g)(1) through (g)(5) is a potential source of contamination.

► Verifying Compliance with this Regulation

IPP should examine and assess the establishment's use of nonpotable water or reuse water that might contain pathogens, chemicals, or physical contaminants in one or more areas of the establishment. IPP should **verify** that this type of non-potable water is not used where edible product is processed, handled, or stored, or in a manner that creates insanitary conditions.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Is non-potable water or reuse water that might contain pathogens, chemicals, or physical contaminants used where edible product is processed, handled, or stored or in a manner that creates insanitary conditions?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for non-potable water or reuse water that might contain pathogens, chemicals, or physical contaminants being used to clean floors or equipment in edible product areas.
- Look for non-potable water or reuse water that might contain pathogens, chemicals, or physical contaminants being used to chill or wash raw product.
- Look for non-potable water or reuse water that might contain pathogens, chemicals, or physical contaminants being used in edible product handling and storage areas.
- Look for objectionable odors created from the use of nonpotable water or reuse water that might contain pathogens, chemicals, or physical contaminants.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to

the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the establishment's use of nonpotable water that might contain pathogens, chemicals, or physical contaminants that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(g)(6) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements of this regulation are:

- Using reuse water not meeting the use conditions of paragraphs (g)(1) through (g)(5) in the vapor lines serving **edible** product rendering equipment.
- Using water from a lake not meeting the use conditions of paragraphs (g)(1) through (g)(5) in hog **scalding vats and dehairing machines**.
- Using water from a well not meeting the use conditions of paragraphs (g)(1) through (g)(5) for washing the floors and equipment in **edible** product departments.

§416.2(h) Dressing rooms, lavatories, and toilets

A potential source of product contamination is cross-contamination from human feces, urine, and foreign materials from employee welfare facilities. Employees can introduce pathogens into product by handling it with contaminated hands and street clothing. Personal belongings carry foreign materials that can indirectly contaminate product or food contact surfaces, therefore, areas designated to accommodate employees' personal needs must be designed to prevent

overcrowding and congestion and be conveniently located within the establishment.

§416.2(h)(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Restrooms are convenient and accessible to establishment employees at all times to encourage them to use the appropriate facilities for disposing of human wastes.
- The Occupational Safety and Health Administration (OSHA) standards in 29 CFR 1910.141(c)(1)(i) concerning the number of toilet facilities required in the workplace are followed when the establishment is constructed or remodeled.
- Dressing rooms and toilet rooms are clean, orderly, pest and odor free, and maintained in good repair.
- Dressing rooms and restrooms are separate from rooms where products are processed, handled, or stored.

► Verifying Compliance with This regulation

IPP should examine one or more dressing rooms and restrooms in production-related areas of the establishment. IPP should **verify** that dressing rooms and restrooms are convenient, ample in size, sanitary, in good repair, and separate from product processing, storage, or handling areas. Inspection personnel examining dressing rooms and toilets of the opposite sex must make arrangements with establishment management before entering.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

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?

Are dressing rooms, toilet rooms, and urinals separate from the rooms and compartments in which products are processed, stored, or handled?

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for street clothes and personal belongings like purses, coats, and shoes stored in edible product areas.
- Look for soiled work clothing (aprons, frocks, uniforms, etc.) under lockers (if provided), lying on benches (seats), or on the floor of dressing rooms and locker rooms.
- Look for trash, dirt, and debris under lockers (if provided) or on the floor of dressing rooms or locker rooms.
- Look for employees always lining up to use the restroom.

Note: If IPP believe there is a problem with the number of existing toilet facilities in the establishment, the IIC should contact the Policy Development Division (PDD) for guidance.

- Look for accumulations of used toilet tissue, trash, and debris on the floor of restrooms.
- Look for nonfunctional commodes and no supply of tissue paper in the bathroom stalls.
- Look for backed-up (clogged) or overflowing commodes.
- Look for dressing rooms, locker rooms, and restrooms that are not separate from product processing, storage, or handling areas.
- Look for objectionable odors in dressing rooms or restrooms or foul odors coming from lockers (if provided).

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers

to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to dressing rooms and restrooms that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(h)(1) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements for this regulation are:

- Used toilet tissue is on the floor around several commodes in a restroom used by production employees.
- Both receptacles in the dressing room are overflowing, allowing used paper towels and trash to be tracked around.

§416.2(h)(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Handwashing facilities (lavatories or sinks) are located either in the restroom or adjacent to it and convenient to employee work areas (e.g., in production rooms) for proper and routine hand washing to prevent contamination of product and food-contact surfaces.

- Hand wash lavatories or sinks have both hot and cold water and a hand cleanser available to aid in reducing microorganisms and removing particulate matter found on the hands.
- Hand wash lavatories or sinks have a supply of sanitary towels for hand drying so employees will not dry their hands on their clothing or other unclean materials.
- Hand wash lavatories or sinks are accessible and maintained in operating order.

► Verifying Compliance with This Regulation

IPP should examine and assess one or more hand washing lavatories or sinks located in restrooms and production related areas of the establishment. IPP should **verify** that they have hot and cold water, a supply of soap and towels, and are located where needed in the establishment.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question

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?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for handwash sinks with no hot or cold running water, soap, or towels.
- Look for areas where employees handle product that do not have handwashing facilities.
- Look for inaccessible handwash sinks, e.g., blocked from use by pallets of supplies, product, or other items not moveable by hand.
- Look for handwash sinks equipped with paper towels for hand drying without a receptacle for collecting used towels.

Note: The regulation does not require a refuse receptacle be placed near hand wash sinks. The lack of one, however, could lead to an insanitary condition [see §416.4(b)] if used towels were accumulating on the floor around the sink.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to handwash lavatories or sinks that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(h)(2) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

You observe pallets of packaging material blocking access to the only handwash sink in the beef patty pack-off area. The sink being inaccessible to employees does not mean that there is an insanitary condition. You are still in the area when you see an employee cover her mouth and nose with her hand and sneeze. The employee goes to the handwash sink to clean her hands but is unable to because she cannot get to the sink. Because the employee was unable to clean her hand after contaminating it, an insanitary condition that could lead to the contamination of product has now been created. There is noncompliance with the requirements of 416.5(a), so you should document this noncompliance on an NR.

Scenario

You find both foot pedals for turning on the water to the only handwash sink in the poultry cut-up room are broken. While looking for the floor supervisor to

inform him of their finding, you observe an employee contaminate his hands by opening the lids of several boxes of ice-packed whole birds. The employee realizes he has contaminated his hands and goes to the handwash sink to clean them. Since there is no water, the employee does not clean his hands. He returns to his work area, and removes whole birds from the boxes, and cuts them up before you could inform the supervisor of the insanitary condition. In this case, an insanitary condition has lead to the direct contamination of product. You should document this noncompliance under the appropriate SSOP task and regulations.

Examples of the failure to meet the requirements for this regulation are:

- There are no paper towels at the only handwash sink in the ready-to-eat product room.
- There is no hand cleaner in the dispenser for the only handwash sink in the cutting and boning room.

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

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Receptacles and containers for handling, storing, and transporting waste are made of materials that do not create an insanitary condition.
- The refuse receptacles or containers are maintained in a good state of repair and cleaned as needed to avoid creating insanitary conditions.

► Verifying Compliance with This Regulation

IPP should examine and assess one or more refuse receptacles or containers in welfare facilities or production related areas of the establishment. IPP should **verify** that they are constructed and maintained in a sanitary manner.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question

Are refuse receptacles constructed and maintained in a sanitary manner?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for refuse receptacles or containers made of materials that cannot be easily cleaned, e.g., materials that absorb moisture.
- Look for refuse receptacles or containers with holes in them that are leaking waste materials.
- Look for refuse receptacles or containers that are giving off objectionable odors.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to refuse receptacles or containers that is creating an insanitary condition, there is noncompliance with the requirements of 416.2(h)(3) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations

Examples of the failure to meet the requirements for this regulation are:

- A plastic trash container in the lunchroom has a hole in the bottom, allowing food particles to fall out onto the floor and liquids to drain onto the floor.
- A plastic trash container outside the receiving office in the ingredient dry storage area has a buildup of soil on the inner surface that is giving off a foul odor.

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§416.3 Equipment and Utensils

Equipment used in meat and poultry slaughter and processing establishments range from utensils (simple hand tools) to large, highly complex electronically operated machinery. Since product contacts a variety of equipment surfaces, there is a potential for it to be contaminated. Equipment design and construction can have a significant impact on sanitation in the establishment and the goal of preventing product contamination.

§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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Equipment and utensils used in the preparation, handling, and storage of edible product and ingredients **are not** a source of product contamination or adulteration.
- Equipment and utensils are made of materials that are easy to clean.
- Materials used in the construction of equipment will not deteriorate under normal use conditions in the establishment, allowing the harborage of microorganisms that could lead to adulteration of product.

