

HACCP OVERVIEW

Objectives

1. Describe the regulatory requirements related to the Sanitation Performance Standards.
2. Describe the regulatory requirements related to the Sanitation Standard Operating Procedures.
3. Describe the 7 principles of HACCP.
4. Describe the regulatory requirements related to Pathogen Reduction for the *Salmonella* performance standards.
5. Describe the regulatory requirements related to Pathogen Reduction for generic *E. coli* Testing.
6. Describe the regulatory requirements for the food safety standard related to fecal contamination.
7. Explain how FSIS Directive 5000.1, Rev. 1 is used to verify these requirements.

Introduction

The FSIS Pathogen Reduction/HACCP rule introduced the following four requirements of establishments.

- Sanitation Performance Standards
- Sanitation Standard Operating Procedures
- HACCP
- Pathogen reduction (*Salmonella* performance standards, generic *E. coli* testing)

This module will walk through the regulatory requirements that establishments must meet, and cover a brief overview of the inspection verification procedures that are performed by the Consumer Safety Inspector (off-line) that are described in FSIS Directive 5000.1, Rev. 1, "Verifying an Establishment's Food Safety System." Although these procedures are not performed by Food Inspectors, it is important for you to know about these requirements and how compliance with them is verified because all of these activities have an impact on the environment in which you work. We will also cover the food safety standards related to fecal contamination.

Sanitation Performance Standards (SPS) (9 CFR 416.1-416.7)

9 CFR 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.

Proper and effective sanitation practices and conditions are an essential part of all safe food manufacturing processes. Insanitary facilities and equipment and poor food handling and personal hygiene practices by employees create an environment in which pathogens and other food safety hazards can contaminate and adulterate products. Consequently, proper

sanitation is a fundamental requirement under both the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

The SPS regulation requires establishments to maintain sanitary environment. Performance standards stated in the regulations are results-oriented, allowing the establishment flexibility in achieving the specified results. Simply put, the results expected are defined in the regulation but the means or methods to achieve the results are not specified. Although establishments can use different and varying means to meet the performance standards, the required results are always the same – establishments must operate under sanitary conditions in a manner that ensures product is not adulterated and in a way that does not interfere with FSIS inspection.

9 CFR 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.

Proper maintenance of the grounds around an establishment is essential for ensuring good sanitation. Establishments are responsible for preventing sources of adulteration of product even if the cause of the adulteration originates from conditions outside the designated boundaries of the establishment.

Establishments must implement and maintain an integrated pest control program to eliminate the harborage and breeding of pests on the grounds and within the establishment facilities and must safely and effectively use interventions, such as pesticides, fumigants, and rodenticides. This regulation does not require the integrated pest control program to be a written document. This regulation does not require that pest control substances be approved by FSIS prior to use.

The performance standards regulations also require the establishment to be responsible for the safe and effective use and storage of pesticides. Product must not be adulterated by the misapplication of pest control products. It is the establishment's responsibility to ensure that Environmental Protection Agency (EPA) requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are followed, including the application of a pesticide or the safety of a chemical. Pesticides must also be properly stored, labeled, and applied in accordance with label instructions. It is important that such supporting documentation is on file in the establishment file.

Examples of failure to meet grounds and pest control performance standards are:

- an accumulation of old equipment outside providing harborage for rodents and insects.
- storage of pesticides in an open container next to food ingredients

9 CFR Sec. 416.2 Establishment grounds and facilities. (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.

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

Buildings, walls, ceilings, and floors must be sound and in good repair to prevent insanitary conditions or the adulteration of product.

Example of failure to meet performance standards:

- flaking or chipping paint on the walls or ceilings of edible product areas.

The walls, floors, and ceilings should be made of durable materials impervious to moisture.

Example of failure to meet performance standards:

- holes in glassboard permitting moisture to penetrate the wood behind it.

Doors and windows must also close properly and prevent the entrance of vermin.

Example of failure to meet performance standard:

- gaps around the outside doors.

9 CFR Sec. 416.2 Establishment grounds and facilities (b) Construction. (4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

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 the adulteration of the edible product or the creation of insanitary conditions.

Example of failure to meet performance standard:

- grinding meat and storing condemned product together in a room too small to keep employees and products separated.

9 CFR Sec. 416.2 Establishment grounds and facilities. (c) Lighting. Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

Specific regulatory requirements for lighting combine the meat and poultry lighting requirements into one performance standard. However, FSIS has reserved specific lighting requirements in meat establishments at post mortem inspection stations and in poultry establishments at the post mortem inspection stations and at reinspection stations (§ 307.2 and § 381.36 et seq).

While establishments have flexibility in providing lighting, illumination must be adequate in quality and quantity, and well distributed. It must allow for proper monitoring of sanitary conditions and processing conditions, and for examination of product for evidence of adulteration.

Examples of failure to meet performance standard:

- low lighting in the gizzard peeling area that prevents inspection of the product.
- shadows on carcasses at final rail inspection preventing inspection of product.

9 CFR Sec. 416.2 Establishment grounds and facilities. (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.

The Agency does not expect the establishment to completely eliminate all odors, vapors, and condensation. However, plants must control ventilation to prevent adulteration of the environment that, in turn, can lead to adulteration of product or the creation of insanitary conditions.

Examples of failure to meet performance standard:

- diesel fumes from parked trucks being drawn into the establishment at receiving areas.
- excessive odors from condemned/inedible rendering area spreading onto slaughter floor.

9 CFR Sec. 416.2 Establishment grounds and facilities. (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.

It is the responsibility of the establishment to ensure that plumbing and sewage systems provide an adequate supply of potable water to the establishment to prevent product adulteration or creation of insanitary conditions.

Example of failure to meet performance standard:

- inadequate water pressure for cleanup.
- plumbing system not providing adequate floor drainage.

It is the responsibility of the establishment to ensure that plumbing and sewage systems remove waste and sewage from the establishment without adulterating product or creating insanitary conditions.

Example of failure to meet performance standard:

- plugged sewer line preventing cleanup water from draining from the plant.

9 CFR Sec. 416.2 Establishment grounds and facilities. (e) Plumbing. (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

The design, installation and maintenance of an adequate plumbing system are key responsibilities of the establishment. Because plumbing systems carry water into establishments and convey water from the establishments, problems with plumbing systems can easily cause product contamination or adulteration.

Example of failure to meet performance standard:

- dead-end pipes on potable water lines.

9 CFR Sec. 416.2 Establishment grounds and facilities. (e) Plumbing. (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;

Floor drainage must be adequate to prevent the spread of contaminants into the production environment during cleaning and normal operation.

Example of failure to meet performance standard:

- a stopped up drain in the cooler where carcasses are stored.

Cross-connection between potable and non-potable water is not acceptable. The plumbing system must be installed and maintained to prevent adulteration. Back-flow devices must also be used as appropriate to prevent cross contamination of potable water sources.

Example of failure to meet performance standard:

- a water hose nozzle left submerged in the evisceration flow away drain.

9 CFR Sec. 416.2 Establishment grounds and facilities. (e) Plumbing. (6) Prevent the backup of sewer gases.

Example of failure to meet performance standard:

- sewer gas emitting from a floor drain in the smokehouse area.

9 CFR Sec. 416.2 Establishment grounds and facilities. (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.

The establishment must ensure that sewage does not back up into processing areas. Documentation from a State or local authority approving private sewage disposal systems must be on-site and available to FSIS upon request.

Example of failure to meet performance standard:

- establishment has no documentation on file from state or local health authority for approval of private sewer or system.

9 CFR 416.2 (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.

The water performance standard requires that potable water comply with EPA's National Primary Drinking Water regulations. Certifications of water potability provided by the state or local governments or other responsible entities are evidence that the establishment meets the EPA requirements.

Some meat and poultry establishments use private wells for their water supply. EPA does not require testing for these water sources, but FSIS requires it semi-annually. Generally, State or local governments do not test private wells for potability. Establishments can obtain such documentation from private laboratories.

Example of failure to meet performance standard:

- no documentation on file demonstrating that the municipal water supply complies with the National Primary Drinking Water regulations.

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

FSIS expects establishments to produce ready-to-eat products that are free of pathogens; therefore, reuse water used to chill or cook ready-to-eat product must be free of pathogens.

In many cases establishments monitor water reuse activities as part of their HACCP plans because the water treatments or conditioning can eliminate or reduce hazards they have determined to be reasonably likely to occur. The requirement that water be reused only "for the same purpose" refers to reusing water from the ready-to-eat area only in the ready-to eat area, and reusing water from the not-ready-to-eat areas only in not-ready-to-eat areas. For

example, chiller water or water from the final bird washer that is reconditioned can be reused in the scalding.

Example of failure to meet performance standard:

- reusing brine solution without filtering or treating.

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

Establishments can reuse water in a manner that does not adulterate product or create insanitary condition. For example, an establishment recirculating water in a chill tank for raw poultry might add chlorine to the water to reduce the number of pathogens. An establishment reusing ice to chill raw poultry might bag the ice to prevent it from contacting product. The performance standards allow the reuse of water in numerous processing contexts, as long as the establishment takes actions necessary to ensure that the water does not adulterate product and that sanitation is not compromised.

Example of failure to meet performance standard:

- reusing ice from wax lined boxes to chill salvage parts without bagging it.

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

Some establishments recondition their water through an advanced wastewater treatment facility, either onsite or under contract. To prevent establishments from using water from sewage lines, reconditioned water must never have contained human waste. Because reconditioned water is of high quality, it can be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas. Product, facilities, and equipment coming in contact with this reconditioned water must undergo a separate final rinse with potable, non-reconditioned water.

FSIS believes it is likely that most establishments will use the reconditioned water in this provision to wash equipment, floors, and carcasses on the kill floor, all of which can easily be rinsed.

Example of failure to meet performance standard:

- No final potable water rinse on product after using reconditioned water.

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

Any water can be used for any purpose in edible or inedible product areas, provided it:

- has never contained human waste.
Establishments must not reuse water from sewage lines, therefore, it is required that the reuse water never have contained human waste.
- has been conditioned to be free of pathogenic organisms.
Reuse water must be free of pathogenic organisms to prevent their spread throughout the establishment, which could lead to cross-contamination of product.
- does not contact edible product.
Reuse water might contain coliforms or chemical or physical contaminants, so it cannot contact edible product.

Example of failure to meet performance standard:

- using treated or untreated water from the employee welfare area to clean antemortem pens.

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

To prevent contamination or adulteration of the product, establishment must not use water contaminated with pathogens, chemicals, or physical contaminants in edible product areas.

Example of failure to meet performance standard:

- using reuse water not meeting conditions of (g)(1) through (g)(5) to flush evisceration troughs in edible product areas.

9 CFR 416.2 (h) Dressing rooms, lavatories, and toilets. (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

OSHA standards (29 CFR 1910.141) for lavatories must be followed when plants are constructed or remodeled. FSIS does not regulate the number of lavatories required. The establishment must maintain lavatory facilities in good repair and in a sanitary manner.

Example of failure to meet performance standard:

- used toilet tissue piled on the floor in the welfare facility.

9 CFR 416.2 (h) Dressing rooms, lavatories, and toilets (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.

Example of failure to meet performance standard:

- no hot water or soap in the toilet area.

9 CFR 416.2 (h) Dressing rooms, lavatories, and toilets (3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

Leaking refuse receptacles allow the spread of pathogenic organisms into the environment, which could then lead to cross-contamination of product and product areas.

Example of failure to meet performance standard:

- holes in the bottom of a trash receptacle in the dressing room with liquids draining onto the floor.

9 CFR 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.

Establishments may select any method to clean utensils and equipment as long as they are maintained in a sanitary condition.

Example of failure to meet performance standard:

- meat residues from previous days use on the underside of a product transfer belt.

9 CFR 416.3 Equipment and utensils (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.

Equipment and utensils must be designed in a manner that allows FSIS inspection personnel to view them for compliance with sanitary requirements. They must be located so that they are safely accessible to inspection prior to and during operation.

Example of failure to meet performance standard:

- a piece of equipment is constructed in a manner that prevents thorough cleaning, such as a splashguard located over the auger to the meat grinder that prevents access the equipment for inspection.
- when equipment is installed preventing inspection from making a sanitary condition determination.

