5000.1 Walk Through

OBJECTIVES

To demonstrate mastery of Directive 5000.1, the trainee will:

1. Describe the inspection verification procedures performed to verify establishment compliance with the Sanitation Performance Standards.

2. Describe the inspection verification procedures performed to verify establishment compliance with Sanitation SOP regulations.

3. Describe the inspection verification procedures performed to verify establishment compliance with HACCP regulations.

4. Identify the procedure performed to verify compliance with generic *E*. *coli* requirements.

5. Describe the responsibility for inspection personnel to verify compliance with the *Salmonella* and *Campylobacter* performance standards.

Sanitation Performance Standards
9 CFR 416.1 – 416.6

SPS REGULATIONS

§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.

The regulation requires establishments to operate in a 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 and enforcement of such standards.

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 Sanitation Performance Standards regulations significantly reduce the number of sanitation regulations and consolidate the sanitation requirements for both meat and poultry into part 416. This consolidation not only simplifies the sanitation regulation for the user, but also establishes uniform sanitation performance standards that would provide flexibility to establishments while maintaining the rigorous sanitation standards necessary to ensure food safety. The establishment's responsibility for maintaining sanitary conditions and preventing the contamination and adulteration of product remains unchanged.

For the HACCP and Sanitation SOP requirements to be successful, FSIS believes that it must reduce its reliance on detailed, command-and-control regulations. Command-and-control regulations prescribe step-by-step procedures establishments must use toward the goal of safe meat and poultry products. Such regulations can be incompatible with HACCP and Sanitation SOP requirements to the extent that they deprive establishments of the flexibility to innovate and deter them from assuming their full share of responsibility for food safety.

Insanitary conditions are defined as "a state, condition or occurrence in which any edible meat or poultry products may become contaminated or adulterated through exposure, slaughter, processing, handling, and packaging or by any other means."

§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

(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.

FSIS does not require establishments to be innovative in regard to facility construction or layout. The performance standards for construction do, however, 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. The walls, floors, and ceilings should be made of durable materials impervious to moisture.

Example of failure to meet performance standards:
- flaking or chipping paint on the walls or ceilings of edible product areas
- holes in glass board 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

> ***(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

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

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 postmortem inspection stations and in poultry establishments at the postmortem 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

(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, establishments 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.

(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 establishment

(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

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

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

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

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

(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

(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

(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

> ***(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 scalder.

Example of failure to meet performance standard:

- reusing brine solution without filtering or treating

> ***(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's 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

> ***(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

> ***(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.

(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

(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 establishments 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

(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

(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 trash receptacle in the dressing room with liquids draining onto the floor.

§ 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

(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 Ex: 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

(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

§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 (Sanitation SOP) (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

(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

(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 establishment 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

(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

§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.

The performance standards allow establishments to develop alternative or innovative means to ensure that employee hygiene practices do not result in product adulteration or contamination.

Example of failure to meet performance standard:

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

(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.

The sanitation performance standards require establishments to develop acceptable policies for prescribing when garments must be changed during the day to prevent contamination or adulteration of product.

Example of failure to meet performance standard:

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

(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 forearm

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

It is appropriate to take regulatory control action, which may include tagging affected areas, when an official establishment operates in a manner that leads to insanitary conditions or product adulteration. Regulatory control actions should remain in effect until the establishment has taken corrective action and has proposed effective preventive measures.

Sanitation Standard Operating Procedures
9 CFR 416.11— 416.17

SANITATION SOP REGULATIONS

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

The establishment is responsible for developing, implementing, and maintaining written sanitation standard operating procedures (Sanitation SOPs) that meet the requirements of part 416. FSIS believes that effective establishment sanitation is essential for food safety and for successful implementation of HACCP. Insanitary facilities or equipment, improper personal hygiene, and similar insanitary practices create an environment conducive to contamination of products. Direct and substantial links exist between inadequate sanitation and the contamination of meat and poultry products by pathogenic bacteria. Sanitation SOP clearly defines the establishment's responsibility to consistently follow effective sanitation procedures that will substantially minimize the risk of product contamination and adulteration.