- Equipment is designed, installed, and maintained to prevent deteriorating surfaces that could lead to **both** microorganisms and chemicals being transferred to product.
- The design, installation, and maintenance of equipment in the establishment ensure that all surfaces and parts are capable of being cleaned and maintained in a sanitary manner.

Note: Microorganisms may grow and cause objectionable odors inside equipment where meat and poultry fat and juices, cleanup water, and other debris are allowed to accumulate. Food-contact surfaces with pits, open seams, cracks, crevices, interrupted welds, etc., and external surfaces of equipment with open seams, gaps, crevices, inaccessible recesses, etc., may prevent the adequate removal of organic matter (product residues) from the surface and allow the development of biofilms. A **biofilm** is composed of closely packed colonies of bacteria that have attached themselves to the surface by producing a complex carbohydrate or polysaccharide substance that firmly adheres to the surface (including stainless steel) and traps nutrients, other microorganisms, fat, proteins, and other debris. Once established, these biofilms can transfer pathogens to product. Biofilms **are not** easily removed by ordinary cleaning measures and resist penetration of sanitizers.

- Equipment is designed and installed in such a manner that foreign materials such as lubricants, heat exchanger media, condensate, cleaning solutions, sanitizers, and other nonfood materials do not create insanitary conditions or adulterate product.
- Cleaning and sanitizing of clean-in-place (CIP) systems are as complete and effective as the cleaning and sanitizing of disassembled equipment. The CIP design should ensure that the circulating cleaning and sanitizing solutions and rinse water contact all food-contact surfaces of the equipment. Dead spots in the system, i.e., areas not contacted by the circulating cleaning and sanitizing solutions and rinse water, could cause insanitary conditions and adulteration by permitting the build-up of product residue. The CIP system should be self-draining because cleaning and sanitizing solutions remaining in the system may result in insanitary conditions and product adulteration.

Note: CIP systems are used on equipment that is difficult or impractical to disassemble. CIP equipment is cleaned by circulating detergent solutions and rinse water at a flow velocity high enough to remove all product residues from internal surfaces. Band saws, mixers, grinders, etc., that are subject to in-place manual cleaning are not considered CIP system equipment.

► Verifying Compliance with This Regulation

IPP should examine and assess equipment and utensils used to prepare and handle edible product in one or more areas of the establishment. IPP should verify that the design, construction, and installation of the equipment and utensils permits easy cleaning, and that the equipment and utensils are in good repair.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Are equipment and utensils used in processing and other handling of edible product or ingredients of material and construction that facilitates thorough cleaning?

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

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for corrosion, rust, blisters, pits, cracks or other defects on equipment and utensil surfaces.
- Look for surfaces of equipment and utensils that can absorb moisture.
- Look for difficult-to-clean areas or surfaces on equipment and utensils.

Note: There are many types of equipment used in the slaughtering and processing of meat and poultry products. It is not possible to list all of the pieces of equipment or the areas of the equipment that may be difficult to clean. Most pieces of equipment have areas that are difficult to clean or are accessible for cleaning but are not cleaned on a regular basis. For instance, grinders, conveyors, augers, blenders, emulsifiers, patty machines, linkers, stuffers, and packaging machines all have areas on them that are difficult to clean. Undersides of equipment, around motors, and behind deflectors or guards are some of the areas that might not be cleaned regularly and create insanitary conditions. IPP should not only learn to look, but should be sensitive to odors that might indicate there is an accumulation of product or product juices within a piece of equipment that has not had regular cleaning.

- Look for surfaces of equipment and utensils that could allow the migration of deleterious substances or impart colors or odors to product.

Note: Aluminum, copper, brass, and bronze are metals that can discolor, stain, or migrate into the product. For instance, when friction occurs between aluminum and meat or fat, a black oxide is produced that discolors the meat. When copper and copper alloys (brass and bronze) contact acidic foods like meat and poultry, fats or oils, an objectionable greenish discoloration is formed in the product.

- Look for rough areas or recesses, open seams, gaps, protruding ledges, inside threads, bolts, or rivets on food-contact surfaces of equipment and utensils.
- Look for open seams, gaps, crevices, inaccessible recesses, or slot or hollow-headed fasteners, etc., on nonfood-contact surfaces of equipment.
- Look for rough, interrupted, or uneven welds on equipment and utensil surfaces.
- Look for low areas, depressions, or sagging areas on or in equipment where cleanup water may accumulate and create an insanitary condition.
- Look for parts or components of equipment such as pulleys, bearings, or gears that could contaminate product and food-contact surfaces with foreign materials.
- Look for equipment and utensils that are not in good repair.

Note: The equipment in large establishments handles large volumes of product. Equipment parts may become worn or damaged under normal use. Equipment that is not properly operated or maintained may have damaged or worn parts. Therefore, IPP should also learn to listen for noises that are not normal, such as metal rubbing on metal. Worn or damaged equipment can create insanitary conditions and adulteration of product.

- Look for equipment, compartments, and bins used to make and store ice that could contaminate the ice.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to equipment and utensils that is creating an insanitary condition, there is noncompliance with the requirements of 416.3(a) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

*You observe a rough, uneven weld with crevices that connects one of the agitating paddles to the shaft in a vertical mixer **ready for use** in the curing room. You closely examine the weld and conclude that no product will be contaminated when the mixer is used because you found no accumulation of product residue stuck in the crevices or around the weld; therefore you document the noncompliance on an NR using the appropriate SPS regulations the surface does not facilitate cleaning. However, if you had found an accumulation of product residue stuck in the crevices or around the weld, then product would be contaminated when it came in contact with the weld. If the establishment could demonstrate there was no food safety hazard associated with the contamination, you would have documented this noncompliance using the appropriate SSOP task and regulations.*

Scenario

You observe a black substance on the surface of a piece of equipment during operations. You examine the piece of equipment and the product around it and find there is no product contamination occurring; therefore, you document the noncompliance using the appropriate SPS regulations. If the black substance was contacting product and the establishment could demonstrate there were no food safety hazards associated with the contamination, you would document this using the appropriate SSOP task and regulations. If the black substance contacting the product were coming from a heavy metal, such as lead, the

establishment would probably not be able to support the claim that there is no food safety hazard associated with that contamination, therefore you would document the noncompliance using the appropriate HACCP verification task and regulations.

Examples of the failure to meet the requirements for this regulation are:

- A food-contact surface of a piece of equipment is corroded and has several pits.
- A piece of equipment used to handle edible product has an **external** surface (nonfood contact) with an exposed bolt and open seam that have a build-up of encrusted product residue around and in them.
- A polyester conveyor belt that moves exposed product to the packaging machines has two deep cuts and has been gouged.
- The plastic cutting boards on the pork boning tables have been scored by hand knives and have wizard knife gouges.
- A stainless steel shovel used to handle edible product has a rough and curled edge.
- An accumulation of product residue is under the edges of the floor mounts for the legs of three large permanently installed cooking kettles.
- A foul odor emitted from a gearbox on a piece of equipment.

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

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Equipment and utensils are designed, constructed, installed, and operated in a manner that allows inspection personnel access to inspect them. Because of the closed nature of CIP systems, there should be inspection openings through-out the system so the IPP can verify that all parts have been cleaned and sanitized.

- Conveyor guides, splash guards, safety guards etc., that are installed on equipment that cover food-contact surfaces can be removed to permit inspection.

► Verifying Compliance with This Regulation

IPP should examine and assess equipment and utensils used to prepare and handle edible product in one or more areas of the establishment. IPP should **verify** that the construction, location, or operation of the equipment and utensils does not prevent or impede inspection tasks.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

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?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for equipment and utensils whose construction or installation interferes with sanitation inspection.
- Look for equipment and utensils with nonfood contact surfaces that are not accessible for inspection.
- Look for equipment and utensils with food-contact surfaces that are not visible for inspection.

2. Assess the Information IPP Gathered.

If IPP cannot visually inspect the surfaces or parts of equipment, IPP cannot determine if an insanitary condition is being created or if product is being contaminated.

Scenario

You find that a section of the establishment's CIP piping system is not disassembled for inspection and it does not have access points for you to inspect the interior surfaces for cleanliness. At this point, you do not know if the piping is not clean, but there is noncompliance with the requirements of 416.3(b) so you should document this noncompliance on an NR.

The establishment installs quick disconnects and removable elbows at each change of direction to allow inspection. You ask the establishment to disconnect the pipes for inspection and a solution of water pours out of them. Now you will have to gather more information and make the determination whether or not this condition is creating an insanitary condition or contaminating product.

Examples of the failure to meet the requirements for this regulation are:

- A splash guard is permanently installed on a portable screw conveyor that carries trimmings to a meat grinder hopper that prevents the IPP from inspecting the sanitary condition of the auger.
- A large piece of equipment is installed so close to the wall that the IPP cannot inspect the sanitary condition of one side of it.