9 CFR 416.3 Equipment and utensils (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.

Inedible receptacles used for storing inedible product must be properly and conspicuously marked.

Example of failure to meet performance standard:

- unmarked inedible barrels.

9 CFR 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.

Generally, establishments clean their operations once a day; however, some establishments conduct chemical cleanup procedures less than once a day. Such extended cleanup procedures should be incorporated into the firm's Sanitation Standard Operating Procedures (SSOP) (See § 416.12). 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.

Example of failure to meet performance standard:

- accumulation of fat on a belt rubbing against metal guard creating oxidized fat on the belt.

9 CFR 416.4 Sanitary operations (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.

During the normal course of operations meat and poultry products should not come in contact with non-food contact surfaces. If non-food contact surfaces are not properly cleaned and sanitized, insanitary conditions could result, leading to potential adulteration of product.

Example of failure to meet performance standard:

- dried meat scraps on a wall located away from product but in a production area.

9 CFR 416.4 Sanitary operations (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.

It is required that meat and poultry products be neither adulterated nor misbranded through the misuse of proprietary substances and nonfood compounds. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available for FSIS review. The documentation can vary with the nature and intended use of that chemical. For example, the establishment should have documentation showing that a pesticide used in the plant is registered with EPA, and the label information for the pesticide should be on file. For a chemical sanitizer used on food contact surfaces, an establishment should have documentation showing that the compound complies with the relevant Food and Drug Administration (FDA) regulations in 21 CFR 178.1010. (Sanitizers meeting FDA requirements are usually identified as "Food Grade.")

Meat and poultry establishments must ensure that all proprietary substances and nonfood compounds are safe for their intended use and used appropriately.

Example of failure to meet performance standard:

- no documentation showing that the sanitizers used in the facility are safe as used.

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

As product moves through the process there might be elements in the environment that could adulterate it. Employees who move and handle product improperly are another possible source of contamination. The establishment must decide, depending upon the situation and the circumstances within the establishment, how the product should be protected through all phases of the process. For example, the establishment might cover the product when it is stored in the cooler to prevent contamination.

Example of failure to meet performance standard:

- combos stored in tiered storage racks not appropriately covered creating an insanitary condition.

9 CFR 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.

Example of failure to meet performance standard:

- an employee wiping his runny nose on the sleeve of his smock

9 CFR 416.5 Employee hygiene. (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.

Example of failure to meet performance standard:

- an employee wearing a soiled smock from the raw product area entering the sausage drying room.

9 CFR 416.5 Employee hygiene. (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.

FSIS has 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.

Example of failure to meet performance standard:

- an employee handling edible product with an open sore on her hand.

9 CFR 416.6 Tagging insanitary equipment, utensils, rooms or compartments.

When the Consumer Safety Inspector 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 or she will attach a "U.S. Rejected" tag to it. Equipment, utensils, rooms, or compartments that are tagged cannot be used until they are made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag. The regulatory control actions should remain in effect until the establishment has taken corrective action and has proposed effective preventive measures.

Sanitation Standard Operating Procedures (SSOPs)

9 CFR 416.11 General Rules. Each establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOPs) in accordance with the requirements of this part.

The establishment is responsible for developing, implementing, and maintaining written Sanitation Standard Operating Procedures (SSOPs) that meet the requirements of part 416. Insanitary facilities or equipment, improper personal hygiene, and similar insanitary practices create an environment conducive to contamination of products. Sanitation SOPs clearly define the establishment's responsibility to consistently follow effective sanitation procedures that will substantially minimize the risk of product contamination and adulteration.

9 CFR 416.12 Development of Sanitation SOPs (a) The Sanitation SOPs shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

It is a regulatory requirement that the plant have written SSOPs describing the daily procedures conducted before and during operations to prevent direct contamination or adulteration of products.

9 CFR 416.12 Development of Sanitation SOPs (b) The Sanitation SOPs shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOPs as specified and will maintain the Sanitation SOPs in accordance with the requirements

of this part. The Sanitation SOPs shall be signed and dated upon initially implementing the Sanitation SOPs and upon any modification to the Sanitation SOPs.

The SSOP written procedure is signed and dated by an official with overall sanitation authority or a higher-level official of the establishment. It is not required that the person be listed on the Grant of Inspection or the PBIS plant profile. Written procedures must be signed upon initiation and whenever they are modified.

9 CFR 416.12 Development of Sanitation (c) Procedures in the Sanitation SOPs that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

The written procedures must identify pre-operational sanitation procedures. At a minimum, SSOPs must address the cleaning of food contact surfaces of facilities, equipment, and utensils. The regulation does not specify how much detail SSOPs must contain.

9 CFR 416.12 Development of Sanitation (d) The Sanitation SOPs shall specify the frequency with which each procedure in the Sanitation SOPs is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

The Sanitation SOP must contain:

- The frequency the procedures in the SSOP are conducted
- Identification of the employee(s) responsible for the implementation and maintenance of the SSOPs (does not have to be the people performing the activities but the person responsible)

Plants may identify individual(s) by name or job title. The individuals or positions identified do not have to have separate lines of authority from the production process. Production employees, lead line personnel, department forepersons, etc. may be identified. The employee(s) identified may or may not be the employee who actually performs the activities.

9 CFR 416.13 Implementation of SOPs (a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations.

Establishments are responsible for implementing the Sanitation SOP daily. They must perform their procedures before the start of operations as prescribed in their written pre-operational procedures. An establishment may have several departments, starting at different times during the approved hours of operation. They may perform their pre-operational procedures at staggered times prior to the approved starting time. In other words, the establishment does not have to perform pre-operational procedures in all the departments prior to starting operations in any one department.

9 CFR 416.13 Implementation of SOPs (b) Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified.

Establishments are responsible for the daily implementation of all procedures identified in the Sanitation SOP that occur during operations. An example procedure is an SSOP that includes a procedure for using a footbath prior to entering the ready-to-eat area.

9 CFR 416.13 Implementation of SOPs (c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOPs.

Establishments must monitor the SSOP procedures they conduct daily to ensure they effectively prevent direct product contamination or adulteration. For example, an establishment might have a procedure that calls for cleaning and examining all equipment prior to operations and a monitoring procedure that includes examining a random selection of representative equipment prior to operations.

9 CFR 416.14 Maintenance of Sanitation SOPs. Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOPs' and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

Establishments should routinely evaluate the content and effectiveness of the SSOP and modify it accordingly. The Sanitation SOPs must be kept current. When facilities, personnel, or operations change, the establishment must still prevent direct product contamination and adulteration. For example, if the establishment changed their operations by expanding the facility and adding new pieces of equipment, they must reevaluate their written procedures and, if necessary, make changes to effectively prevent direct contamination or adulteration of product.

9 CFR 416.15 Corrective Actions (a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).

The establishment must take corrective actions any time the establishment or FSIS determines that the SSOP has failed to prevent direct product contamination or adulteration of product. SSOP failure can be the result of either not implementing or not maintaining the SSOP, and it can occur before or during operations. This applies to contamination or adulteration of direct product contact surfaces or direct product zones found by the establishment or FSIS procedures before or during operations. For example, in a poultry cut-up operation, the establishment has a procedure for the salvage of product that contacts the floor written into its SSOP. The SSOP says that the product will be removed from the floor promptly by an employee in the cut-up area and trimmed, washed, and treated with a chlorine rinse before it is returned to production. The SSOP further states that this procedure will be monitored once per hour by the QC technician. If the procedure were followed as written, corrective actions would not have to be implemented. However, if during a monitoring procedure the QC technician finds that the procedure is not followed, corrective actions must be implemented.

9 CFR 416.15 Corrective Actions (b) Corrective Actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs or the procedures specified therein.

Establishments must initiate corrective actions when either the plant or FSIS determines implementation of the procedures fails to prevent direct product contamination or adulteration. Establishments must implement all three parts of the corrective action, i.e., they must:

- 1) dispose of contaminated or adulterated product appropriately
- 2) restore sanitary conditions
- 3) prevent recurrence of failure

Corrective actions may also include reevaluation and modification of the Sanitation SOP or the procedures specified in it. However, it might not be necessary to modify the SSOP in every case.

The establishment is not required to document specifics in the SSOP regarding exactly which corrective actions will be taken in every single possible case of contamination or adulteration. They must, however, address all three parts of corrective action and include these actions in the records if product contamination or adulteration occurs.

9 CFR 416 Recordkeeping (a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.

Establishments must maintain daily records that document they are carrying out the sanitation procedures outlined in the SSOP, including the corrective actions taken. Plant management may exercise flexibility in designing records. There is no set format, and records do not have to be included in the written SSOP.

For example, the SSOP might describe a hygienic procedure where all employees must wash their hands after returning from break and that the QC manager is responsible for monitoring the procedure. The record should document that employees were monitored after break before returning to work. If an employee was observed returning to work without washing his hands, a description of the incident, and the three parts of corrective actions taken by the establishment must be documented.

9 CFR 416 Recordkeeping (b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

Records may be maintained on a computer in lieu of hard copy as long as they are accessible to inspection personnel. The establishment must prevent tampering with the electronic records. It is up to them to determine how to ensure integrity of the electronic data.

9 CFR 416 Recordkeeping (c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

All SSOP records generated must be retained for six months. For oversight and enforcement purposes FSIS requires access to all establishment sanitation records. The plant is required to keep records on-site for 48 hours and make them available to FSIS upon request. Afterwards,

records may be stored off-premises as long as they can be provided to FSIS within 24 hours of a request for them.

9 CFR 416.17 Agency Verification. FSIS shall verify the adequacy and effectiveness of the Sanitation SOPs and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

- (a) Reviewing the Sanitation SOPs;*
- (b) Reviewing the daily records documenting the implementation of the Sanitation SOPs and the procedures specified therein and any corrective actions taken or required to be taken;*
- (c) Direct observation of the implementation of the Sanitation SOPs and the procedures specified therein and any corrective actions taken or required to be taken; and*
- (d) Direct observation or testing to assess the sanitary conditions in the establishment.*

The Consumer Safety Inspector verifies that SSOPs are developed, implemented, maintained, and that they are effective. FSIS also verifies that the establishment maintains daily records.

HACCP: Establishment Responsibilities

FSIS has the overall authority and oversight to regulate meat/poultry products intended for distribution into commerce. The official establishment's responsibility is to produce safe wholesome meat/poultry products. When the Pathogen Reduction/HACCP System Final Rule was published in July 1996, and the regulation was first implemented in large establishments in January 1998, in small establishments in January 1999, and in very small establishments in January 2000, FSIS required all establishments that produce federally inspected meat and poultry products to design and operate HACCP systems. HACCP provides a framework for establishments to conduct science-based process controls that can be validated as effective in eliminating, preventing, or reducing to an acceptable level the food safety hazards that are reasonably likely to occur in an official establishment's particular production processes. Under the HACCP regulatory system, establishments assume full responsibility for producing products that are safe for consumers.

The 7 HACCP Principles

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) Working group created guidelines and redefined the seven basic principles of HACCP as an effective and rational means of assuring food safety from harvest to consumption. This paper is not a regulatory document. However, it is a document that was utilized by FSIS when the HACCP regulation was developed and then published in the Federal Register. As regulators, you will be responsible for verifying compliance with the HACCP regulation. The HACCP guideline with the seven principles is not an enforceable document; however, it is helpful for inspection personnel to be familiar with the basis for the development of the HACCP plan which will be regulated under Title 9 Code of Federal Regulation (CFR) Part 417.

The 7 HACCP Principles

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures

Principle 1: Conduct a hazard analysis.

A thorough hazard analysis is the key to preparing an effectively designed HACCP plan. The NACMCF identified the purpose of the hazard analysis in the guidance document as a process used to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns.

A hazard is defined by NACMCF as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Establishments must consider all three types of hazards – biological, chemical, and physical – at each step of the production process. A food safety hazard that is reasonably likely to occur is one for which a prudent plant would establish controls because the hazard has historically occurred in the product/process or because there is a reasonable probability that the hazard would occur in the absence of these controls.

Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. A summary of the HACCP team decisions and the rationale developed during the hazard analysis should be kept for future reference.