§416.12 Development of Sanitation SOP's

> ***(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).***

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

IPP need to be able to read and understand the Sanitation SOP. This means that Sanitation SOPs written in a foreign language may need to be translated into English.

> ***(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.***

The Sanitation SOP 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 establishment profile. Written procedures must be signed upon initiation and whenever they are modified. For example, the establishment manager might sign the Sanitation SOP .

> ***(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.***

The written procedures must identify pre-operational sanitation procedures. At a minimum, Sanitation SOPs must address the cleaning of food contact surfaces of facilities, equipment, and utensils. The regulation does not specify how much detail Sanitation SOPs must contain. For example, the Sanitation SOP may describe the pre-operational procedures as follows. "The food contact surfaces in the facility will be cleaned with hot soapy water. Equipment that can be disassembled will be taken apart prior to cleaning. After cleaning, a sanitizer will be applied to product contact surfaces followed by a potable water rinse." When followed the procedures should be sufficient to ensure prevention of direct product contamination or adulteration.

> ***(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 Sanitation SOP are conducted
- identification of the employee(s) responsible for the implementation and maintenance of the Sanitation SOPs (does not have to be the people performing the activities but the person responsible).

Establishments 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.

For example, the Sanitation SOP might specify that overheads are wiped every half-hour of operation to prevent product contamination or adulteration. The QA technician might be the person responsible for monitoring this procedure, but the QA manager is responsible for the overall implementation of Sanitation SOP.

§416.13 Implementation of SOP's

> ***(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.***

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.

> ***(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's 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 a Sanitation SOP that includes a procedure for using a footbath prior to entering the ready-to-eat area.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

Establishments must monitor the Sanitation SOP 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.

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

Establishments should routinely evaluate the content and effectiveness of the Sanitation SOP 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.

§***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 SOP's 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 Sanitation SOP has failed to prevent direct product contamination or adulteration of product. Sanitation SOP failure can be the result of either not implementing or not maintaining the Sanitation SOP, 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 Sanitation SOP. The Sanitation SOP 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 Sanitation SOP 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.

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

Establishments must initiate corrective actions when either the establishment 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:

- dispose of contaminated or adulterated product appropriately
- restore sanitary conditions
- 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 Sanitation SOP in every case.

The establishment is not required to document specifics in the Sanitation SOP 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.

§416.16 Recordkeeping requirements

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

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

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.

(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.

(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 Sanitation SOP records generated must be retained for six months. For oversight and enforcement purposes FSIS requires access to all establishment sanitation records. The establishment 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.

§416.17 Agency verification
FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

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

(c)Direct observation of the implementation of the Sanitation SOP's 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.

FSIS verifies that Sanitation SOPs are developed, implemented, maintained, and that they are effective. FSIS also verifies that the establishment maintains daily records.

Hazard Analysis and Critical Control Point (HACCP) System
9 CFR 417.1 — 417.8

HACCP REGULATIONS

§417.1 Definitions.
For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. 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 limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plans in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

Above are the regulatory definitions for these specific terms when used throughout regulation 417.

§417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis.

(1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the

particular type of product being processed, in the absence of those controls.

With the implementation of the Pathogen Reduction/HACCP (PR/HACCP) regulation, each federally inspected establishment either conducted or had conducted for it a hazard analysis. At a minimum a hazard analysis must be developed for each processing category in the establishment. The purpose of the hazard analysis is to identify biological, chemical, and physical hazards reasonably likely to occur in the process and to identify preventive measures to control those hazards. Regulation 417.1 defines preventive measures as physical, chemical, or other means that can be used to control an identified food safety hazard. FSIS is unaware of any meat or poultry production process that can be deemed categorically to pose no food safety hazards. All three types of hazards (biological, chemical, or physical) must be considered at all steps in the process, e.g. receiving, storage, and grinding.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

The flow chart is often a simple schematic picture of the process used to produce the product for an example of process flow charts refer to “Regulated Industries” module, p 30-42). The establishment should verify the process flow chart by walking through the establishment and comparing the steps in the process to the flow chart. Examples of steps in a slaughter process might include antemortem, stunning, head removal, evisceration, carcass splitting, final trim, and cooling. Steps in a processing establishment might include receiving, formulation, cooking, and cooling. Examples of steps that have been overlooked by establishments are returned product and rework.