§416.3(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Containers or receptacles for handling, storing, and transporting inedible materials are made of materials that do not create an insanitary condition.
- Inedible receptacles or containers are maintained in a good state of repair and cleaned as needed to avoid creating insanitary conditions. Containers that are not watertight or that leak can spread contaminants into the environment, which could become a source of contamination of product, equipment, and utensils.
- The permitted use of the receptacle or container is identified through conspicuous and distinctive markings, a color-coding system, or some other means. Simply put, establishment employees need to be able to recognize the inedible product containers from the edible product containers.
- Inedible receptacles or containers are not used to handle, store, and transport edible product.

► Verifying Compliance with This Regulation

IPP should examine and assess inedible receptacles in one or more areas of the establishment. IPP should verify that receptacles or containers are clearly marked or identified, and constructed and used in a sanitary manner.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

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

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

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for proper identification on the inedible material receptacles.
- Look for inedible receptacles made of materials that cannot be cleaned.
- Look for inedible receptacles that are not watertight or are leaking.
- Look for inedible receptacles that are giving off objectionable odors.
- Look for inedible receptacles that are used to handle, store, and transport edible product.

2. Assess the Information Gathered by IPP.

If IPP find inedible containers that **are not** clearly marked or **readily distinguishable** from edible product containers, it would represent noncompliance with §416.3(c).

When IPP find one of the other conditions listed above, IPP should assess all of the information surrounding their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to inedible receptacles or containers that is creating an insanitary condition, there is noncompliance with the requirements of 416.3(c) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

*You observe a plastic trash can marked “inedible” in the cooler being used to store **edible** bologna rework (stick ends and broken slices). You take an official control action and retain the bologna rework. To salvage the rework, the establishment must demonstrate that the rework is not contaminated. Even if the establishment is able to demonstrate that the rework is not contaminated, there is still noncompliance with the requirements of 416.3(c) and you should document this noncompliance on an NR using the appropriate SPS regulations. If the establishment cannot demonstrate that the rework is not contaminated, you would document this noncompliance under the SSOP task.*

Examples of the failure to meet the requirements of this regulation are:

- There is a hole in the bottom of an inedible container allowing purged juices (blood, water, etc.) to leak onto the production room floor.
- Several metal inedible product barrels located in production-related areas have a large build-up of dried, encrusted product residue on the inside surface and are emitting an objectionable odor.

§416.4 Sanitary Operations

Frequent and effective cleaning of certain areas of the establishment is necessary to (1) prevent the accumulation of organic wastes resulting from meat

and poultry operations on equipment and utensils, (2) prevent the development of foul odors that could attract insects, rodents, and other vermin, and (3) remove product debris or dirt on nonfood-contact surfaces that may provide an environment suitable for the growth of microorganisms that employees could indirectly transfer to product. The method, frequency, and area to be cleaned may vary with establishment operations.

§416.4(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Utensils and equipment surfaces that contact exposed edible product are cleaned and sanitized on a schedule that prevents the creation of insanitary conditions and the adulteration of product.
- Food-contact surfaces of utensils and equipment are cleaned and sanitized whenever there is a change from working with raw product or raw components to working with ready-to-eat products.
- Food-contact surfaces of utensils and equipment are cleaned and sanitized whenever they become contaminated during operation.

Note: Many establishments will comply with the requirements of §416.4(a) through SSOP activities. Generally, establishments clean their operations once a day, however, some establishments conduct chemical cleanup procedures less than once a day. These extended cleanup procedures should be incorporated into the establishment's SSOP. To ensure that extended cleanup procedures prevent insanitation and the adulteration of product, establishments might conduct microbiological testing to evaluate the effectiveness of the extended cleanup. If IPP have concerns about the establishment's frequency for cleaning and sanitizing food-contact surfaces IPP should confer with the Policy Development Staff (PDS).

An example of failure to meet this performance standard is insufficient cleaning of a belt allowing a build-up of fat. When the fat rubs against a stainless steel guard on the belt, a black substance is deposited on the accumulated fat.

Based on the regulatory requirements of 9 CFR 417.2(a)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request. These monitoring and testing records should be available to FSIS whether or not these activities are listed in the HACCP plan or hazard analysis. These records include, but are not limited to, all records, results, and supporting documentation associated with each HACCP plan, records, results, and supporting documentation associated with each procedure or prerequisite program, testing conducted for the establishment's business customers, aerobic plate count testing, and total plate count testing.

The IPP should be aware of all monitoring and testing conducted by the establishment and should ask establishment management to share the data that is generated by this monitoring and testing. The IPP should review the results when performing the Hazard Analysis Verification (HAV) task, the HACCP verification task, or the Review Establishment Data task. When reviewing records, results, and supporting documentation associated with testing, monitoring, and verification activities that are from procedures or prerequisite programs outside the HACCP plans, IPPs should not apply the same criteria as they would when verifying the regulatory requirements of HACCP plans. For example, these records associated with monitoring and testing may include occasional instances of less than perfect control without resulting in threat to product safety. However, records generated from these programs must continue to support the decisions made in the establishment's hazard analysis.

IPP should assess the testing results and monitoring results to verify the overall effectiveness of the procedures or programs. IPP should verify that if there is information in the records that requires the establishment to reevaluate the effectiveness of the Sanitation SOPs or reassess its HACCP plan, the establishment has done so. If the establishment has gathered information that indicates the Sanitation SOPs are no longer effective in preventing direct contamination or adulteration of product, there is noncompliance with 9CFR 416.14. If the establishment has gathered information that indicates the HACCP plan should be reassessed and has not done so, there is noncompliance with 9 CFR 417.4.

If IPP have concerns about the design or results from testing, procedures or programs, IPP can contact the PDS or an EIAO through supervisory channels. The EIAO needs to conduct a comprehensive food safety assessment in the establishment to verify that the design of the food safety systems in operation meet regulatory requirements.

If the establishment does not provide IPP with these records when they are requested, IPP should document this as noncompliance with the requirements specified in 9 CFR 417.5(a)(1) or as per FSIS Directive 5000.1.

§416.4(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that nonfood-contact surfaces of facilities, equipment and utensils are cleaned and sanitized at a frequency that will prevent the accumulation of dust, dirt, product residue, and other debris that could create insanitary conditions and adulterate product.

Note: During the normal course of operations exposed meat and poultry product should not come into contact with nonfood-contact surfaces such as the floor; posts, walls, door jambs, and other fixed parts of the building; flexible plastic strips or curtains on doors; or the inside surfaces of truck trailers. Nevertheless, the cleaning of the facilities is an important measure ensuring the protection and sanitary preparation of product. Unclean noncontact surfaces can cause sanitation problems by attracting vermin or by promoting the growth and reproduction of microbes. These microbes may spread to the exposed product areas in air currents, on employee clothing, on utensils or equipment, or cause odors that spread to the exposed product areas in air currents. A regular cleaning schedule should be established and followed to maintain nonfood-contact surfaces of the facility in a clean and sanitary manner.

► Verifying Compliance with this Regulation

IPP should observe and assess the cleanliness of nonfood-contact surfaces in one or more areas of the establishment. IPP should **verify** that nonfood-contact surfaces in production related areas have been cleaned at a frequency necessary to preclude the build-up of soil residues.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Are nonfood-contact surfaces of facilities, equipment, and utensils in the establishment cleaned and sanitized as necessary to prevent the creation of insanitary conditions and the adulteration of product?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for the accumulation of dried or encrusted product residue from the previous days' production on the underside and legs of equipment, e.g., conveyors, work tables, platforms, hand trucks, kettles, blenders.
- Look for the build-up of product residue, dust, and debris in hard-to-clean areas such as a wall behind a large piece of equipment, mounted cabinets, or electrical boxes in edible product areas.
- Look for posts, doors, doorjambs, rail switch pulls, and other fixed parts of the building coated with fat and meat juices from previous days' production.
- Look for accumulations of dust and rust on overhead pipes, rails, ducts, wires, lights, and any other overhead structures in edible product areas.
- Look for accumulations of product residue, trash, dust, or debris on the floors in production rooms, coolers, freezers, and ingredient dry storage areas.
- Look for accumulations of rubbish, trash, dust, or debris on the floor in lunchrooms and break rooms, and of packaging material in dry storage areas.
- Look for a build-up of black tar-like residues from previous days' smoke cycles on the ceiling, walls, and smoke ducts of smokehouses.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information surrounding their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the cleanliness of nonfood-contact surfaces of facilities, equipment, and utensils that is creating an insanitary condition, there is noncompliance with the requirements of §416.4(b) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

You observe a rail in the carcass cooler with an accumulation of rust on it. Beef sides are stored directly under the rusted area on the rail. You decide to examine the hock and round area of several sides of beef. You find numerous black specks on one side and a few black specks on the other sides of beef. Because product was contaminated by flaking rust, you should document this noncompliance using the appropriate SSOP regulations.

If you did not find rust specks on the sides of beef when you examined them, there is still noncompliance with the requirements of 416.4(b) because the rail was not maintained and cleaned at frequency to prevent the build-up of rust.