Flow Charts

At each step in its processes, the establishment must determine what food safety hazards may be associated with that step, if that hazard is reasonably likely to occur in the process, and what controls will be used to prevent, eliminate, or reduce the hazard to an acceptable level. The control point for a hazard may be further along in the process than the point at which the hazard occurs. For example, the cooking step is the most common control for biological hazards that have been introduced into the product at previous steps.

Each establishment is responsible for identifying the hazards reasonably likely to occur in its process, and for determining how it will control those hazards to prevent, eliminate, or reduce them to an acceptable level. Different establishments may have identified different hazards as reasonably likely to occur and different control measures for them, even though their processes may appear to be similar. For example, differences may exist in the type of equipment, incoming product, employee training, or production practices.

The hazard analysis shall include hazards that can occur before, during and after entry into the plant.

This provides a basis for determining the critical control points (CCPs).

Principle 2: Determine critical control points

The hazards that were identified in the hazard analysis must be addressed in the HACCP plan. A hazard is controlled by one or more critical control points (CCPs).

A **critical control point** is defined as a point, step, or procedure in a food process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Critical control points are locations in a process at which some aspect of control can be applied to control food safety hazards that have been determined reasonably likely to occur.

Examples of CCPs include product temperature, certification of incoming product, microbiological testing, testing for foreign objects such as metal contamination, the chemical concentration of a carcass rinse or spray, and other such parameters.

The step of the process at which the critical control point is located does not necessarily have to be at the point where the hazard is introduced into the system. It is the plant's responsibility to determine the location of its CCPs. They may be placed at any location deemed adequate to prevent, eliminate, or effectively control the hazard in the meat/poultry product produced.

Control may actually be achieved as a cumulative effect. There may be several steps in the process that together attain sufficient control, but individually do so only partially. For example, an official establishment that slaughters cattle may have a pre-evisceration organic acid rinse, a post evisceration organic acid rinse, and a wash step followed by steam pasteurization.

For **each** hazard that is determined to be reasonably likely to occur, the establishment must identify critical control points and corresponding critical limits that are measurable or observable. Establishments must have documentation supporting all of these decisions, and they must be able to demonstrate that their plan designs are valid and effective in operation.

Principle 3: Establish critical limits

The next step in the development of a HACCP plan is to establish critical limits for each critical control point. **Critical limits** (CL) are the parameters that indicate whether the control measure at the CCP is in or out of control. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) states that a CL is a **maximum or minimum value** to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. The HACCP team must consider the food safety standard that must be met at each CCP. Critical limits are designed to ensure applicable targets or performance standards pertaining to the specific process or product. Critical limit design should be based on applicable FSIS **regulations** or guidelines, FDA tolerances and action levels, scientific and technical literature, surveys, experimental studies, or the recommendations of recognized experts in the industry, academia, trade associations, or processing authorities. Critical limits should not be confused with operational limits which are established for reasons other than food safety.

Critical limits are most often based on process parameters such as temperature, time, physical dimensions, or presence of target pathogens. Critical limits must be actual values that can be measured or quantified. Regardless of the parameter used, the critical limit must be sufficient

to prevent, eliminate, or reduce to an acceptable level the occurrence of the food safety hazard it is designed to control. The establishment must be able to provide the basis for their decision documents regarding the selection and development of the critical limits. The HACCP team must develop CLs that work effectively given the capabilities and limitations of the plant's processes.

Principle 4: Establish monitoring procedures

Once critical limits are set for each CCP during the HACCP plan development, procedures must be established to monitor the CCPs to determine whether the critical limits are being met. **Monitoring** is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Every CCP that is in the HACCP plan must be monitored to ensure that the critical limits are consistently met and that the process is producing safe product. Establishments are responsible for determining the procedure used to monitor each CCP. Monitoring procedures usually involve either a measurement or an observation. If the critical limit is a numerical value, then monitoring usually involves a measurement. If the critical limit is defined as the presence or absence of an attribute, then the monitoring procedure may involve observation. Monitoring procedures should be designed to determine when deviations from the critical limit occur so that appropriate corrective actions can be initiated.

Establishments must determine how often they need to monitor CCPs. Ideally, the monitoring frequency would be continuous whenever possible. An example is the continual recording of cooking temperatures on temperature recording charts. The advantage of continuous monitoring is that it allows a plant to see what is occurring at a CCP throughout the production process at any given time.

When it is not possible to monitor a CCP on a continuous basis then it is monitored intermittently and the frequency must be determined. The frequency selected should be adequate to determine that the CCP is under control. Statistically designed data collection or sampling systems are used to establish the frequency when monitoring is not on a continuous basis. Establishments can select any employee to conduct monitoring activities. Assigning monitoring responsibilities is an important consideration for establishment management. HACCP monitors are often production employees or quality control personnel. Employees selected to be HACCP monitors should be adequately trained and should understand the purpose and significance of monitoring. They should also be trained to immediately report unusual occurrences to the individual responsible for initiating corrective actions. The HACCP plan does not have to specify **who** will do the monitoring.

Principle 5: Establish corrective actions

Next, the HACCP team determines corrective actions for each CCP that must be taken in cases where the CL is not met. The specific corrective actions depend upon the process used and type of food produced.

When there is a deviation from the critical limit, corrective actions are required to prevent potentially hazardous foods from reaching consumers. The HACCP plan must include corrective actions to be taken when a deviation from the critical limit occurs at a critical control point. The corrective actions consist of

- Identifying and eliminating the cause of the deviation,

- Ensuring that the CCP is under control after the corrective action is taken,
- Ensuring that measures are established to prevent recurrence, and
- Ensuring that no product affected by the deviation is shipped.

HACCP plans should specify what is to take place when a deviation occurs, who is responsible for implementing corrective actions, and that corrective actions will be documented as part of the HACCP records. When designing their HACCP plans, establishments can either specify particular corrective actions they will take when a deviation occurs, or can simply state that they will address the regulatory requirements in Title 9 CFR Section 417.3 Corrective Action. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

Principle 6: Establish recordkeeping and documentation procedures

When developing the HACCP plan, the HACCP team must ensure that the HACCP system has an effective recordkeeping system. **Records** are written evidence documenting the operation of the HACCP system. All measurements taken at a CCP, and any corrective actions taken, should be documented and kept on file. These records can be used to trace the production history of a finished product. If any questions arise about the product, a review of records may be the only way to determine whether the product was produced in a safe manner according to the HACCP plan.

The **HACCP plan** outlines the formal procedures the establishment will follow to meet the seven principles. The NACMCF recommends that the HACCP plan records a

- List of the HACCP team and assigned responsibilities
- Description of the food, its distribution, intended use, and consumer
- Verified flow chart for the entire manufacturing process with CCPs indicated
- HACCP Plan Summary Table that lists the following for each hazard of concern—the CCP, critical limit, the monitoring procedures and frequencies, the corrective actions, the verification procedures and frequencies, and the recordkeeping system.

The **supporting documentation** includes the rationale used to establish CCPs, critical limits, monitoring procedures and frequencies, corrective action procedures, and verification procedures and frequencies. This includes all scientific references, regulatory resources, and materials from other sources (e.g., extension services, academic experts, consultants, industry trade associations) that have been used in the development of the HACCP plan.

The **daily operational records** are what most of us think of when we think of HACCP records. These include the actual records from the implementation of the HACCP plan (monitoring, corrective actions, and verification).

The HACCP regulation requires that HACCP records:

- Contain the date and time of the activity reflected on the record
- Contain the signature or initials of the employee making the entry
- Have the information entered on the record at the time it is being observed
- Contain actual observations or data values obtained

Principle 7: Establish verification procedures

HACCP systems must be systematically verified. In the NACMCF explanation of the verification principle, which FSIS is following, four processes are involved in the verification of the establishment's HACCP system. The establishment is responsible for the first three; FSIS is responsible for the fourth. The first is the scientific and technical process, known as validation for determining that the CCP and associated critical limits are adequate and sufficient to control likely hazards. The second process is to ensure, initially and on an ongoing basis, that the entire HACCP system functions properly. The third process consists of

documented, periodic, reassessment of the HACCP plan. The fourth process defines FSIS's responsibility for certain actions (government verification) to ensure that the establishment's HACCP system is functioning adequately.

Verification establishes the accuracy of, or confirms the monitoring of, the critical control points. The verification procedures demonstrate that the HACCP system is adequately controlling food safety hazards. After initial validation the system must be verified periodically. Periodic verification involves the use of methods, procedures, or tests in addition to those used for monitoring, to determine whether the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and revalidation to achieve its food safety objective. Establishments must also be able to provide supporting documentation for the verification procedures and frequencies specified in the HACCP plan.

Ongoing verification activities consist at a minimum of calibration procedures (if there are instruments that require calibration), direct observations of monitoring and corrective actions, and records review. All three of these will be described in the HACCP plan, as applicable.

The goal of **calibration procedures** is to ensure that all measurements are accurate. If the findings from the procedures show that the measuring device is incorrect, then the device must be recalibrated or replaced. The establishment should determine if the inaccurate process-monitoring instrument permitted the production of products that did not meet the critical limit. If it is determined that the critical limit was not met, the establishment would have to implement corrective actions.

The **direct observation** procedures and frequency for this type of verification procedure usually involve observing the monitor.

The purpose of **records review** is to ensure that the records were prepared correctly, that all activities were performed as required by the HACCP plan, that no activity was missed, and that all results were within the critical limits.

Not all CCPs require the calibration of process-monitoring equipment. Establishments are not limited to only these three types of verification activities. Other types of verification procedures that establishments may use include independent checks or measurements to verify the accuracy of monitoring and microbiological testing.

Hazard analysis

During the development and design of the HACCP plan, the official establishment determines if there are any biological, chemical, or physical hazards that are reasonably likely to occur before, during, or after entry into the establishment. A food safety hazard is defined as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. In this section we will introduce the food safety hazards that may be associated with raw processes. Most of the food safety hazards inherent in these processes originate with the live animals that enter the slaughter establishment and commonly include the **biological** hazards of bacterial pathogens, the **chemical** hazard of residues, and the **physical** hazards of foreign material.

Biological Hazards

The biological hazards of meat and poultry products result from the presence of potentially pathogenic bacteria in and on the live animal or bird, including intestinal contents and exterior surfaces such as hide, hair, feathers, and hooves. Bacterial contamination of carcass surfaces is an unavoidable consequence of processing animals and birds into meat and poultry for human consumption. The types of bacteria present on the live animal or bird will largely determine the bacterial population that exists on the carcass surface. Consequently, products derived from carcasses will contain the same types of bacteria present on the carcass surfaces. The establishment faces a challenge, in that the raw processes do not commonly include a lethality step, a procedure that would eliminate the bacteria. These establishments must do their best to control or reduce the hazard, or to prevent it from entering the process.

The prevalence of the pathogen ***Salmonella*** in beef, lamb, pork, and poultry carcasses varies greatly. The overall contamination of meat and poultry carcasses with these pathogens depends not only on the numbers of the pathogens on the hair, feathers, skin, and in the intestinal tract of the animals, but is also significantly affected by the degree of cross-contamination occurring from these sources during slaughter and processing. Plant operators must adhere to pathogen reduction performance standards for *Salmonella*, as specified in 9 CFR 310.25 for livestock and in 9 CFR 381.94 for poultry.

Escherichia coli is commonly found as part of the normal bacteria of the intestinal tract of humans and animals. Some strains, including ***Escherichia coli* O157:H7**, can cause serious illness in humans. Cattle may carry *Escherichia coli* O157:H7 in the intestinal tract at the time of slaughter, although it is actually harmless to these animals. Beef has been implicated in a number of foodborne illnesses associated with this pathogen. Contamination with *Escherichia coli* O157:H7 can be reduced through the use of sanitary dressing procedures during slaughter (dehiding and evisceration) and pathogen reduction intervention treatments (organic acid rinses, hot water rinses, and steam pasteurization). FSIS considers raw ground beef contaminated with *E. coli* O157:H7 to be adulterated, unless the ground beef is further processed to destroy this pathogen. FSIS samples and tests ground beef for *E. coli* O157:H7.