The establishment should consider whether “at risk” populations, such as the elderly or children, are intended consumers of the product.

(3) Food safety hazards might be expected to arise from the following:
(i) Natural toxins;
(ii) Microbiological contamination;
(iii) Chemical contamination;
(iv) Pesticides;
(v) Drug residues;
(vi) Zoonotic diseases;
(vii) Decomposition;
(viii) Parasites;
(ix) Unapproved use of direct or indirect food or color additives; and
(x) Physical hazards

FSIS believes an establishment should consider the ten areas above when performing a hazard analysis.

The establishment should consider all potential food safety hazards at all steps in the process. If an establishment determines that a food safety hazard is reasonably likely to occur, they must address it with a critical control point somewhere in the process. During the initial stages of the hazard analysis, the establishment might list many different potential hazards. During assessment, however, they might find that many hazards are not

reasonably likely to occur. For example, an establishment might determine that product contamination is a potential hazard at the receiving step. After assessing the situation, the establishment determines that this is not a food safety hazard likely to occur in the process because they have a procedure in their Sanitation SOP that addresses the situation.

(b) The HACCP plan.

(1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:
(i) Slaughter—all species.
(ii) Raw product—ground.
(iii) Raw product—not ground.
(iv) Thermally processed—commercially sterile.
(v) Not heat treated—shelf stable.
(vi) Heat treated—shelf stable.
(vii) Fully cooked—not shelf stable.
(viii) Heat treated but not fully cooked—not shelf stable.
(ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

Every product must be produced under a HACCP plan when a hazard analysis reveals a food safety hazard likely to occur within the process. The establishment may develop one HACCP plan to control hazards for all products in the same processing category. For example, if an establishment produces different fully cooked products such as franks and cooked beef, they could be included in the same HACCP plan.

An establishment may develop one HACCP plan for a product that passes through multiple process categories. As an example, if an establishment slaughters and produces cut-up chicken, the product passes through both “slaughter” and “raw intact” (raw not ground) processes. The establishment may use two HACCP plans or it may address the entire slaughter and cut-up process under one HACCP plan. If an establishment slaughters chickens, produces cut-up chicken, and produces mechanically separated chicken, it would need a minimum of two HACCP plans.

The processing category is determined by the product label when it leaves the establishment. For example, certain products such as country hams and lard may be in different processing categories depending on the establishment process and l

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance

with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

Establishments producing thermally processed commercially sterile products are not required to address microbiological hazards if the product is produced in accordance with the canning regulations. However, the hazard analysis must still consider physical and chemical hazards at every step in the process because the current canning regulations exclusively address microbial hazards. For example, if the establishment determines foreign material is a food safety hazard likely to occur in the process, there must be a CCP somewhere in the process to control foreign material.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:
(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

Each establishment must provide a list of the food safety hazards identified while conducting the hazard analysis. Some commonly identified hazards are pathogens such as *Listeria*, *E. coli* O157:H7, and foreign material, such as metal.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:
(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and
(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

If a food safety hazard is identified in the hazard analysis, and is determined to be reasonably likely to occur, there must be a critical control point somewhere in the process to address it. As an example, if a biological hazard is identified at the receiving step in an establishment that produces fully cooked product, the CCP to control the hazard might be lethality at the cooking.

(***3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product are met;***

Regulation 417.1 defines a critical limit as the minimum or maximum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard. (Note: critical limits may also be expressed as a range if the decision making documents support that limit, such as in the case of the use of lactic acid as an antimicrobial intervention. If the establishment utilizes FSIS Directive 7120.1 to support the critical limit for lactic acid, the range would be 2% to 5% lactic acid in solution.) Critical limits are expressed as numbers or specific parameters and need to be measurable. Establishments must have documents supporting the selection of CCPs and critical limits. The documents should be scientific, regulatory, or technical, and show that when the critical limits are achieved, the product produced will be safe.

For example, an establishment that slaughters 4-pound birds put a CCP in the cooler 4 hours post-evisceration. The critical limit is that the average internal temperature of three carcasses must be 40° F or less. While performing a monitoring check the establishment records temperatures of 39° F, 39 ° F, and 42 ° F. The average for the three is 40 ° F. The average temperature critical limit does not meet the regulatory requirement of 417.1 because each carcass must meet the 40° F critical limit.