Examples of the failure to meet the requirements for this regulation are:

- There is mold growing on a wall in an edible product area.
- There are meat and fat particles from previous days' use on the underside of a product transfer belt.
- There is an accumulation of food particles, trash, and dust under the vending machines in the cafeteria.

§416.4(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Meat and poultry products are not contaminated or adulterated through the misuse of proprietary substances and nonfood compounds.
- All proprietary substances and nonfood compounds are safe for their intended use and used, handled, and stored to prevent the creation of insanitary conditions.
- Documentation substantiating safe use of a chemical in a food-processing environment is available for FSIS review.

Safety Documentation

Safety documentation can vary with the nature and intended use of the chemical. Some chemicals must meet certain requirements set forth by other Federal Agencies. For example, sanitizers used on food-contact surfaces and some lubricants used in food processing areas must meet the Food and Drug Administration (FDA) requirements. The establishment should have documentation showing that the compound complies with the relevant FDA regulations (21 CFR §178.1010 or §178.3570). Sanitizers meeting FDA requirements are usually identified as "Food Grade."

The use of many chemicals is not approved by any Federal agency. In this case, the establishment may have a Safety Data Sheet (SDS), label, use instructions, or a letter of guaranty from the manufacturer to substantiate the safety of the chemical when used in a food-processing environment.

IPP may see documentation in the form of a statement that the chemical was previously approved by FSIS and listed in the **old** USDA List of Proprietary Substances and Nonfood Compounds Book. IPP can accept this statement as proof that the chemical and its use are safe as long as the chemical's formulation and use has not changed since the book was printed.

► Verifying Compliance with This Regulation

IPP should observe and assess the use, handling, and storage of proprietary substances and nonfood compounds in one or more areas of the establishment and review establishment documentation that supports the safety of their use in the food processing area. IPP should **verify** that these chemicals are used, handled, and stored in a manner that does not create insanitary conditions or

adulterate product and that documentation describing the safe use of the chemical is on file in the establishment.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

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

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

The following list of observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for proprietary substances and nonfood compounds used in a manner that is inconsistent with their label instructions and precautions.
- Look for clear identification (labeled name of the compound) on containers used to store, dispense, or transport amounts of nonfood compounds (e.g., cleaners and sanitizers) that have been removed from their **original** fully labeled (bulk) container.
- Look for proprietary substances and nonfood compounds stored directly above or adjacent to (commingled with) food ingredients or product-packaging materials.
- Look for containers that held toxic materials used to handle, store, or transport **edible** product or food ingredients.
- Look for documents that support the safety of a substance or compound used in the food-processing environment.

2. Assess the Information Gathered by IPP.

When the establishment has no documentation on file to support the safety of a proprietary substance and nonfood compound that is used in the facility, there is noncompliance with §416.4(c).

When IPP find one of the other conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should

use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to use, handling, and storage of chemicals that is creating an insanitary condition, there is noncompliance with the requirements of 416.4(c) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

*You observe an employee preparing a solution of quaternary ammonium sanitizer to be applied to the blades of the slicers and surfaces of the conveyor belts that move sliced product to the packaging machine. The employee removes a cup (8 oz.) of the sanitizer from a gallon container and adds it to a two gallon spray bottle filled with water. You review the general use instructions that are printed on the one-gallon container of sanitizer. The instructions state "to attain a 200 ppm dilution, add 8 oz of sanitizer to 4 gallons of water." The label also states that treated equipment does not need to be rinsed with potable water. In past observations, you have not seen the establishment rinse the blades of the slicers or conveyor belts with potable water after treatment with the sanitizer. You inform management of their observation. A management official discards the sanitizer solution and correctly mixes another solution of sanitizer. At this point, you **do not know for a fact** that product has been adulterated.*

*You have seen the employee that mixed the sanitizer applying it to the equipment before. Therefore, you are concerned that the sanitizer may have been previously misused. Chemical sanitizers used in excessive amounts can be harmful if they end up in food. You conclude that you are **unable to determine** that the establishment has not produced adulterated product. You ask*

establishment management to demonstrate that adulterated product has not been produced.

Examples of the failure to meet the requirements for this regulation are:

- The establishment's documentation that is kept on file to support the safety of the substances and compounds used in the facility is not available to the IPP upon request.
- A five-gallon container of liquid cleaning agent is stored on a rack directly above bags of salt in the ingredient dry storage area.
- There are several containers with a chemical solution in them stored in the dry storage area without any identification on the container.

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

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Product is not contaminated or adulterated by elements in the environment such as microorganisms, dust, wood splinters, scaling paint, flaking rust, condensate, oil, grease, metal fragments, plastic, etc.
- Products are not adulterated or misbranded because they contain undeclared ingredients that are potential sources of food sensitivities and intolerances (i.e., allergens).
- Products are protected from being contaminated by dust, dirt, or insects during loading, unloading, and transportation from the establishment.
- No handling or storing of nonfood materials (barrels, boxes, pallets, trash, etc.) creates insanitary conditions in areas where product is prepared, handled, or stored.
- Supplies such as packaging materials or paper wrappings that might contact edible products are handled and stored under sanitary conditions, e.g., measures are taken to prevent dust collection, footwear contamination, cleanup water splash, or contact with any insanitary surface.

- Wet cleaning operations are conducted in a manner that minimizes the danger of contaminating product or food-contact surfaces with splashes from cleanup water. The establishment should have a separate area or washroom for cleaning utensils, pans, trays, hand trucks, demountable equipment, etc.
- Employee traffic patterns do not create insanitary conditions or lead to the cross-contamination of product. Pathogens can be transported by employee clothing or boots. Therefore, employees not routinely assigned to specific work areas should not travel through those work areas. For example, employees working in the inedible product department should not travel through edible product areas.

Similarly, employees that work in slaughter areas or raw product areas should not travel through cooked or ready-to-eat product areas.

Note: Depending upon the situation and the circumstances, the establishment must decide how to protect the product through all phases of the process. For example, the establishment may decide to cover all product that is stored in the finished product freezer with plastic to prevent condensate from soiling the boxes while it is working to fix the refrigeration system in the freezer.

This performance standard allows establishments to devise their own means of limiting microbial growth in their processing operations. The establishment may control microbial growth in product by using the traditional method of reducing the ambient temperature or use a different method. For instance, the establishment may use heat exchangers on equipment to immediately reduce product temperature, which more effectively limits the growth of microorganisms than maintaining a specific room temperature.

► Verifying Compliance with This Regulation

IPP should observe the preparation and handling of product at one or more points or steps in the production process. IPP should **verify** that product is protected from sources of contamination as it moves through the process.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

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

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for inadequate sanitation between production runs of products that have ingredients that cause food sensitivities declared on their label and products that do not have these ingredients declared on their label.
- Look for raw (not rinsed or washed) vegetables being handled in the same area as exposed edible product.
- Look for cloth or paper containers of meat or poultry or of ingredients (sugar, salt and spices, etc.) added to equipment (mixers, blenders, grinders, etc.) that allows lint, dirt, or debris from the outer surface to fall into product.
- Look for supplies that might contact product that are not handled and stored in a manner to preclude contamination
- Look for food ingredients that are not handled and stored in a manner to preclude contamination, e.g., spices stored in containers without lids in the spice room, open broken bags of ingredients in the dry storage area, etc.
- Look for products (carcasses or carcass parts, trimmings in combo-bins or gondolas, etc.) received and distributed from the establishment that are not protected from dust, dirt, insects, etc.
- Look for transport vehicles that are not constructed to protect product being hauled from weather or road contamination.
- Look for containers (wooden, fiberboard, or metal) **reused** as edible product containers that are structurally unsound or not clean, e.g., torn, broken or wet; soiled or stained; give off odors; or contain meat and fat particles, wood splinters, and any other foreign material.
- Look for transport vehicles that give off objectionable odors or that have accumulations of dried meat and fat or foreign materials such as grease and trash in them.
- Look for pallets in edible product areas that have a build-up of grease, meat tissues and juices, animal excreta, feathers, or hair, or are giving off offensive odors.

- Look for accumulations of rubbish such as paper towels, empty product cartons, or labeling materials in edible product areas.
- Look for employees traveling through areas of the establishment where they are not assigned.

2. Assess the Information Gathered by IPP.

When IPP find one of the conditions listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to the processing, handling, storage, loading and unloading, and transportation of product that is creating an insanitary condition, there is noncompliance with the requirements of §416.4(d) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

You observe an employee preparing a pickle cure solution. The pickle ingredients are staged on a wooden pallet next to the stainless steel pickle cure vat. The employee fills the vat up with water and then begins to add 50 lb bags of salt to the water. He stands the bag on end, opens the top of the bag of salt, picks it up, places it on the rim of the vat with the bag over the edge, and pours the salt from the bag. Since the bags of salt were in direct contact with the pallet and he did not strip the outer layer of the bag before placing it over the edge of the vat, you decide to examine the condition of the solution. You find extraneous

material (lint, dust, debris, etc.) floating on top of the water. Because a product ingredient was contaminated, you should document this noncompliance using the SSOP regulations. If you did not find foreign or extraneous material in the solution when you examined it, there is still noncompliance with the requirements of 416.4(d) because the method the employee used to add the salt when formulating the pickle solution does not protect the solution from contaminants that may fall off the outside surface of the bags. You should document this noncompliance on an NR using the appropriate SPS regulations.