Raw poultry is the major source of ***Campylobacter***. Cross-contamination during preparation of raw chicken and the consumption of inadequately cooked poultry appear to be significant sources of this human illness. FSIS is conducting research about the prevalence of this organism. Current evidence is not conclusive about the risk, and FSIS does not regularly test for *Campylobacter*.

Chemical Hazards

Animals may be presented at slaughter with violative levels of chemical residues. This hazard includes chemical residues resulting from use of, or exposure to, drugs, pesticides, and other compounds. For example, dairy cows may be given antibiotics by the producer to treat infections like mastitis, and failure to observe the required withdrawal time may result in violative residues. Some examples of environmental contaminants that may be consumed by animals include lead, cadmium, mercury, arsenic, dioxins, or polychlorinated biphenyls or PCBs.

The potential health consequences of exposures to chemicals in food can be serious, are often inadequately understood, and deserve serious consideration. The long-term and cumulative effects of exposure associated with chemicals in food pose special difficulties in identifying and addressing these risks. Chemical residues have been linked through research

to various types of cancers. The public health concerns associated with the long-term effects of exposure to chemicals from ingestion of food is not well understood or well documented.

Physical Hazards

A physical hazard is a physical component of a food that is unexpected and may cause illness or injury to the person consuming the food. Physical hazards, such as pieces of metal, sometimes occur because equipment has not been properly maintained. In some processes, such as raw—ground, product may be received that is contaminated by foreign material, which if not controlled, may subsequently become incorporated into the ground product. Foreign material would include non-animal objects such as metal, wood, rubber, glass, steel, lead, or other objects. For example, lead shot in a carcass may be considered by the establishment as a food safety hazard reasonably likely to occur in their operation, especially if the establishment historically receives animals containing such material. Another example might be a poultry operation that historically has a problem with metal shavings in its carcass chillers. Keep in mind that the foreign material we discuss here does not include things such as rail dust or rust, which would be covered by sanitation performance standards or SSOP requirements. The size, shape, and consistency of the foreign object should be considered in determining whether it is or is not a hazard.

Typical public health concerns associated with consuming products that contain physical hazards include broken teeth and damage, such as tears, to the mouth, esophagus, stomach, and intestines. These physical hazards may obstruct air passages or intestines. In some cases, death may result due to suffocation or infections (intestinal blockages). Small children are particularly susceptible to problems brought on by physical hazards since their body structures are smaller, and the physical objects may have a greater effect.

Methods that establishments use to control physical hazards include visual observation of product, sanitation procedures, SOPs for product handling, GMPs to ensure proper maintenance and inspections of facilities and equipment, and foreign materials detection equipment (inline magnets, screens, traps, filters, etc.) used during the production process.

HACCP: FSIS Responsibilities - Inspection Verification Procedures

FSIS responsibilities are outlined in **FSIS Directive 5000.1, Revision 1**. The off-line inspectors, known as Consumer Safety Inspectors, are responsible for properly performing the procedures as described in this Directive. The information in the Directive describes the regulatory process.

The regulatory process for HACCP procedures are as follows.

- **Methodology**
- **Decision-making**
- **Documentation**
- **Enforcement**

Verification Methodology

HACCP 01 and 02 procedures are performed by CSI's to verify that establishments are complying with Part 417. CSI's focus on the execution or implementation of the HACCP plan when performing verification procedures.

The thought process that is described in Directive 5000.1 that the off-line CSI uses when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

For each of the regulatory requirements, the Directive outlines questions to consider. This thought process is used to verify all of the regulatory requirements.

The Five Regulatory Requirements

There are five regulatory requirements that the establishment must comply with during the day-to-day or ongoing operation of the HACCP system. The regulatory requirements are:

1. Monitoring
2. Verification
3. Recordkeeping
4. Corrective Actions
5. Reassessment

CSI's use the 01 and 02 procedures to verify that the establishment complies with these five regulatory requirements.

01 and 02 HACCP Procedures

The 01 and 02 HACCP procedures are performed by the off-line CSI's to verify ongoing compliance with the regulatory requirements of 9 CFR Part 417 as the establishment executes its HACCP plan for the raw processing categories. The HACCP 01 and 02 procedures can be performed as scheduled or unscheduled procedures. Each of these procedures has two components:

- recordkeeping component
- review and observation component.

In most instances, CSI's use one of these components. There may be occasions when both are used. For example, the CSI may perform recordkeeping at one CCP and review and observation at another CCP. Or, the CSI may observe something during recordkeeping that may prompt him or her to perform a review and observation of that CCP.

How the CSI Performs the Two Components

- Recordkeeping

To perform the **recordkeeping** (Rk) component, the CSI reviews HACCP records to determine if the establishment recorded its tests or measurements at the required frequency, if all required data was recorded, if the data is accurate, if critical limits have been met, and if corrective action was taken when necessary. When CSI's perform the recordkeeping component, they are only reviewing records. Typically this review would take place where the records are maintained and may not be at the physical location of the CCP.

Example: *The CSI is performing an 01 procedure and are verifying a monitoring procedure. The CSI decides to perform the recordkeeping component. They examine the records associated with this monitoring procedure. They look at the frequency of the entries and the data recorded, and compare the recorded data to the critical limit at this step.*

- Review and Observation

To perform the **review and observation** (R&O) component, the off-line CSI may directly observe plant employees performing the procedures as stated in the HACCP plan (observation) or may take measurements to see if the values obtained match those recorded by the establishment (review).

Example: *The CSI is performing an 01 procedure to verify a monitoring requirement, which in this case is a product temperature check. The CSI decides to perform both parts of the review and observation component. The CSI directly observes the plant employee carry out the product temperature check. Then, takes a product temperature measurement, and compares the result obtained to the one just recorded by the plant employee.*

01 Procedure

The 01 procedure is for verifying one or more of the HACCP regulatory requirements as the establishment executes its HACCP plan for raw processes. The 01 procedure is designed to provide a "snapshot" of the HACCP system.

There are three requirements that are **randomly** verified during the 01 procedure: monitoring, verification, and recordkeeping. Corrective Actions and reassessment are not randomly verified as part of the 01 procedure since they are performed as a result of some event that triggers them. For example, the CSI would verify the corrective action requirements are met anytime there is a deviation from a critical limit, a deviation not covered by a specific corrective action, or an unforeseen hazard. Similarly, the CSI would verify the reassessment requirement if the establishment significantly changes its process, or encounters an unforeseen hazard.

The off-line CSI must have a method to randomly select one (or more) of the three requirements to be verified during the performance of the procedure. For example, the CSI may choose to draw pieces numbered one through three from a container. The CSI can use the FSIS, FAIM computer to select random numbers. See appendix 1 for instructions.

To perform the 01 procedure, the CSI will do the following:

1. **Randomly** select one (or more) of the three HACCP requirements to verify
2. Select one (or more) of the CCPs from the HACCP plan to verify
3. Determine which component (review and observation or recordkeeping) to perform

4. Perform the verification for **that requirement for that CCP**

Note: If the CSI finds noncompliance while performing the 01 procedure, the 02 procedure must then be performed.

02 Procedure

The 02 procedure is for verifying **all regulatory requirements** at all of the critical control points in the HACCP plan for a **specific production**. The 02 procedure cannot be completed until the establishment performs the pre-shipment review for that specific production. Because 02 covers a specific production, when the CSI performs it, he or she is determining whether the establishment prevented the distribution of adulterated product. When noncompliance is found while performing an 01 procedure, the 02 procedure must be performed on that specific production that had the noncompliance.

Specific production refers to whatever method the establishment uses to group product. FSIS does not determine the method used to define specific production. This is an establishment's responsibility. Many methods can be used. For example, a poultry slaughter plant might define all the birds from one house as specific production, another might define it by all carcasses produced in one hour on one line. Establishment's might define all product from one formulation batch, one shift's production, or the product in one chiller as a specific production. The method that is used can be determined by asking plant management.

To perform the 02 procedure, the CSI does the following:

1. Verify that **all** of the HACCP requirements have been met for **all CCPs** in the HACCP plan for that **specific production**.
2. Verify that the **pre-shipment review** requirement for that specific production has been met.

Salmonella Performance Standards

Pathogen reduction performance standard for Salmonella in meat (§310.25(b)) and poultry (§381.94(b)) products

The pathogen reduction program is an integral part of the FSIS food safety strategy. It stimulates improvements in food safety practices by establishing guidelines and ensuring proper process control. FSIS established performance standards for *Salmonella* as part of the *Pathogen Reduction; Hazard Analysis Critical Control Point (HACCP) Systems; final rule*.

FSIS adopted pathogen reduction performance standards for *Salmonella* to verify that plant HACCP systems are effective in reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat and poultry products with *Salmonella* prevalence below the current national level is achievable with available technology and production methods. *Salmonella* was selected as the target pathogen because it is the leading cause of foodborne illness among enteric pathogens, it is present at varying frequencies on all types of raw meat and poultry products, and it can easily be tested for in a variety of products. Improvements in process control that result in reductions in *Salmonella* are expected to result in reductions of other pathogens found in the intestines of animals.

Based on §310.25(b)(1) for meat and §381.94(b)(1) for poultry products, FSIS collects raw meat and poultry products samples from establishments and test the samples for *Salmonella* to verify that establishments are meeting the pathogen reduction performance standards. Pathogen reduction performance standards for raw products are an essential component of FSIS's food safety strategy as they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products. Accordingly, the collection of samples in plants by inspection program personnel is a significant Agency priority.

§310.25(b) (1) Raw meat product performance standards for Salmonella. An establishment's raw meat products, when sampled and tested by FSIS for Salmonella, as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 1:

Table 1:

SALMONELLA PERFORMANCE STANDARDS			
Class of product	Performance Standard (percent positive for <i>Salmonella</i>) ^a	Number of samples tested (sample sets) (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	N.A. ^b	N.A.	N.A.

^aThe last two columns do not equal the percentage because of sampling variations.

^bNot available, values will be added upon completion of rulemaking.

§381.94(b) Pathogen reduction performance standards; Salmonella. (1) Raw poultry product performance standards for Salmonella. (i) An establishment's raw poultry products, when sampled and tested by FSIS for Salmonella as set forth in this section, may not test positive for Salmonella at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

Table 2:

SALMONELLA PERFORMANCE STANDARDS			
Class of product	Performance Standard (percent positive for <u>Salmonella</u>) ^a	Number of samples tested (sample sets) (n)	Maximum number of positives to achieve Standard (c)
Broilers	20.0%	51	12
Ground Chicken	44.6%	53	26
Ground Turkey	49.9%	53	29
Turkeys	N.A. ^b	N.A.	N.A.

^aThe last two columns do not equal the percentage because of sampling variations.

^bNot available, values will be added upon completion of rulemaking.

Enforcement – meat (§310.25(b)(2)) and poultry (§381.94(b)(2)) products

FSIS will sample and test raw meat and poultry products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of the testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products. However, under current policy normally one species at a time is tested.

FSIS inspection personnel collect *Salmonella* samples in accordance with FSIS Directive 10,230.5. For meat products, steers, heifers, cows, bulls, hogs and ground beef are sampled. For poultry products, broilers, turkeys, ground chicken and ground turkey are sampled. These samples are forwarded to the FSIS laboratories via Federal Express. The lab analyzes the samples and the Office of Public Health and Safety tracks the data and results.

§310.25(b)(3) and §381.94(b)(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard: (i) the establishment shall take immediate action to meet the standard.

If an establishment fails to meet the *Salmonella* performance standard after the first sample set is complete the firm must take immediate action to meet the standard. In addition, the District Manager will send a letter to the establishment indicating they did not meet the performance standard. The Frontline Supervisor (FLS) and IIC will conduct an assessment of the HACCP and SSOP procedures, and in establishments producing meat products will also analyze data from generic *E. coli* (if applicable), focusing on any corrective and further planned actions initiated by the establishment. The IIC/SVMO will document the establishment's

immediate action or an explanation of compliance and maintain a copy of the documentation in the inspection files. The FLS and SVMO/IIC will develop, document and implement a verification plan, using the 01 and 02 SSOP and HACCP procedure codes, to verify any corrective actions implemented by the establishment. The establishment is then placed in establishment specific-targeted testing and a second set of tests will be collected.