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

The monitoring procedures and frequencies in the HACCP plan must describe a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification. Reading the monitoring procedures and frequencies in the HACCP plan should allow visualization of what is taking place during the monitoring of a CCP. The establishment should use monitoring records to track process control. Continuous monitoring is always preferred when feasible. For example, an establishment, which uses a smokehouse to cook hams, may use a continuous time and temperature recording device to chart the time and temperature of the product in the ovens as it is cooked. When continuous monitoring is not possible, discontinuous monitoring must be performed often enough to show that the process is under control. An example of a continuous operation with discontinuous monitoring is an establishment that cooks chicken patties on a conveyor and measures the internal temperature of 10 patties every 30 minutes.

(5) Include all corrective actions that have been developed in accordance with §417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

The HACCP plan must contain the corrective actions taken when a deviation from a critical limit occurs. An establishment may simply state “the regulatory requirements of 417.3(a) will be met when a deviation occurs” to satisfy this regulatory requirement. A prudent establishment would consider the different causes of a deviation and work through scenarios to address them. This additional information is not required to be part of the official HACCP plan.

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

The HACCP plan shall list the records used to document monitoring critical control points. Records must contain actual values and observations obtained during monitoring. An example of such a HACCP record is the monitoring log. Actual values and observations must be entered on the monitoring log at the time the event occurs.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with §417.4 of this part.

Verification procedures and frequencies must be present in the HACCP plan. The verification procedures should be very clear. Anyone reading the verification procedures in

the HACCP plan should be able to visualize what takes place when the verification procedure is performed.

(d) Signing and dating the HACCP plan.

(1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under §417.4 (a) (3) of this part.

The HACCP plan must be signed and dated when the establishment develops and implements the HACCP plan, when it is modified, and to indicate the annual reassessment has been performed.

(e) Pursuant to 21 U.S.C 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

If an establishment does not develop and implement a HACCP plan as required by Part 417 of the regulations, any product produced without a HACCP plan may be determined to be adulterated.

§417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

When there has been a deviation from a critical limit, the establishment must implement all four parts of corrective actions. They must:

- identify and eliminate the cause of the deviation
- ensure the CCP is under control after the corrective action is taken
- prevent recurrence of the deviation
- ensure that no product injurious to health or otherwise adulterated enters commerce

Affected product is generally considered to be that produced since the last acceptable monitoring result recorded by the establishment.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

If a deviation from a critical limit occurs that is not covered by a specified corrective action or if an unforeseen hazard is identified, the establishment must implement the following corrective actions:

- segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
- perform a review to determine the acceptability of the affected product for distribution;
- take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation enters commerce;
- perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with §417.4 (a)(2)(iii) and the recordkeeping requirements of §417.5 of this part.

Whatever an establishment does to fulfill all four parts of corrective action should be documented in the HACCP records. The records must be available for FSIS review.

§417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

It is the establishment's responsibility to develop a HACCP plan and to ensure its adequacy. Establishments may use independent consultants, process authorities, or employees trained as per 417.7 to develop and validate the plan. Validation means scientifically demonstrating that a HACCP system, as designed, effectively controls the food safety hazards identified in

the hazard analysis. While no particular validation method must be used, the data assembled to support a HACCP plan are usually of two types:

- theoretical principles from process authorities, scientific data etc.
- in-plant observations, measurements, test results, or other information demonstrating that control measures achieve the intended food safety objective

Validation must demonstrate that the HACCP plan is scientifically sound. Establishments must support the critical limits selected. They may use Appendices A or B ("Compliance guidelines for cooling heat-treated meat and poultry products"), modeling programs, or other scientific support for their critical limits. For example, a slaughter establishment with steam pasteurization has a CCP with a critical limit at 180° F for 10 seconds at the carcass surface. The establishment supported this critical limit with a scientific journal article that indicated steam applied at 180° F for 10 seconds to the carcass surface reduces pathogens by 1 log. The establishment also had records demonstrating their ability to meet the parameters of steam at 180° F for 10 seconds on the carcass surface.