Examples of the failure to meet the requirements for this regulation are:

- The establishment is loading forequarters of beef onto a truck trailer that has an accumulation of dried blood, fat, and meat particles on the floor.
- Several overhead pipes in the grinding room have an accumulation of dust on them.
- Several uncovered combo bins of pork trimmings were removed from a truck trailer and are now sitting on the receiving dock waiting to move into the cooler. The receiving dock is open to environmental elements.
- The surface of a roll of packaging material that contacts product is stored in direct contact with the surface of a pallet in the dry storage area.
- Two employees who work in the picking room are walking through the cut-up room.
- Combo bins of raw pork products are stored in racks three tiers high in the cooler. Two combo bins of pork bellies stored on the bottom tier were not covered.

§416.5 Employee Hygiene

Employees can be disease carriers and bring contaminants from the outside such as dirt, debris, and other foreign materials that can both directly and indirectly contaminate food. Foodborne illness outbreaks have been linked to poor personal hygiene of workers involved in food processing and handling. Therefore, personal hygienic practices for employees are essential to the production of safe and wholesome meat and poultry products. The performance standard allows establishments to develop alternative or innovative means to ensure that employee practices do not result in insanitary conditions or adulteration of product.

§416.5 (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.

► **Establishment's Responsibilities**

The establishment has the responsibility to ensure that employees are engaging in personal hygienic practices and product handling practices that prevent insanitary conditions and reduce the likelihood of contaminating product, food-contact surfaces, and product-packaging materials.

Note: The hands can serve as a vehicle for transferring microorganisms to meat and poultry products, food-contact surfaces of equipment, and packaging materials. The hands can pick up microorganisms from such actions as touching utensils, equipment, raw product, product cartons, pallets, and door handles; using the toilet; eating; shaking hands; and touching the nose, mouth, or face. For example, many people have the pathogen *Staphylococcus aureus* in their nasal passages and can transfer these organisms to their hands by touching or blowing their nose.

Handwashing is a very important practice in a food-processing environment. Establishment employees that handle any edible product should keep their hands clean. Insanitary personal practices like indiscriminate and uncovered coughing and sneezing over exposed product, and wiping discharges from the eyes, nose, or mouth on outer clothing could result in product contamination.

Employees using poor food handling techniques can contaminate product and food-contact surfaces with perspiration, hair, cosmetics, tobacco/snuff, chewing gum, and foreign objects like jewelry. Pieces of the jewelry such as the setting or stones or the whole item itself, like a wristwatch, might fall into the product being prepared. Some jewelry may have crevices or recesses that can collect product residue and hinder routine cleaning. As a result, the jewelry can act as a reservoir of microorganisms that can be transferred to product.

FSIS has the authority to take action against any unhygienic practice that could result in insanitary conditions or adulterated product. This includes handling procedures that might contaminate edible products or create insanitary conditions.

► Verifying Compliance with This Regulation

IPP should observe and assess employees **working in contact with product, food-contact surfaces and product packaging materials** in one or more areas of the establishment. IPP should **verify** that employees are engaging in personal hygienic practices and product handling practices that minimize the possibility of transferring microorganisms and other contaminants to product, food-contact surfaces, and packaging materials.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Are the persons in contact with product, food-contact surfaces, and product packaging materials adhering to hygienic practices?

The following list of observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for employees who do not wash their hands or change gloves after touching a contaminated surface (e.g., pallet; box; head, nose, mouth, or other areas of the body).
- Look for employees engaging in insanitary personal practices such as uncovered coughing over exposed product or wiping discharges from their nose or mouth on their outer clothing.
- Look for employees using their mouth to temporarily hold metal tag fasteners, shroud pins, cards, or other objects, etc., that will be handled subsequently by the employee or contact product.
- Look for employees who have handled raw product or raw components who do not wash and sanitize their hands prior to handling ready-to-eat products.

Note: The establishment may include hygienic handling procedures for preventing cross-contamination of ready-to-eat products in its SSOP. When the establishment includes these procedures in the SSOP, management must implement and monitor such procedures and document the monitoring results, including any corrective actions taken on the SSOP records. In this case, IPP should verify compliance with the regulatory requirements while performing the SSOP task.

- Look for employees handling products or components who are wearing loose jewelry such as wristwatches and bracelets, and rings with settings or high crowns.
- Look for employees who do not wash their hands after using the toilet room, eating, or smoking prior to handling product or implements used in the preparation of product.
- Look for employees who are not preventing dislodged hair, perspiration, or cosmetics from either falling into or ending up in the product.
- Look for employees eating and using tobacco products in nondesignated areas of the establishment.
- Look for employees who do not remove aprons, outer garments, scabbards, knives, steels, etc., before using the toilet or urinal.

2. Access the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to employee cleanliness that is creating an insanitary condition, there is noncompliance with the requirements of 416.5(a) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

*You observe the employee who places frozen blocks of beef trimmings into the hydroflaker pick up several empty beef trimming cartons off the floor (touching the outside surface of the carton with his hands) and put them in a trash bin. You watch to see if the employee realizes he has touched an unclean surface. The employee does not attempt to wash his hands and continues to perform the **same** work duties. At this point, there is noncompliance with §416.5(a) because an insanitary condition exists that **could lead** to direct product contamination and you would document this noncompliance on an NR using the appropriate SPS regulation. However, if the employee eventually touches one of the frozen blocks of beef trimmings with his hands prior to washing them, product would be contaminated. If the establishment can demonstrate there was no food safety hazard associated with the contamination, you would document this noncompliance using the appropriate SSOP regulations.*

Scenario

*You see an employee leave the restroom without washing his hands. Careful consideration of the circumstances is required when **it is not known for a fact** that an employee's hands will serve as a vehicle for cross-contamination of product. In cases where an employee has engaged in a nonwork activity like using the toilet, smoking, or eating, further investigation or observation may be necessary before you conclude that an insanitary condition exists.*

It is reasonable to conclude that the employee's hands touched an unclean surface when he used the toilet. However, if the employee does not return to the production room, then the employee's unclean hands do not create an insanitary condition that could result in contaminated product or food-contact surfaces. Likewise, if the employee washes his hands at a sink immediately upon entering the production room, then his hands were cleaned prior to handling product or touching a food-contact surface. However, if the employee goes directly to his workstation and does not wash his hands, his poor personal hygienic practice creates an insanitary condition and there is noncompliance with §416.5(a) because his hands might transfer contaminants to products or a food-contact surface. You would document this SPS noncompliance on an NR.

Examples of the failure to meet the requirements for this regulation are:

- An employee handling exposed product with her bare hands is wearing nail polish.
- An employee wipes his runny nose on the sleeve of his smock.

- Two employees handling exposed product are not taking measures to prevent their hair from falling into product.
- An employee adding pork trimmings into grinders is wearing a wristwatch.

§416.5(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- The outer clothing (aprons, frocks, smocks, garments, etc.) worn by employees handling product is either made of a disposable material or a readily cleanable material.
- Employees handling product wear clean outer clothing (free of **visible** product residues and other soiling matter) at the beginning of operations.

Note: These regulations **do not** require establishment employees to wear frocks or smocks. The outer clothing the employee is wearing at the start of the day must be clean. Outer clothing that is not made of a material that can be washed or laundered to remove product residues and other soiling matter (e.g., dirt and grease) or has not been laundered or washed between operations can harbor disease-causing microorganisms and other contaminants. Employees that wear soiled outer clothing when production begins may touch their clothing and contaminate their hands or contaminate product through direct contact with the dirty or soiled clothing.

- Employees handling product change their frock, smock, garment or outer clothing as needed during the day. For instance, employees change their frocks, smocks, garments, or outer clothing whenever it becomes contaminated. Employees working in departments where there is routine contact between product and outer clothing (employees boning carcasses, employees moving trimmings in luggers, etc.), change their garments and cloth (cotton) gloves (if worn) at a frequency that prevents the build-up of microorganisms.

- Employees change their outer clothing, frocks, smocks, garments, etc., when they go from raw product areas to ready-to-eat product areas to prevent the possible cross-contamination of ready-to-eat products with pathogenic bacteria associated with raw product.

► **Verifying Compliance with This Regulation**

IPP should observe and assess employees **handling product** in one or more areas of the establishment. IPP should **verify** that employees wear disposable or cleanable outer clothing, that they are wearing clean outer clothing at the beginning of the shift, and that they change their outer clothing as often as needed to prevent insanitary conditions or adulteration of product.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Questions.