Example – meat product: A pork slaughter establishment receives notification that they failed to meet the *Salmonella* performance standard for pork carcasses on the initial, or “A” set, of samples. The firm takes the minimum action required by §310.25(b)(3)(i) by reviewing their procedures. Through this review the firm determines that additional measures can be taken on the slaughter floor to meet the *Salmonella* performance standards. The establishment proposes the following actions to meet the standard:

- Replacement of the nozzles in the final washer for better dispersion
- Replacement of paddles in the hog dehairer for better removal of hair
- Retraining of slaughter floor employees on proper dressing procedures

After receiving notification of the plant's failure to meet the performance standard, the FLS and IIC conducted and documented an assessment of the establishment's HACCP and SSOP procedures as well as analyzing data from the establishment's generic E. coli testing. The IIC documented the plant's immediate action and placed it in the inspection files. The FLS and IIC developed and documented a verification plan, using the 01 and 02 SSOP and HACCP procedure codes to verify the plant's corrective actions. The IIC will verify during the performance of the HACCP and SSOP 01 and 02 procedures that the following occurred: replacement of nozzles in the final washer for better dispersion; replacement of paddles in the hog dehairer for better removal of hair; and retraining of slaughter floor employees on proper dressing procedures.

Example – poultry product: A poultry slaughter and processing establishment receives notification that they failed to meet the *Salmonella* performance standard for ground chicken upon completion of the second sample set. The establishment reassesses their HACCP plan for raw ground chicken and for the poultry slaughter floor. They determine that additional measures can be taken on the slaughter floor to assist in meeting the *Salmonella* performance standard for ground chicken. An additional critical control point (CCP) was added – a chlorinated bird washer for an additional microbiological intervention both inside and outside of the carcass. The critical limit (CL) was set at 20 ppm of available chlorine. Additionally, the establishment is undertaking the following actions:

- Lengthening the final washer
- Placement of the nozzles in the final washer for better dispersion
- Installation of a 2-stage scalding
 - Installation of an automatic transfer machine from the picking line to the evisceration line to reduce handling and the addition of possible contaminants
 - Installation of a new cropping machine to reduce the incidence of contamination of the carcasses with ingesta

§310.25(b)(3) and §381.94(b)(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard: (ii) If the establishment fails to meet the standard on the next series of compliance tests for that

product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

If the establishment fails to meet the *Salmonella* performance standard for the second sample the firm must reassess its HACCP plan and take appropriate corrective actions. In addition, the District Manager will send a letter to the establishment indicating they did not meet the performance standard and once the establishment has completed their reassessment and taken corrective actions per their reassessment an In-Depth Verification (IDV) review will be scheduled. As part of the IDV, the IDV team will be looking at the corrective actions the establishment implemented as a result of the plant's failure to meet the performance standard. An EIAO will be a member of the IDV team. Based on the results of the IDV, FSIS would initiate an enforcement action, issue a 30-day reassessment letter, or schedule the 3rd sample set.

The EIAO will take the lead in developing a verification plan to be used by in-plant inspection program personnel to assess corrective actions and further planned actions provided in response to an enforcement action or a 30-day reassessment letter. The EIAO will send a copy of the verification plan to the CS and DM and a copy will be maintained in the inspection files at the establishment. The verification plan will be based on the SSOP and HACCP 01 and 02 inspection procedures. The EIAO, CS, SVM/OIIC, and in-plant inspection program personnel will correlate to ensure the plan is fully understood and executed as intended.

§310.25(b)(3) and §381.94(b)(3) Noncompliance and establishment response. When FSIS determines that an establishment has not met the performance standard: (iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

The District Manager will send a letter to the establishment indicating they did not meet the performance standard. An EIAO in conjunction with a Compliance Officer (CO) will visit the establishment and conduct a focused assessment of the establishment's total food safety program to investigate the reasons why, in light of previous reassessments and corrective actions, the establishment failed a C set. Based on findings of the EIAO and the CO, the DM and officials from headquarters will determine what actions the Agency will take, including enforcement actions, in accordance with the Rules of Practice. In rare instances, if FSIS is unable to make this determination, then it will provide the establishment with the opportunity to reassess its HACCP plan within 30 days. Agency personnel would conduct in-plant verifications and follow-up verification testing will occur. The Agency may also decide to conduct an IDV at some or all of the establishment's suppliers (for ground beef establishments).

Directives and Policies Concerning *Salmonella*

Per FSIS Directive 10,011.1, *Enforcement Instructions for the Salmonella Performance Standards*, anytime, during the process of completing a sample set, more than half of the maximum number of samples are positive as identified an Early Warning Report is generated.

This Early Warning Report is issued by the District Office to notify establishment management that the firm's sanitation system or HACCP verification might be failing. Sharing this information before the set is complete, gives the establishment an opportunity to take preventive actions to ensure the sample set meets the *Salmonella* performance standards. Early Warning notification is applicable to any *Salmonella* set being collected.

If an establishment fails to meet the *Salmonella* performance standard after the first sample set is complete the firm must take immediate action to meet the standard. The District Manager will send a letter to the establishment indicating they did not meet the performance standard. The Frontline Supervisor (FLS) and IIC will conduct an assessment of the HACCP and SSOP procedures, and analyze data from generic *E. coli* (if applicable), focusing on any corrective and further planned actions initiated by the establishment. The IIC/SVMO will document the establishment's immediate action or an explanation of compliance and maintain a copy of the documentation in the inspection files. The FLS and SVMO/IIC will develop, document and implement a verification plan, using the 01 and 02 SSOP and HACCP procedure codes, to verify any corrective actions implemented by the establishment.

The establishment is placed in establishment specific-targeted testing and a second set of tests is collected. The District Manager determines the scheduling for the second set of tests, which normally will occur within 60 days. It may occur in a shorter or longer period of time based on such factors as the establishment's actions and the efficient use of resources.

If the second set of results fails to meet the performance standard, the District Manager will send a letter to the establishment indicating they did not meet the performance standard and inform the establishment that they must reassess their HACCP plan for that product in accordance with sections 310.25(b)(3)(ii) or 381.94(b)(3)(ii) of the regulations.

Failure of the second set of samples to meet the *Salmonella* performance standards also initiates an In-Depth Verification (IDV). IDV's are scheduled by the District Manager after the establishment has enough time to reassess the HACCP plan and implement any corrective actions or preventive measures needed.

The DM's designee will analyze the findings of the IDV report, determining whether the establishment complies with regulatory requirements, and proposing regulatory action, as appropriate. Also, at this point for grinding establishments, FSIS may decide to conduct an IDV at some or all of the establishment's suppliers. Based on the results of the IDV, FSIS would initiate an enforcement action, issue a 30-day reassessment letter, or schedule the 3rd sample set.

If no action is required, the IC prepares a letter for the DM's signature communicating the results of the assessment to the establishment and states that the IDV report is being provided as a final report. Regardless of the actions taken, the IDV report should be submitted to establishment management before the "C" sample set is initiated.

If the *Salmonella* performance standards are not met by the establishment after the third, or "C", set of samples, the District Manager will send a letter to the establishment indicating they did not meet the performance standard. An EIAO in conjunction with a Compliance Officer (CO) will visit the establishment and conduct a focused assessment of the establishment's total food safety program to investigate the reasons why, in light of previous reassessments and corrective actions, the establishment failed a C set. Based on findings of the EIAO and the

CO, the DM and officials from headquarters will determine what actions the Agency will take, including enforcement actions, in accordance with the Rules of Practice. In rare instances, if FSIS is unable to make this determination, then it will provide the establishment with the opportunity to reassess its HACCP plan within 30 days. Agency personnel would conduct in-plant verifications and follow-up verification testing will occur. The Agency may also decide to conduct an IDV at some or all of the establishment's suppliers (for ground beef establishments).

Generic *E. coli* Testing

Livestock

Sec. 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards. (a) Criteria for verifying process control; E. coli testing. (1) Each official establishment that slaughters livestock must test for Escherichia coli Biotype 1 (E. coli) Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number.

FSIS requires all slaughter plants to conduct microbial testing for generic *E. coli*, Biotype 1, a species of *E. coli* that is commonly found in the intestinal tract of food animals. Generic *E. coli* is an excellent indicator of fecal contamination, which is the primary pathway for contamination of meat and poultry with pathogens such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter*. The testing requirement helps plants determine how adequate their process control for fecal contamination is. Using an Agency baseline study FSIS established verification performance criteria that reflect the prevalence of *E. coli* contamination on carcasses. Not all species tested by establishments have performance criteria available. The Agency is currently conducting field surveys to develop additional criteria.

FSIS *E. coli* criteria are **guidelines**, not regulatory standards. FSIS does not use company test results by themselves to take regulatory action. *E. coli* test results are considered in conjunction with other information. The company test results can support more objective assessments and help determine whether plants meet current statutory requirements for sanitation and the prevention of adulteration. The generic *E. coli* test results play an integral role in the successful implementation of HACCP in slaughter plants.

If the establishment only slaughters one species and it is not listed in the *E. coli* regulations, the establishment is not required to test for generic *E. coli*.

The establishment must test the species that it slaughters in greatest number (major species) and that is listed in the regulations. When the major species slaughtered in a multiple-species slaughter establishment is not required by regulation to be tested the establishment must test the species produced in the next greatest number that is listed in the *E. coli* regulations.

§ 310.25 (a)(1)The establishment shall:(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section; (ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and (iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section. (2) Sampling requirements. Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and

handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

§ 310.25 (a)(2)(i) requires that the establishment identify the employee(s) who will collect samples. The plant procedure may simply designate a company position or title to identify the sample collector.

The regulation also requires that carcasses be selected at random. The establishment determines the methods by which randomness is achieved. For example, random number tables, computer-generated random numbers, or drawing cards may be used. In cattle, each half-carcass represents one unit eligible for sampling. Both the “leading” and “trailing” sides of a carcass should have an equal chance of being selected within the designated time frame. In swine, each whole carcass represents one unit eligible for sampling.

The location requirement in the regulation refers to the place within the establishment where the sample is collected. The half-carcass or carcass eligible for sampling should be selected from those in the cooler 12 or more hours after slaughter. The location of selection may also be at the transfer chain, a rail, or a similar place that contains carcasses that have chilled 12 hours or more. In cases where the carcasses are inaccessible in the cooler, or employee safety is jeopardized, it is acceptable to select random samples before carcasses enter the cooler. Selected carcasses may be chilled in a more accessible area and sampled after 12 hours. Similar random sample selection methods are used in establishments conducting hot-boning operations, but the samples are selected after the final wash.

If more than one shift is operating at the plant, the sample can be taken from either shift, provided the sample selection time is based on the appropriate sampling frequency. The half-carcass or carcass for sampling must be selected at random from all the eligible half-carcasses or carcasses. The time of sampling is based on the appropriate sampling frequency. Sample selection method in establishments conducting hot-boning operations on whole or split carcasses are selected at the end of the slaughter line prior to chilling.

Finally, the written procedure must declare the actions the plant will take to ensure the sample is handled in a manner that protects the integrity of the sample.

(ii) Sample collection. The establishment must collect samples from all chilled livestock carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples must be collected in the following manner;

(A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank, brisket and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.

§ 310.25 (a)(2)(ii) requires carcasses to be hot-boned be sampled after the final wash. There are two sampling methods an establishment may use to collect *E. coli* samples: excision sampling and sponging. Establishments slaughtering cattle and swine may choose either method. These are described as follows:

1. Excision sampling involves aseptically cutting a surface section from the carcass (8 x 6 x ½ inch thick for beef and 10 x 5 x ½ inch thick for swine) and either sending the excision sample for laboratory analysis or running the analysis in-house. Excising tissue from a carcass is a destructive method of sampling.
2. Sponging involves aseptically swabbing a sterile sponge on a surface of the carcass (10 cm x 10 cm for beef, swine, and equines; and 10 cm x 5 cm for sheep and goats) and either sending the sponge to the laboratory for analysis or running the analysis in-house. Sponging is a nondestructive method of sampling.