FSIS believes validated data for any HACCP plan must also include some practical data or information reflecting initial validation in implementing the HACCP plan. Validation must demonstrate that the monitoring can be performed by the establishment as per the HACCP plan and when the monitoring is performed the establishment can meet the critical control points and critical limits.

> ***(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:***
> ***(i) The calibration of process-monitoring instruments;***
> ***(ii) Direct observations of monitoring activities and corrective actions; and***
> ***(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.***

Verification procedures must ensure the HACCP plan functions as intended. All plans must, at a minimum, include three types of ongoing verification: calibration of process monitoring equipment, observation of monitoring activities and corrective actions, and records review, except for cases where one or more of the minimum ongoing verification activities are not necessary. Such scenarios may be when there are no process monitoring devices used (e.g. visual inspection at zero tolerance CCP), or in a one person operation where direct observation can not be performed. Validation and reassessment are two additional types of verification.

For example, a verification procedure for equipment calibration might look like this: "A hand-held dial thermometer is placed in slush ice water and calibrated to within ±1° of 32° F." The establishment should have supporting data that this procedure effectively calibrates dial thermometers.

> ***(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems;***

or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

HACCP plans are dynamic and evolving. The establishment should reassess its HACCP plan whenever any significant change in the processing environment occurs. Changes in product formulation, addition or removal of equipment, an increase in the amount of production, and the addition of new customers are just a few examples of instances when an establishment needs to reassess. The HACCP plan must be immediately modified if the reassessment reveals that the plan is no longer adequate. The individual performing the reassessment must be trained as per 417.7. FSIS believes that reassessment encompasses the different types of evaluation, from re-analyzing the verification procedures for an updated CCP to repeating the validation procedures when necessary.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Even if an establishment previously did not have a HACCP plan, changes such as product formulation, new slaughter or processing methods, or the use of new raw materials should cause the establishment to reassess its hazard analysis. If any changes result in identification of a food safety hazard, the establishment should then develop a HACCP Plan.

For example, an establishment received pork pellets cooked by another establishment. The producing establishment certified that lethality adequate to control the pathogen of concern was applied, that the product was tested, and that sample results were negative. The receiving establishment addressed employee hygiene and product handling in the Sanitation SOP. The receiving establishment determined there were no food safety hazards likely to occur in the process of popping and packaging the pellets, so they did not have a HACCP plan for the process. At a later time the establishment decided to start popping raw pork skins. When the incoming materials changed, the establishment reassessed the hazard analysis to determine if a food safety hazard was likely to occur.

§417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;

The hazard analysis and all supporting documents must be in the establishment file. Supporting documentation varies from establishment to establishment because the decision making process differs. Examples of supporting data establishments might have for the hazard analysis are historical data and scientific journal articles.

(2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

The establishment must have supporting data for CCPs and critical limits. Supporting data may include FSIS regulations, FSIS Guidelines, the FDA food code, journal articles from reputable publications, etc. Establishments may use universities, extension services, and industry associations for assistance in gathering supporting documentation. One example of supporting data for a critical limit is using Appendix B to support a stabilization CCP.

The establishment must also have supporting documentation for their monitoring procedures. The establishment must be able to support that the monitoring frequency is adequate to demonstrate process control.

This regulation also requires the establishment to have supporting documentation for verification procedures and frequencies listed in the HACCP plan. The establishment must have documents that explain how the verification procedures were determined and what information was used to determine the frequencies for these procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

This regulation lists specific information that the establishment must document on their records when HACCP activities are performed. When monitoring each CCP and its critical limits, actual values must be recorded, e.g. times, temperatures, or other quantifiable values. The establishment must also document all corrective actions, calibration of process-monitoring instruments, and verification procedures and frequencies.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and includes the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

The establishment shall make all entries on the records at the time the specific event occurs and sign or initial the entry. Each time a monitoring procedure is performed, the establishment must record the time, product identity, actual value and initials of the person performing the monitoring. Example: date: 9/9/01, time: 8:02 a.m., product identity: Lot A6 - chicken carcasses, actual value: 39^{o}F, initials: MPT. When the establishment performs a verification procedure, the records must include the verification procedure performed and the results of that procedure, as well as the date, time and initials or signature of the person performing verification. For example, when the establishment performs a direct observation, the record entry might show “direct observation performed, monitoring performed as per the HACCP plan”.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

Before shipping product, an establishment must review all records associated with the production of that product. As part of the pre-shipment review the establishment needs to insure that all critical limits have been met and all corrective actions are taken, if necessary.