Are aprons, frocks, and other outer clothing worn by persons who handle product made of material that is disposable or readily cleaned?

Are clean garments worn at the start of the day and changed during the day as often as necessary?

The following observations may assist IPP in answering these questions. IPP may perform additional observations.

- Look for employees wearing outer clothing that is not disposable or made of a material that is not readily cleaned.
- Look for employees wearing dirty or soiled frocks, smocks, garments, or other outer clothing at the start of operations.
- Look for employees who do not change their frocks, smocks, garments, or other outer clothing when they have touched a contaminated surface.
- Look for employees who do not change their frocks, smocks, garments, or other outer clothing as needed during the day.
- Look for employees who do not change their frocks, smocks, or outer garments when they go from raw product areas to ready-to-eat product areas.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to employee clothing that is creating an insanitary condition, there is noncompliance with the requirements of 416.5(b) and IPP should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

You see an employee who is cutting beef primal parts into steaks pick a wooden pallet up off the floor, place it under his arm against his side, drag it the to the wall next to the cutting table, and rest it against the wall. The employee immediately goes to the hand wash sink and washes his hands but he does not change his frock. The inner portion of employee's frock sleeve that contacted the pallet has contacted product because it has product residue (bloodstains) on it. Because the employee's frock sleeve touched an unclean surface, contaminants like microorganisms, wood splinters, dust, dirt, debris, etc., could be transferred to product when it comes in contact with the sleeve. There is noncompliance with the requirements of 416.5(b) and you should document that SPS noncompliance on an NR.

Examples of the failure to meet the requirements for this regulation are:

- An employee from the sausage stuffing area wearing a soiled smock entered the ready-to-eat product cooler.
- Two employees in the boning department have frocks with product residue from the previous day's production on them at the start of operations.

§416.5(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.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that no person affected with a disease in a communicable form, while a carrier of such disease, or while afflicted with boils, sores, infected wounds, or other abnormal sources of microorganism contamination, works in any area of the establishment where there is a likelihood of disease transmission or meat, poultry, or food ingredients becoming contaminated, until the condition is corrected.

Note: A wide range of communicable diseases and infections may be transmitted by food handlers to other employees and consumers through contaminated meat and poultry products and careless handling practices.

Foodborne pathogens may be shed from infected workers during the incubation period of a disease, before the affected person displays clinical symptoms.

Employees working in edible product areas exhibiting flu-like symptoms such as persistent sneezing or coughing can contaminate exposed product, food-contact surfaces (hands, equipment, and utensils), and product packaging materials with discharges from the mouth and nose.

Skin infections, such as boils, open lesions, and infected cuts, frequently contain large numbers of streptococci or staphylococci organisms that can easily become food contaminants. These infections may be sources of contamination that can lead to foodborne illness.

IPP should be able to recognize obvious symptoms and lesions like those mentioned above. However, since IPP are not trained to diagnose

infectious diseases, if IPP have questions about an employee having an infectious disease, IPP should discuss this with establishment management.

► Verifying Compliance with this Regulation

IPP should observe and assess employees **working in contact with product, food-contact surfaces, and product packaging materials** in one or more areas of the establishment. IPP should **verify** that no employees have infectious diseases or open lesions such as boils or sores that could create insanitary conditions or adulterated product.

1. IPP May Gather Needed Information by Seeking the Answer to the Following Question.

Are persons who appear to have an infectious disease; an 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?

The following observations may assist IPP in answering this question. IPP may perform additional observations.

- Look for employees who appear to be exhibiting symptoms of an infectious disease or condition.
- Look for employees with an open lesion, including a boil, sore, infected wound, or any other abnormal source of microbial contamination on their hands or forearms.

2. Assess the Information Gathered by IPP.

When IPP find conditions like the examples listed above, IPP should assess all of the information related to their observation and then make a determination whether the establishment is meeting the regulatory requirements. IPP should use good judgment in making these determinations and might seek answers to the following questions in order to determine if there is noncompliance.

Are the conditions observed by IPP creating an insanitary condition?

If IPP find any condition relating to employee health that is creating an insanitary condition, there is noncompliance with the requirements of 416.5(c) and IPP

should document that noncompliance on an NR. If the conditions IPP observed are not creating an insanitary condition or adulteration of product, there is no noncompliance.

Are the conditions observed by IPP contaminating product?

If product is contaminated, IPP might need to make a further assessment by seeking answers to more questions. Is there a food safety hazard associated with the contaminated product? If there is no food safety hazard associated with the product, IPP should document the noncompliance using the appropriate SSOP task and regulations. If there is a food safety hazard associated with the contaminated product, IPP should document the noncompliance using the appropriate HACCP verification task and regulations.

Scenario

You observe an employee working in the inedible product department exhibiting flu-like symptoms such as persistent sneezing or coughing. The inedible product department is separate from areas used for edible products. The establishment also has separate welfare facilities (toilet and dressing rooms, lunchrooms, etc.) for employees who work in the inedible product department. Since the employee's potential health condition does not present a risk of transmitting foodborne pathogens to edible product, edible food-contact surfaces, and edible product packaging materials, there is not an insanitary condition.

Scenario

You observe an employee handling raw edible product with a cut on her forefinger near the first knuckle. The cut has some redness around it but you are not sure that it is infected. The cut is not protected with an impermeable cover. Because of the potential of transferring microorganisms to product, there is noncompliance with the requirements of §416.5(c) and you should document the SPS noncompliance on an NR.

*If the cut was infected (pus pockets and fluid oozing), then product would have been contaminated. If the establishment could demonstrate there was no food safety hazard associated with the contamination, you would document this noncompliance using the appropriate SSOP task and regulations. The establishment would probably not be able to support a claim that there is no food safety hazard associated with the contamination because of the possibility of transferring the pathogen *Staphylococcus aureus* to the exposed product; therefore, you would document the noncompliance using the appropriate HACCP verification task and regulations.*

Examples of the failure to meet the requirements for this regulation are:

- An employee who is handing exposed product has an uncovered sore on his bare forearm.
- An employee moving pallets of boxed product from the end of the production lines to the freezer appears to have a cold (exhibiting symptoms such as persistent coughing, sneezing, sniffing, etc.).

Note: The regulatory requirements pertaining to employee hygiene also apply to the IPP. As a representative of a public health agency, it is imperative that IPP lead through example and follows 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. If the establishment has requirements that are more stringent than the SPS requirements, e.g., hairnets must be worn by **all** employees working in production related areas or no items can be carried in frock pockets, IPP are expected to follow those requirements.

INSANITARY CONDITIONS (CONTAMINATION) DURING SLAUGHTER

Slaughter establishments must design and implement sanitary dressing procedures to prevent insanitary conditions and the contamination of carcasses. During slaughter incidental contamination may occur from substances not related to the species being slaughtered (e.g. oils, rail dust, condensate, and unidentified foreign material) or from substances related to the species being slaughtered like digestive content, milk, ingesta or bile.

Incidental contamination does not automatically represent an insanitary condition. Even if there are observations of contamination on carcasses during the slaughter process, the establishment still has the opportunity to implement antimicrobial measures, e.g., knife trimming, steam vacuum, and acid/hot water rinses, that will address the contamination before the carcasses complete the slaughter process. ***Since the establishment has the opportunity to implement antimicrobial measures to address incidental contamination before the carcasses leave the slaughter process such contamination is not considered to be a failure of the establishment's Sanitation SOP.***

IPP must assess the available information and evaluate each occurrence of incidental contamination to determine whether the establishment has failed to prevent the creation of insanitary slaughter conditions prior to carcasses completing the process.

When there is evidence that the establishment is not implementing its sanitary dressing procedures, or the procedures are ineffective in preventing the creation of ongoing insanitary conditions, off-line IPP are to cite ***appropriate regulations including relevant SPS regulations.***

Sanitary dressing will be covered in more detail later in the course.

CUSTOM-EXEMPT FACILITIES

§303.1a(2)(i)

Establishments that conduct custom exempt operations must be maintained and operated in accordance with the provisions of §416.1 through 416.6, except for §416.2(g)(2) through (6) of this chapter, regarding the water reuse and any provisions of Part 416 of this chapter relating to inspection or supervision of specified activities or other action by a program employee. If custom exempt operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter shall apply to those operations.

► Establishment's Responsibilities

The establishment has the responsibility to ensure that:

- Operations are conducted in a manner sufficient to prevent the creation of insanitary conditions.
- Conditions in and around the establishment do not lead to adulterated product.
- The requirements in §416.1 through §416.6, except those addressing water reuse, are met.

Note: Custom operations conducted in official establishments are subject to all of 9 CFR Part 416 including implementing the SSOP per 9 CFR 303.1(a)(2)(i). If the official establishment includes its written procedure to remove, segregate, and dispose of SRMs in its SSOP, it must meet all the requirements of 9 CFR 416, including SSOP recordkeeping for its custom operations. IPP should **verify** that custom exempt operations are maintained and operated in accordance with the SPS regulations. IPP should also follow the instructions in FSIS Directive 5930.1.