Samples must also be taken from specific sites on cattle and swine carcasses, sheep, goat, horse, mule, or other equine carcasses. The three sites from which either excision or sponging samples must be taken on **cattle** carcasses are the:

- Flank
- Brisket
- Rump

In the case of **hide-on** calves, sheep, goats, horses, mules, or other equines the three sites from which sponging samples must be taken are **inside** the:

- Flank
- Brisket
- Rump

In the case of **swine**, the three excision or sponging samples must be taken from the:

- Belly
- Ham
- Jowls

FSIS assumes that meat plants following the "*Guidelines for E. coli Testing for Process Control Verification in Cattle and Swine Slaughter Establishments*" will conduct their sampling in a manner that does not jeopardize the integrity of the sample or the reliability of the test results. Because these guidelines are not regulatory requirements, the plant may choose to use a comparable sampling technique and not be out of compliance.

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the volume of production at the following rates:

(A) Cattle, sheep, goats, horses, mules, and other equines: 1 test per 300 carcasses, but, a minimum of one sample during each week of operation. Swine: 1 test per 1,000 carcasses, but a minimum of one sample during each week of operation.

The required frequency of *E. coli* testing is based on production volume.

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with Sec. 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if, (A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan

and, (B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

In some cases an establishment operating under a validated HACCP plan may substitute an alternative frequency for the frequency in the regulation. This is allowed when the alternative frequency is an integral part of the establishment's verification procedures for its HACCP plan. An example is the case in which *E. coli* testing is built into a critical control point in the HACCP plan. The m/M criteria or the statistical process control upper limit is the critical limit for the CCP. The establishment that slaughters 9,000 cattle includes alternative testing frequency in the HACCP plan to sample once per week for a total of 52 samples per year, not 30 samples as would be required by the 1 test per 300 carcasses frequency.

In smaller plants slaughtering no more than 50 animals per year, not more than 25% of the carcasses will be sampled.

(v) Sampling in very low volume establishments. (A) Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000 horses, mules or other equines, 20,000 swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

SPECIES	VERY LOW VOLUME REQUIREMENT
Cattle	Annually slaughter < 6,000 head
Horses, Mules, Equines	Annually slaughter < 6,000 head
Sheep, Goats	Annually slaughter < 6,000 head
Swine	Annually slaughter < 20,000 head

Whether the establishment collects samples by sponging or the excision method, the regulation requires that at least one sample be collected each week of the year that the plant slaughters. The sample year begins on June 1 of each year. Starting the first full week of operation after June 1st the establishment must collect samples as required until 13 samples and test results have been accumulated.

There is no regulatory limitation on the maximum number of tests that can be performed weekly to meet the thirteen tests requirement of § 310.25 (a)(2)(iv). It is hypothetically possible for the establishments to collect all thirteen samples in one week and meet regulatory requirement for the production year.

(A) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes

have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

After the initial 13 tests are completed for the production year, further *E. coli* testing is optional for the plant. However, if the establishment determines that there have been changes (remodeling, new equipment, new employees, or new procedures) that affect how well the process works, the establishment must resume weekly testing. Another series of 13 tests can establish the effectiveness of the changed process.

If FSIS determines there have been changes that affect the process, the information must be provided to the company in writing. The establishment would then be required to resume *E. coli* testing to judge the process control.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of E. coli that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm² of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) Criteria for evaluation of test results. (i) An establishment excising samples from carcasses is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

Table 1. --Evaluation of *E. coli* Test Results

Types of Livestock or Poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of samples tested (n)	Maximum number permitted in marginal range (c)
Cattle	Negative*	100 CFU/cm ²	13	3
Swine	10 CFU/cm ²	10,000 CFU/cm ²	13	3

*Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 CFU/cm² carcass surface area.

Cattle and swine slaughter establishments may choose either excision or sponge sampling, however, the performance criteria of “m” (minimum value) and “M” (maximum value) are currently only available for excision samples. Table 1 above shows the “m” and “M” values for

E. coli performance criteria set forth by the Agency for the species that have had a baseline study completed.

Establishments must document or record *E. coli* test results. Each test result must be recorded in terms of colony forming units per square centimeter (cfu/cm²) for excision and sponging results.

As stated earlier, the *E. coli* performance criteria, or “m” and “M”, are not enforceable regulatory standards.

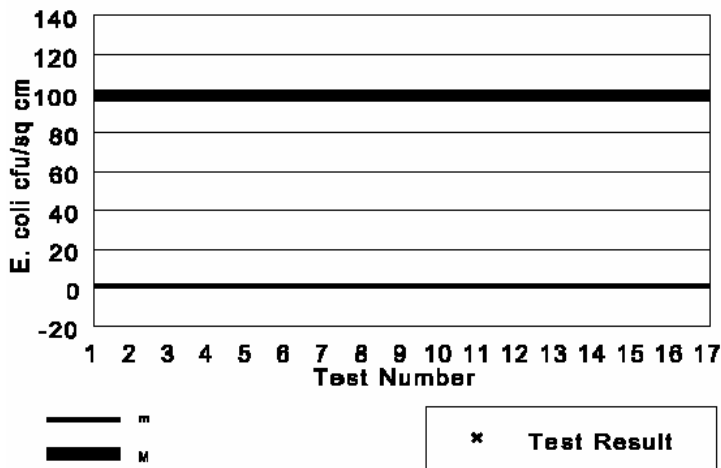
E. coli test result levels are separated into three categories for the purpose of process control verification:

- acceptable, marginal (represented by “m”)
- unacceptable (represented by “M”)

Marginal results (“m”) are those within the worst 20% of overall industry performance in terms of *E. coli* counts. More than three marginal results in the last 13 tests are deemed unacceptable.

Results above “M” are within the worst 2% of overall industry performance. Any single test result exceeding “M” is deemed unacceptable.

The “m” and “M” values are applied to a moving window of 13 test results. Only the last 13 test results are evaluated to determine if the performance criteria are met. Any single test result exceeding “M” is unacceptable. More than three results exceeding the marginal limit in the last 13 tests is also unacceptable. The establishment may elect to use a table type form or a control chart to plot *E. coli* results. Examples of these types of documents follow.



The example on the left is a control chart. The *E. coli* test results are plotted vertically (up and down) by *E. coli* CFU/cm² axis. Each sample result is plotted, starting at Test Number “1” in the horizontal axis and moving to the right. The heavier dark line (at 100 CFU/cm²) represents the upper limit of the marginal range or big “M”. The lighter dark line (at 0 CFU/cm²) represents the lower limit of the marginal range or little “m.”

Test #	Date	Time Collected	Test Result (cfu/cm ²)	Result unacceptable?	Result marginal?	Number marginal or unacceptable in last 13	Pass/Fail ?
1							
2							
3							
4							
5							
6							
7							
8							
9							

This is an example of a table form. The *E. coli* test results are entered from the top down as they are received. The results are evaluated using a moving window of the last thirteen samples

collected. Example: Test 1-13, 2-14, 3-15, 4-16, etc., would be used to determine if the *E. coli* test results meet the m/M criteria. With each new test result recorded the window would move ahead one result so that a set of thirteen sample results is maintained at all times.

In the table to the left, “results unacceptable” is marked “yes” if the upper control limit or big “M” has been exceeded. “Results marginal” is marked “yes” if the result of the *E. coli* sample is above the little “m”, but not above big “M”. The “number of marginal or unacceptable in the last 13” column tracks the number of results in the marginal range within the last thirteen results.

To illustrate the use of *E. Coli* performance criteria, *E. coli* sample results covering a period of seventeen tests have been plotted on each of the two types of formats previously illustrated. The data plotted on both forms is from an establishment that slaughters cattle and samples were taken using the excision method (refer to Figure 1 and Figure 2).

Figure 1

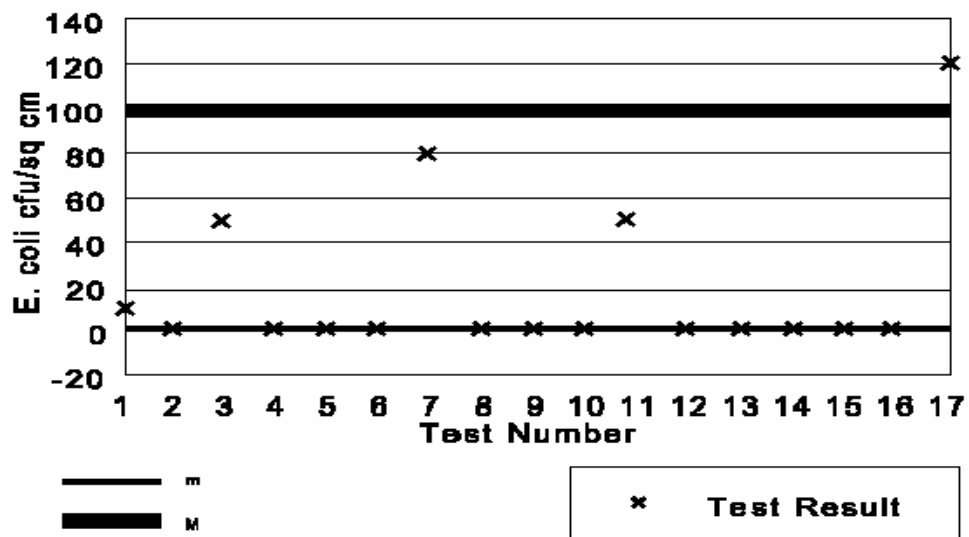


Figure 2

Test #	Date	Time Collected	Test Result (cfu/cm ²)	Result unacceptable?	Result marginal?	Number marginal or unacceptable in last 13	Pass/Fail ?
1	10-07	08:50	10	No	Yes	1	Pass
2	10-07	14:00	Negative	No	No	1	Pass
3	10-08	07:10	50	No	Yes	2	Pass
4	10-08	13:00	Negative	No	No	2	Pass
5	10-09	10:00	Negative	No	No	2	Pass
6	10-09	12:20	Negative	No	No	2	Pass
7	10-10	09:20	80	No	Yes	3	Pass
8	10-10	13:30	Negative	No	No	3	Pass
9	10-11	10:50	Negative	No	No	3	Pass
10	10-11	14:50	Negative	No	No	3	Pass
11	10-14	08:40	50	No	Yes	4	Fail
12	10-14	12:00	Negative	No	No	4	Fail
13	10-15	09:30	Negative	No	No	4	Fail
14	10-15	15:20	Negative	No	No	3	Pass
15	10-16	07:30	Negative	No	No	3	Pass
16	10-16	11:40	Negative	No	No	2	Pass
17	10-17	10:20	120	Yes	No	3	Fail

The following observations can be made from the above data. First, test number eleven documents the fourth test result in the marginal (“m”) range. Therefore, the plant has entered an unacceptable process control status because the fourth marginal result exceeds the limit of no more than three marginal results in the past 13 consecutive tests.

Secondly, tests number twelve and thirteen are negative, therefore, in the acceptable range. However, if you consider the last 13 test results, or the 13-test moving window, there are still more than three results in the marginal range. The company has marked its record to show that it is still in a failing mode because of the four marginal test results. In reality this is *not* an unacceptable result because tests twelve and thirteen are negative, indicating the process is back in control. The failure documented on the table for tests twelve and thirteen cannot be gleaned as evidence of a new problem. The log or documentation of corrective action taken for the first failure at test number eleven should be adequate to verify that the problem was addressed.

Third, at test number fourteen the number of marginal results in the last thirteen tests window is reduced to three. The marginal result for test number one is dropped and replaced by an acceptable result as the 13-test window moves ahead one line; i.e. the moving window is tests 2 through 14.

The fourth observation possibly made from the data annotated on the records is that the test result for test number seventeen exceeds 100 cfu/cm², the “M” value for cattle. Any result over 100 cfu/cm² is automatically unacceptable. It only takes one test in the “M” range to indicate the establishment may not have adequate process control.

(ii) Establishments sponging carcasses shall evaluate E. coli test results using statistical process control techniques.

If the sponging method is selected, the establishment must use statistical process control for evaluating test results.

If the cattle or swine establishment is using the sponge technique, statistical process control must be used, not the “m” and “M” criteria. Charts or tables of the sample results must show at least the most recent 13 test results, if they are available.

(6) Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

Whenever a plant determines that its *E. coli* test results do not meet “m” and “M” performance criteria it must take corrective action to bring the process back into control. In the case of plants using statistical process control, when *E. coli* test results do not meet *E. coli* limits set by the plant, corrective action to regain process control must be taken.

Although the plant is required to make corrections to its process to regain control of contamination, it is **not** required to document those corrective actions.

(7) Failure to test and record. Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a) (1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

When establishments do not evaluate their test results § 318.94(a)(5), they might not be maintaining process controls sufficient to prevent fecal contamination. The District Office will be notified of these instances. District management and will decide what further action should be taken to ensure all applicable provisions of the law are being met.

Poultry

Sec. 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; E. coli testing.

(1) Each official establishment that slaughters poultry shall test for Escherichia coli Biotype I (E. coli). Establishments that slaughter more than one type of poultry and/or poultry and livestock shall test the type of poultry or livestock slaughtered in the greatest number.

FSIS requires all slaughter plants to conduct microbial testing for generic *E. coli*, Biotype 1, a species of *E. coli* that is commonly found in the intestinal tract of food animals. Generic *E. coli* is an excellent indicator of fecal contamination, which is the primary pathway for contamination of meat and poultry with pathogens such as *E. coli* O157:H7, *Salmonella*, and *Campylobacter*. The testing requirement helps plants determine how adequate their process control for fecal contamination is. Using an Agency baseline study FSIS established verification performance criteria that reflect the prevalence of *E. coli* contamination on carcasses. Not all species tested by establishments have performance criteria available. The Agency is currently conducting field surveys to develop additional criteria.

FSIS criteria are **guidelines**, not regulatory standards. FSIS does not use company test results by themselves to take regulatory action. *E. coli* test results are considered in conjunction with other information. The company test results can support more objective assessments and help determine whether plants meet current statutory requirements for sanitation and the prevention of adulteration. The generic *E. coli* test results play an integral role in the successful implementation of HACCP in slaughter plants.

If the establishment only slaughters one species and it is not listed in the *E. coli* regulations, the establishment is not required to test for generic *E. coli*.

The establishment must test the species that it slaughters in greatest number (major species) and that is listed in the regulations. When the major species slaughtered in a multiple-species slaughter establishment is not required by regulation to be tested the establishment must test the species produced in the next greatest number that is listed in the *E. coli* regulations.

The establishment shall: (i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section; (ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and (iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(1) Sampling requirements.

(i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of

the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

§ 310.25 (a)(2)(i) requires that the establishment identify the employee(s) who will collect samples. The plant procedure may simply designate a company position or title to identify the sample collector.

The regulation also requires that carcasses be selected at random. The establishment determines the methods by which randomness is achieved. For example, random number tables, computer-generated random numbers, or drawing cards may be used. In cattle, each half-carcass represents one unit eligible for sampling. Both the “leading” and “trailing” sides of a carcass should have an equal chance of being selected within the designated time frame. In swine, each whole carcass represents one unit eligible for sampling.

The location requirement in the regulation refers to the place within the establishment where the sample is collected. Poultry carcasses must be selected at random after chilling, at the end of the drip line, or at the last readily accessible point prior to packing or cut-up. A whole, untrimmed carcass (with or without the neck) is required for sampling. For example, the company might identify a carcass at the predetermined collection point – a carcass that was selected by the random number method. In establishments conducting hot-boning operations on whole or split carcasses, similar sample selection methods should be followed.

If more than one shift is operating at the plant, the sample can be taken from either shift, provided the sample selection time is based on the appropriate sampling frequency. The carcass for sampling must be selected at random from all the eligible carcasses. The time of sampling is based on the appropriate sampling frequency. Establishments conducting hot-boning operations on whole or split carcasses select carcasses at the end of the slaughter line prior to chilling.

Finally, the written procedure must declare the actions the plant will take to ensure the sample is handled in a manner that protects the integrity of the sample.

(ii) Sample collection. A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys also may be collected by sponging the carcass on the back and thigh.

§ 381.94 (a)(2)(ii) requires that samples be taken from specific locations in the plant. Chicken, turkey, geese, duck, and guinea carcasses must be sampled after the chill tank, at the end of the drip line, or at the last readily accessible point prior to packing or cut-up. Any carcasses to be hot-boned should be sampled after final wash.

There are two sampling methods an establishment may use to collect *E. coli* samples: whole bird rinse sampling and sponging. Establishments slaughtering chickens, ducks, or guineas must use the whole bird rinse method. Establishments slaughtering turkeys or geese may choose either method.

The two methods are described as follows:

1. Sponging involves aseptically swabbing a sterile sponge on a surface of the carcass (10 cm x 5 cm for turkey and geese) and either sending the sponge to the laboratory for analysis or running the analysis in-house. Sponging is a nondestructive method of sampling.
2. Whole bird rinsing involves shaking the whole carcass in a bag with a sterile sampling solution, collecting the rinse fluid, and either sending it to the laboratory for analysis or running the analysis in-house. This is also a nondestructive technique.

For chickens, ducks, and guineas the whole bird is rinsed in a sterile solution and the rinse is sampled. For turkeys and geese, a whole bird rinse may be used, or the company might elect to use the sponging technique. The sponging technique requires that two sites, the back and the thigh, be swabbed. The size of the sponged area is a 5 cm x 10 cm area.

FSIS assumes that meat plants following the "*Guidelines for E. coli Testing for Process Control Verification in Poultry Slaughter Establishments*" will conduct their sampling in a manner that does not jeopardize the integrity of the sample or the reliability of the test results. Because these guidelines are not regulatory requirements, the plant may choose to use a comparable sampling technique and not be out of compliance.

(iii) Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rates: (A) Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation. (B) Turkeys, Ducks, Geese, and Guineas: 1 sample per 3,000 carcasses, but a minimum of one sample during each week of operation.

The required frequency of *E. coli* testing is based on production volume.

(iv) Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with Sec. 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if, (A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and, (B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

In some cases an establishment operating under a validated HACCP plan may substitute an alternative frequency for the frequency in the regulation. This is allowed when the alternative frequency is an integral part of the establishment's verification procedures for its HACCP plan. An example is the case in which *E. coli* testing is built into a critical control point in the HACCP plan. The m/M criteria or the statistical process control upper limit is the critical limit for the CCP.

(v) Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas or a combination of all

types of poultry not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments that slaughter turkeys, ducks, geese, or guineas in the largest number must collect at least one sample during each week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

SPECIES	VERY LOW VOLUME REQUIREMENT
Chickens	Annually slaughter < 440,000 birds
Ducks, Geese, Guineas	Annually slaughter < 60,000 birds
Turkeys	Annually slaughter < 60,000 birds

Whether the establishment collects samples by sponging or the whole bird rinse method, the regulation requires that at least one sample be collected each week of the year that the plant slaughters. The sample year begins on June 1 of each year. Starting the first full week of operation after June 1st the establishment must collect samples as required until 13 samples and test results have been accumulated.

There is no regulatory limitation on the maximum number of tests that can be performed weekly to meet the thirteen tests requirement of § 310.25 (a)(2)(iv). It is hypothetically possible for the establishments to collect all thirteen samples in one week and meet regulatory requirement for the production year.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

After the initial 13 tests are completed for the production year, further *E. coli* testing is optional for the plant. However, if the establishment determines that there have been changes (remodeling, new equipment, new employees, or new procedures) that affect how well the process works, the establishment must resume weekly testing. Another series of 13 tests can establish the effectiveness of the changed process.

If FSIS determines there have been changes that affect the process, the information must be provided to the company in writing. The establishment would then be required to resume E. coli testing to judge the process control.

(3) Analysis of samples. Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three

tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) *Criteria for Evaluation of test results*

(i) An establishment is operating within the criteria when the most recent E. coli test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) as follows:

Table 1. --Evaluation of *E. coli* Test Results

Types of Livestock or Poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of samples tested (n)	Maximum number permitted in marginal range (c)
Chickens	100 CFU/ml	1,000 CFU/ml	13	3
Turkeys	**N/A	**N/A	**N/A	**N/A
Ducks	**N/A	**N/A	**N/A	**N/A
Geese	**N/A	**N/A	**N/A	**N/A
Guineas	**N/A	**N/A	**N/A	**N/A

**Values will be added upon completion of data collection programs.

(ii) For types of poultry appearing in paragraph (a)(5)(1) Table 1 of this section that do not have m/M criteria, establishments shall evaluate *E. coli* test results using statistical process control techniques.

Chicken slaughter establishments must use the whole bird rinse method and are required to use “m” and “M” performance criteria. Baseline studies have not been established for turkeys, geese, ducks, or guineas, so all these slaughter establishments must use statistical process control methods to evaluate test results whether they use the whole bird rinse method or the sponging method of sampling.

Establishments must document or record *E. coli* test results. Each test result must be recorded in terms of colony forming units per milliliter (cfu/ml) for whole bird rinse tests, or colony forming units per square centimeter (cfu/cm²) for sponging results.

E. coli test result levels are separated into three categories for the purpose of process control verification:

- acceptable, marginal (represented by “m”)
- unacceptable (represented by “M”)

Marginal results (“m”) are those within the worst 20% of overall industry performance in terms of *E. coli* counts. More than three marginal results in the last 13 tests are deemed unacceptable.

Results above “M” are within the worst 2% of overall industry performance. Any single test result exceeding “M” is deemed unacceptable.

The “m” and “M” values are applied to a moving window of 13 test results. That means only the last 13 test results are evaluated to determine if the performance criteria are met. Any single test result exceeding “M” is unacceptable. More than three results exceeding the marginal limit in the last 13 tests are also unacceptable.

The establishment may elect to use a table type form or a control chart to plot *E. coli* results. Examples of these types of documents were provided earlier.

To illustrate the use of *E. Coli* performance criteria, *E. coli* sample results covering a period of seventeen tests have been plotted below on examples of each of the two types of formats. The data plotted on the forms is identical and from an establishment that slaughters chicken where samples were taken using the whole bird rinse method (Figures 1 and 2).

Figure 1

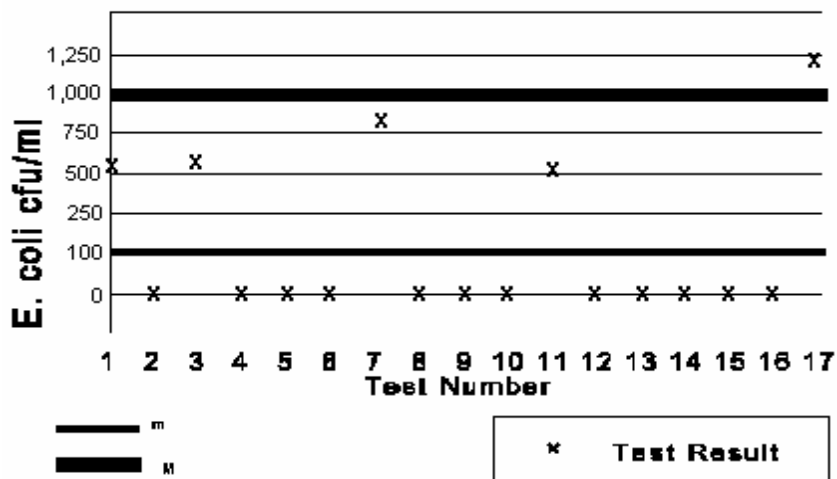


Figure 2

Test #	Date	Time Collected	Test Result (cfu/ml)	Result unacceptable?	Result marginal?	Number marginal or unacceptable in last 13	Pass/Fail ?
1	10-07	08:50	510	No	Yes	1	Pass
2	10-07	14:00	Negative	No	No	1	Pass
3	10-08	07:10	550	No	Yes	2	Pass
4	10-08	13:00	Negative	No	No	2	Pass
5	10-09	10:00	Negative	No	No	2	Pass
6	10-09	12:20	Negative	No	No	2	Pass
7	10-10	09:20	805	No	Yes	3	Pass
8	10-10	13:30	Negative	No	No	3	Pass
9	10-11	10:50	Negative	No	No	3	Pass
10	10-11	14:50	Negative	No	No	3	Pass
11	10-14	08:40	505	No	Yes	4	Fail
12	10-14	12:00	Negative	No	No	4	Fail
13	10-15	09:30	Negative	No	No	4	Fail
14	10-15	15:20	Negative	No	No	3	Pass
15	10-16	07:30	Negative	No	No	3	Pass
16	10-16	11:40	Negative	No	No	2	Pass
17	10-17	10:20	1205	Yes	No	3	Fail

Reviewing the data on the two types of records in figures 1 and 2, the following observations can be made. First, test number eleven documents the fourth test result in the marginal (“m”) range. Therefore, the plant has entered an unacceptable process control status because the fourth marginal result exceeds the limit of no more than three marginal results in the past 13 consecutive tests.