COMPLIANCE GUIDELINES

The Agency has compiled the Sanitation Performance Standards Compliance Guide as an industry guideline for meeting the sanitation performance standards. The guide presents methods that have historically proven to be effective in maintaining sanitary conditions in meat and poultry establishments such as past FSIS regulations and guidance, recommendations from the 2001 Food Code, and other technical sources. The guide is available electronically on the FSIS internet homepage (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/SanitationGuide.htm>).

Establishments that follow the guidance in this document can be fairly certain that they are meeting the SPS requirements. However, since each processing environment is unique, in some cases the methods presented may be inadequate to ensure sanitary conditions. It is important to remember that guidance material is not regulatory requirements and inspection personnel should not take enforcement action if the establishment fails to comply with the methods contained in the guide.

SPS REGULATIONS Workshop #3

Multiple Choice Questions

1. Which federal agency sets the standard for the number of toilet facilities required in the establishment?
 - a. FDA
 - b. OSHA
 - c. FSIS
 - d. EPA

2. According to the performance standard for dressing rooms, lavatories, and toilets, lavatories (handwash sinks) must be:
 - a. Equipped with hot and cold running water, a supply of soap and towels, and located near toilet and urinal rooms and other places in the establishment as needed to ensure cleanliness of employees handling product.
 - b. Conveniently located and equipped with hot and cold running water delivered through a mixing faucet with an outlet 12 inches from the rim of the bowl, to ensure employees wash their arms as well as hands.
 - c. Equipped with hot and cold running water, a supply of soap and towels, and operated by a means other than with the hand, e.g., the knee or foot.
3. How often must an establishment using a municipal water supply renew the water potability certificate?
 - a. There is no mandatory renewal period.
 - b. Every year.
 - c. Twice a year.
4. How often must an establishment using a private well as its water supply renew the water potability certificate?
 - a. There is no mandatory renewal period.
 - b. Every year.
 - c. Twice a year.

5. Establishments can reuse water or solutions if:
 - a. The establishment has a written water and solution reuse program on file.
 - b. The establishment's water and solution reuse program is approved by FSIS.
 - c. The pipes carrying the reuse water or solution are clearly identified by name, colored tape, or other method acceptable to the IPP.
 - d. The reuse of the water or solution does not adulterate product or create insanitary conditions.
6. Equipment and utensils used for processing or otherwise handling edible product or ingredients must:
 - a. Be made of stainless steel (series 300).
 - b. Have their design and construction approved by FSIS or a third (outside) party before being used in the establishment.
 - c. Be made of materials and constructed in a manner that facilitates thorough cleaning.
7. Which of the following statements regarding the sanitation performance standards is **true**?
 - a. All chemicals used in the food- processing environment must be approved by a Federal Agency.
 - b. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available to FSIS for review.
 - c. Extended cleanup procedures must have prior approval by FSIS.

8. According to the sanitary operations performance standard, food-contact surfaces of equipment and utensils must be cleaned and sanitized:
 - a. At a frequency that prevents the creation of insanitary conditions and the adulteration of product.
 - b. Every four hours to prevent the creation of insanitary conditions and the adulteration of product.
 - c. Daily to prevent the creation of insanitary conditions and the adulteration of product.
 - d. Before operations begin and at midshift to prevent the creation of insanitary conditions and the adulteration of product.
9. Food-contact surfaces of equipment and utensils must be:
 - a. Periodically cleaned and sanitized with 180° F water.
 - b. Maintained in a sanitary condition using any effective cleaning and sanitizing method.
 - c. Maintained in a sanitary condition using cleanup water that is at least 140° F and FSIS-approved disinfectants.
10. Outer clothing (e.g., aprons, frocks, smocks, and garments) worn by employees who handle product must be:
 - a. Changed every four hours to prevent insanitary conditions.
 - b. Made of disposable materials or readily cleaned
 - c. White in color so soilage can be easily detected.

11. All persons working in contact with product, food-contact surfaces, and product packaging materials must:
- a. Wear disposable plastic or rubber gloves to prevent their hands from directly contaminating product.
 - b. Wear cleanable caps or hats to prevent dislodged hair from falling into the product or ending up in product.
 - c. Adhere to hygienic practices while on duty to prevent adulteration of product
12. Which of the following statements is **not** listed in the regulations for employee hygiene?
- a. Employees working in contact with product must clean their hands and exposed forearms with a cleaning compound by vigorously rubbing the surfaces of their lathered hands and arms for at least 20 seconds.
 - b. Clean garments must be worn at the start of each working day.
 - c. Any person who has an open lesion such as a boil must be excluded from any operations that could result in product adulteration.
 - d. Garments must be changed during the day as often as necessary to prevent adulteration.

Fill-in the Blank Questions

Refer to the module to fill in the blanks.

1. A supply of running water that complies with _____ at a suitable _____ and under pressure as needed, must be provided in all areas where required.
2. Water from any source not tested for potability or not certified as meeting the National Primary Drinking Water requirements is automatically considered to be a _____ supply.
3. Water, ice, and solutions used on products can be reused only for the _____ purpose.
4. Water, ice or solutions that have come into contact with raw product may not be reused on _____.
5. The permitted use of the inedible receptacle or container must bear conspicuous and distinctive _____, to identify permitted uses (e.g., a system, or some other means).
6. Depending upon the situation and the circumstances, the establishment must decide how to _____ the product through all phases of the _____.
7. _____ has the authority to _____ against any unhygienic practice that could result in insanitary conditions or adulterated product

SPS REGULATIONS WORKSHOP #4

Match the noncompliance in the left column with the appropriate sanitation performance standard in the right column. The SPS can be used more than once.

- | | |
|---|--|
| _____ The establishment is applying a pesticide in a manner that is different than the documented uses. | |
| _____ Odor coming from the condemned/inedible product rendering area is spreading to the slaughter floor. | |
| _____ The establishment is reusing a brine solution to chill ready-to-eat products but has no documentation or other evidence that the reused brine is free of pathogens. | |
| _____ A chute connecting an edible product department to an inedible product department does not have an access point or opening for sanitary inspection. | |
| _____ There are round holes in several drop ceiling panels where pipes and electrical conduits have been removed. | |
| _____ A commode in the men's restroom is backed up and has overflowed onto the floor. | |
| _____ An employee working with exposed product scratched his head with his fingers and did not clean them before continuing his work duties. | |
| _____ A U.S. condemned barrel is leaking fluids from the bottom and there is an accumulation of poultry parts and whole birds on the floor. | |
| _____ There is beaded condensation forming on the vent hood above the wiener casing peeler. | |
- A. Sanitary Operations
 - B. Employee Hygiene
 - C. Sewage Disposal
 - D. Construction
 - E. Grounds and Pest Control
 - F. Plumbing
 - G. Ventilation
 - H. Dressing Rooms, Lavatories, and Toilets
 - I. Equipment and Utensils
 - J. Water Supply and Reuse
 - K. Lighting

SPS Documentation and Enforcement

IPP must verify and document compliance and noncompliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements. Every time IPP find that the establishment is not meeting the SPS requirements, IPP are to document the noncompliance on an NR. IPP should not allow the establishment to address noncompliance without documenting it. If IPP determine that a SPS noncompliance is due to the establishment's repeated failure to maintain sanitary conditions, IPP should document noncompliance with 9 CFR 416.1 in addition to the specific applicable SPS regulations.

Enforcement for SPS Noncompliance *Without* the Finding of Direct Contamination or Adulteration of Product

When IPP have determined that the establishment did not comply with a sanitation performance standard while performing the SPS task, and there is **no** direct contamination or adulteration of product, they next need to determine whether the noncompliance requires a regulatory control action to prevent subsequent contamination or adulteration of product.

If the noncompliance does not need immediate attention, IPP are to notify the establishment management of the noncompliance and document the finding on an NR.

If there is an imminent probability that the noncompliance will result in product contamination or adulteration if not addressed immediately, IPP will take a regulatory control action such as retaining product or rejecting the equipment or room with a tag in accordance with §416.6, notify the establishment as required by §500.2 and document the findings on an NR.

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

Regulatory control actions should remain in effect until the establishment has brought itself back into compliance with regulations.

Documentation and Enforcement for SPS Noncompliance AND the Finding of Direct Contamination or Adulteration of Product

When IPP have determined that the establishment did not comply with a sanitation performance standard while performing the SPS task, and there **is** direct contamination or adulteration of product observed, all noncompliances are documented on **one NR** issued under a Sanitation SOP task. IPP are to record the results of the SPS task without a NR, indicate the regulations verified, and add a note in the Inspection Results Page, Findings Tab, Comment Box that a Sanitation SOP noncompliance was found and reference the Sanitation SOP NR. IPP will verify that the establishment implements corrective actions as part of the Sanitation SOP task.