Secondly, tests number twelve and thirteen are negative, therefore, in the acceptable range. However, if you consider the last 13 test results, or the 13-test moving window, there are still more than three results in the marginal range. The company has marked its record to show that it is still in a failing mode because of the four marginal test results. In reality this is *not* an unacceptable result because tests twelve and thirteen are negative, indicating the process is back in control. The failure documented on the table for tests twelve and thirteen cannot be gleaned as evidence of a new problem. The log or documentation of corrective action taken for the first failure at test number eleven should be adequate to verify that the problem was addressed.

Third, at test number fourteen the number of marginal results in the last thirteen tests window is reduced to three. The marginal result for test number one is dropped and replaced by an acceptable result as the 13-test window moves ahead one test; i.e. the moving window is tests 2 through 14.

The fourth observation possibly made from the data annotated on the records is that the test result for test number seventeen exceeds 1,000 CFU/ml, the “M” value for cattle. Any result over 1,000 CFU/ml is automatically unacceptable. It only takes one test in the “M” range to indicate the establishment may not have adequate process control.

(6) Failure to meet criteria. Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

Whenever a plant determines that its *E. coli* test results do not meet “m” and “M” performance criteria it must take corrective action to bring the process back into control. In the case of plants using statistical process control, when *E. coli* test results do not meet *E. coli* limits set by the plant, corrective action to regain process control must be taken.

Although the plant is required to make corrections to its process to regain control of contamination, it is **not** required to document those corrective actions.

(7) Failure to test and record. Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a) (1)-(4) of this section have not been complied with and written notice of same has been provided to the establishment.

When establishments do not evaluate their test results § 318.94(a)(5), they might not be maintaining process controls sufficient to prevent fecal contamination. The District Office will be notified of these instances and will take further action as appropriate to ensure all applicable provisions of the law are being met.

Slaughter Food Safety Standard

FSIS has food safety standards that require establishments to have controls in place to prevent the contamination of carcasses with certain contaminants, such as fecal material. This section provides an overview for how these food safety standards are verified for livestock and poultry.

Enforcing Food Safety Standard for Livestock Postmortem

References: FSIS Directive 6420.2, Regulations: 9 CFR 310.17(a), 310.18, and part 417.

FSIS enforces food safety standards for fecal, ingesta, and milk contamination on livestock carcasses and on head meat, cheek meat, and weasand meat from beef through postmortem inspection activities at establishments that slaughter livestock. The establishment must meet the food safety standard for visible fecal, milk, and ingesta contamination on livestock carcasses at or after the **postmortem rail inspection station**, regardless of the location of the CCP. The CCP for pathogen contamination or visible contaminants may be at other locations as supported by the hazard analysis.

- For example, the establishment may locate the critical control point after the postmortem rail inspection station.
- In other cases, the establishment may have a CCP prior to the postmortem rail inspection station.

Note: Regardless of the location of the CCP, FSIS off-line inspectors will verify compliance with the zero tolerance standard at the rail inspection station.

When the on-line inspectors at the rail station find feces, ingesta, or milk on livestock carcasses, the establishment reexamines and reconditions the entire carcass (trimming all contamination). **On-line** inspectors are to **stop the slaughter line** for carcass reexamination and reconditioned by the establishment **unless**:

- The establishment has elected to provide a rail-out loop to rail contaminated carcasses off-line for reexamination, trimming, and positioning back on the line for final inspection, **and**
- The IIC has not determined that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses.

Additionally, on-line inspection program personnel are to notify the IIC or, if unavailable, other off-line inspection program personnel when they believe that:

- An establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses, or
- An establishment's slaughter or dressing processes are not under control (for example, when repeated presentation of carcasses contaminated with fecal

material, ingesta, or milk for postmortem inspection at the rail inspection station indicates failure to control dressing processes).

Establishments that slaughter beef must also meet the food safety standard for no visible fecal, milk, or ingesta contamination on head meat, cheek meat, and weasand meat at the end of the harvesting process after all of the establishment controls and interventions have been implemented. This verification may take place at the time of packaging or when product is placed in a container for storage.

When verifying the food safety standard in beef slaughter establishments, inspection personnel should verify that the establishment is meeting all of the requirements, including no fecal, milk, or ingesta contamination on beef carcasses, and the head meat, cheek meat, and weasand meat from beef.

In beef slaughter establishments, if the on-line head inspector finds fecal, milk, or ingesta contamination, the contamination must be removed by the establishment before the head can be passed. Also, if the on-line inspector finds fecal, milk, or ingesta contamination on weasand meat during the harvesting step, the establishment must remove the contamination before the weasand meat can be passed. If fecal, milk, or ingesta contamination is repeatedly found, on-line inspection personnel are to notify the off-line inspection personnel. The off-line inspection personnel will perform verification activities to determine if the establishment's process and sanitary dressing procedures are controlling fecal, milk, and ingesta contamination during the head meat or weasand meat production process.

IICs and other off-line inspection program personnel will verify the adequacy of establishment procedures to ensure compliance with the food safety standard for fecal, ingesta, or milk contamination, **when notified by on-line inspection program personnel of an apparent problem or when scheduled by PBIS.**

Follow these steps when verifying establishment procedures for livestock carcasses:

1. **Off-line** inspection program personnel are to randomly select carcass units at the **postmortem rail inspection station** for examination on-line, at or after the postmortem rail inspection station, **regardless of the location of the CCP.** (This inspection should occur before the final wash. In situations where this is difficult, such as those related to worker safety, the IIC should develop appropriate procedures with plant management in order for this inspection to be properly conducted).
2. Based on the expected slaughter volume for that day (number of animals), determine the number of carcass units to be examined, using the following table. If carcasses are split, each half carcass is ½ of a carcass unit. (Select two times as many half-carcasses.)

Slaughter Volume (# of animals per day)	# of Carcass Units (Unit = whole carcass)
100 or less	2
101 to 250	4
251 to 500	7
More than 500	11

Note: It is not necessary to examine all of these units at the same time.

3. Examine the selected carcass units using the same technique that inspection program personnel use at the postmortem rail inspection station.

Follow these steps in beef slaughter establishments when verifying establishment procedures for beef head meat, cheek meat, and weasand meat:

1. Review the HACCP plan.
2. Examine the same amount of product as the establishment has listed in the HACCP plan for monitoring procedures. (Note: If the establishment does not have documents supporting the monitoring procedures and frequency, there is noncompliance with 9 CFR 417.5(a)(2).)
3. Select product after all of the establishment controls and interventions have been applied. Verification may occur at the time of packaging or when product is placed in a container for storage.

03J01

Off-line inspection program personnel who find feces, ingesta, or milk on carcasses in livestock slaughter establishments, and the head meat, cheek meat, and weasand meat of beef in beef slaughter establishments as part of an **03J01** procedure will:

- a. Notify establishment of the contamination
- b. Verify that the corrective action requirements of 9 CFR 417.3 are met.
- b. Issue an NR using the “monitoring” trend indicator.
- c. Perform procedure 03J02. Focus on the specific production thereafter, in which one or more contaminated carcasses or carcass parts were found.

03J02

Off-line inspection program personnel who find feces, ingesta, or milk on carcasses in livestock slaughter establishments, and the head meat, cheek meat, and weasand meat of beef in beef slaughter establishments as part of an **03J02** procedure will:

- a. Notify establishment of the contamination finding.
- b. Complete the 03J02 procedure for that product, including verification of the corrective action requirement.
- c. Document all noncompliances on an NR using the most appropriate trend indicator. If the only noncompliance was the fecal material, milk, or ingesta contamination, the monitoring trend indicator would be documented.

Enforcing the Food Safety Standard for Poultry Postmortem

References: FSIS Directive 6420.2, 381.65(e), and part 417.

FSIS enforces a food safety standard for visible fecal material on poultry carcasses and poultry carcass parts through postmortem inspection and reinspection activities at poultry slaughter establishments. This food safety standard also is reflected in the regulations. FSIS views preventing carcasses with visible fecal contamination from entering the chilling tank as critical to preventing the cross-contamination of other carcasses.

In each establishment slaughtering poultry, in conjunction with other postmortem inspection and reinspection activities, **off-line** CSI inspection personnel are to perform fecal contamination checks.

These checks are performed at either the same location as pre-chill testing in establishments inspected under the finished products standards (FPS), or the inspection station where Acceptable Quality Level (AQL) testing is conducted in a plant under traditional inspection, regardless of the location of the plant's CCP. To perform a fecal contamination check, inspectors are to:

- Select 10 carcasses randomly (using an established FSIS method), and
- Examine the selected carcasses off line using the the following inspection procedure:
 - For the outside back – While holding the carcass, with the back of the carcass toward the observer, start at the hock area and observe the hocks, back part of the legs, tail area, back of the carcass and top side of the wings.
 - For the outside front – Turn the carcass and observe the bottom side of the wings, breast, and front part of the legs.
 - For the inside – Observe the inside surfaces of the carcass and the abdominal flaps and fat.
 - For the neck flap area – Observe the neck flap and the thoracic inlet area.

At least two fecal checks will be performed for each line on each shift.

Use the procedure code 03J01 or 03J02. If inspection program personnel are only conducting the 10-bird check to verify that the establishment's process is producing carcasses free of visible fecal material, they are performing procedure 03J01. If inspection program personnel are verifying other HACCP regulatory requirements in conjunction with the 10-bird check, inspection program personnel can be performing the 03J01 or 03J02 procedure.

If no visible fecal material is found on a check, the Procedure Schedule will be marked as performed to indicate compliance.

If fecal material is found, the CSI will:

- Notify the establishment of the contamination.
- Verify that the corrective action requirements of 9 CFR 417.3 are met.
- Complete a Noncompliance Record (NR) and mark the monitoring trend indicator.
- If the noncompliance was found when performing an 03J01 procedure, perform 03J02 to ensure the adequacy of the HACCP system for the specific lot of product.

If ingesta is observed during the fecal contamination check, the establishment should be notified of this finding. The ingesta should be removed from the bird. There would be no noncompliance for this finding.

Workshop: Food Safety Standard in Slaughter

Refer to the module and to FSIS Directive 6420.2 to complete the following questions.

LIVESTOCK SLAUGHTER:

1. What contaminants are covered by the food safety standard in livestock slaughter?

2. What beef parts must be free of these contaminants?

3. At what location will FSIS verify the food safety standards for livestock carcasses?

4. Where will FSIS verify the food safety standard for head meat, cheek meat, and weasand meat for beef in slaughter operations?

5. If a livestock slaughter establishment has a CCP for visible contaminants for livestock carcasses at the final washer, where would FSIS verify compliance with the food safety standard?

6. You are an on-line GS-5 inspector working the rail inspection station in a large beef slaughter establishment. You notice a fecal smear on the hindquarter of a carcass. The establishment has a rail-out procedure.
 - a. What action would you take?

 - b. What action would you take if the establishment had no rail-out procedure?

 - c. What is expected of the establishment?

 - d. Would a Noncompliance Record (NR) be completed by the on-line inspector?
By the off-line inspector?

- e. If you had repeated instances of contaminated carcasses during your time at the rail inspection station, what would you do?
-
- 5. How do you determine the amount of product to inspect when performing the off-line procedure in a beef slaughter establishment to verify that the meat from heads, cheeks, and weasands are not contaminated with fecal material, ingesta, or milk?

POULTRY SLAUGHTER:

- 6. What contaminants are covered by the food safety standard in poultry slaughter?

- 7. At what location will FSIS verify the food safety standard for poultry slaughter?