Example of SPS Noncompliance and SSOP Noncompliance Found While Performing the SPS Task

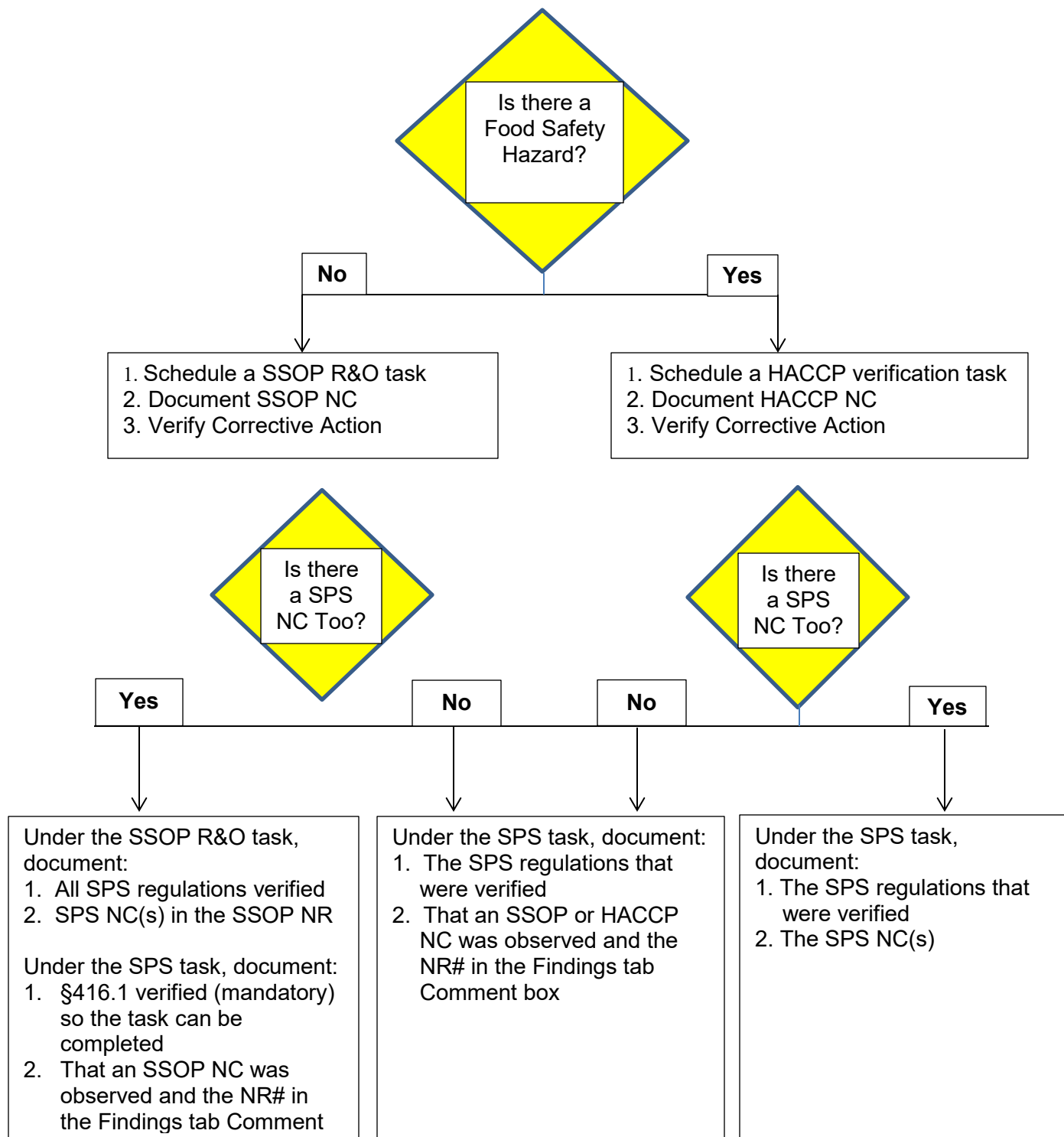
At 10:08 a.m., while verifying whether the establishment's pest management program was effective in preventing the harborage and breeding of pests on the grounds and within the establishment, I observed evidence of rodent activity in the food ingredient dry storage area which is noncompliance with 416.2(a). I found small pieces and shreds of paper and food granules on the floor under the storage rack that resulted from rodents gnawing through the ingredient bag. The ingredient bag was U.S. retained with tag #578690. I found 5 rodent droppings on top of the ingredient bag with the hole in it and 10 droppings along the west wall of the dry storage area. I also found a gnawed opening next to a pipe that enters at the base of the north wall, which is noncompliance with 416.2(b)(3). No evidence of rodent activity was found in adjacent production rooms. The dry storage area was U.S. rejected with tags #B578691 and #B578692. Ms. Jane Doe was notified of the insanitary condition of the food ingredient dry storage area and the direct contamination of a food ingredient and the subsequent regulatory controls. She was informed that the regulatory control actions would remain in effect until the establishment meets the requirements of 416.15.

The SPS noncompliance with §416.2 (a) and 416.2(b)(3)) and the SSOP noncompliance with §416.13(c) would be documented on **one NR** under the Operational SSOP Review and Observation task. Under the SPS verification task, the CSI would identify the regulations verified and add information in the comment box that an SSOP noncompliance was found and reference the NR.

When both SPS noncompliance(s) and HACCP noncompliance(s) involving direct product contamination with a food safety hazard are found while performing a SPS task, IPP are to document the SPS noncompliance(s) under a SPS verification task and the HACCP noncompliance(s) under the appropriate

HACCP verification task. During the HACCP verification task, IPP will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 417.3(b). These corrective actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the HACCP plan. Refer to the decision tree on the next page.

IPP Performs a SPS Task and Determines that Direct Product Contamination has Occurred



U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection	
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.	
4. TO (Name and Title)		5. PERSONNEL NOTIFIED	
6. RELEVANT REGULATIONS		6a. Associated NR(s)	
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION		7a. NAME OF CCP(S) or PREREQUISITE PROGRAM	
8. INSPECTION TASK		9. VERIFICATION ACTIVITY <input type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION 9b. RETAIN/REJECT TAGS	
10. DESCRIPTION OF NONCOMPLIANCE			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>			
12. PLANT MANAGEMENT RESPONSE:			
<i>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</i>			
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE	
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE	

FSIS Form 5400-4

Distribution: Original & 1 copy to Establishment, 1 copy to Inspector

SPS Quick Reference to FSIS Directive 5000.1

Task	What the IPP does	Sections of the Directive that Apply	Sections of the Directive when there is Noncompliance
Sanitation Performance Standard (SPS)	<p>The IPP should select the SPS requirement or requirements that he/she is going to verify. These requirements are in 9 CFR 416.2 – 416.5.</p> <p>Once the IPP has determined which requirements to verify, he/she will verify regulatory compliance with those requirements by following the instructions on the pages listed for each requirement.</p>	<p><i>Grounds & Pest Control (416.2(a)), pages 10–12, Chapter II</i></p> <p><i>Construction (416.2(b)), pages 12–13, Chapter II</i></p> <p><i>Lighting (416.2(c)), pages 13-14, Chapter II</i></p> <p><i>Ventilation (416.2(d)), pages 14-15, Chapter II</i></p> <p><i>Plumbing and Sewage (416.2(e)), page 15, Chapter II</i></p> <p><i>Sewage Disposal (416.2(f)), pages 15-16, Chapter II</i></p> <p><i>Water Supply and Water, Ice, and Solution Reuse (416.2(g)), pages 16-19, Chapter II</i></p> <p><i>Dressing Rooms and Lavatories (416.2(h)), pages 19-21, Chapter II</i></p> <p><i>Equipment and Utensils (416.3(a)(b)(c)), pages 21-22, Chapter II</i></p> <p><i>Sanitary Operations (416.4(a)(b)(c)(d)), pages 22-23, Chapter II</i></p> <p><i>Employee Hygiene (416.5(a)(b)(c)), pages 23-25, Chapter II</i></p>	<p>If the IPP finds that there is noncompliance with one or more of the regulations, IPP should refer to pages 58-65, Chapter V for instructions on the completion of a noncompliance record.</p> <p>If the IPP finds that, there is a trend of noncompliance occurring, IPP should refer to pages 66-67, Chapter V for instructions on NR association.</p> <p>If the IPP finds that an enforcement action should be recommended, IPP should refer to pages 68-74 of Chapter VI for instructions on the Rules of Practice.</p>

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 416--SANITATION--Table of Contents

Sec. 416.1 General rules.

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.

Sec. 416.2 Establishment grounds and facilities

(a) 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 inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the 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) 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.

(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.

(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.

(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.

(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 establishments

(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.

(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.

(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.). 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.

(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.

(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.

Sec. 416.3 Equipment and utensils.

(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.

Sec. 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.

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

Sec. 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.

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

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.