There are many ways an establishment can perform pre-shipment review. They may perform it on a time basis, on specific production, or continuously as the product goes through the process. For example, an establishment might conduct pre-shipment review every hour and conduct records review verification daily. If the pre-shipment review is performed continuously, it is possible that the only documentation on the records at the time of review will be monitoring entries. If monitoring records are the only ones available, the review still satisfies the regulatory requirement. In addition, the frequency at which the verification procedures are performed may not correspond to the frequency at which the pre-shipment review is performed. The verification procedures should be reviewed, if available, at the time the pre-shipment review is performed.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

The establishment may maintain records on computer provided they have controls to protect record integrity. Even though the establishment is keeping records on the computer, they must be readily accessible to Agency personnel.

(e) Record retention.

(1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

It is the establishment's responsibility to maintain the records for the required amount of time per the regulation. If the establishment chooses to store the records off-site after 6 months, then the establishment must be able to provide them, upon request, within 24 hours. If the records are kept on-site after the first 6 months, they must be available upon request. Both

the hazard analysis and HACCP plan should be available upon request. If an FSIS inspector working the second shift at an establishment, requests a copy of the HACCP plan, the establishment should be able to provide it to the inspector at that time.

All of the records specified by 417.5 must be available to FSIS upon request. Along with the records, a prudent establishment would keep the HACCP plan corresponding to those records if changes at some point have been made to the HACCP plan.

§417.6 Inadequate HACCP Systems.
A HACCP system may be found to be inadequate if:

> ***(a) The HACCP plan in operation does not meet the requirements set forth in this part;***
>
> ***(b) Establishment personnel are not performing tasks specified in the HACCP plan;***
>
> ***(c) The establishment fails to take corrective actions, as required by §417.3 of this part;***
>
> ***(d) HACCP records are not being maintained as required in §417.5 of this part; or***
> ***(e) Adulterated product is produced or shipped.***

If establishment personnel do not perform procedures as specified in the HACCP plan, if corrective actions are not taken, or if HACCP records are not maintained, the HACCP system may be inadequate. For example, an establishment had several deviations from a critical limit. When implementing corrective actions, they failed to address 417.3(a)(3), "measures to prevent recurrence are established." If the establishment repeatedly did not meet that regulatory requirement, the system could be deemed inadequate as per 417.6(c).

§417.7 Training.

> ***(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:***
>
> > ***(1) Development of the HACCP plan, in accordance with §417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and***
> >
> > ***(2) Reassessment and modification of the HACCP plan, in accordance with §417.3 of this part.***
>
> ***(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.***

Training is essential to the success of HACCP. The establishment must use trained individuals to develop, conduct reassessments of, and make modifications to HACCP plans. It is not required that the individual be an employee of the establishment or be on-site for the establishment to operate.

§417.8 Agency verification.
FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;
(b) Reviewing the CCP records;
(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
(d) Reviewing the critical limits;
(e) Reviewing other records pertaining to the HACCP plan or system;
(f) Direct observation or measurement at a CCP;
(g) Sample collection and analysis to determine the product meets all safety standards; and
(h) On-site observations and record review.

FSIS uses various steps to verify that HACCP plans are adequate. These are further described in FSIS Directives 5000.1 and 5400.5.

Process Control Verification
E. coli Testing

REGULATIONS – LIVESTOCK

§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 establishments to conduct microbial testing for generic *E. coli*, Biotype 1, an *E. coli* specie 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 establishments 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 establishments 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 establishments.

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) Continued

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.
(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 establishment 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 establishment, 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 establishment 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 establishments 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 establishment 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 §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 per year 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 establishments 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 establishment 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 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 establishment. 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/cm^2 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	Loweer 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 sensitvity of at least 5 CFU/cm^2 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) is 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/cm^2) 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:

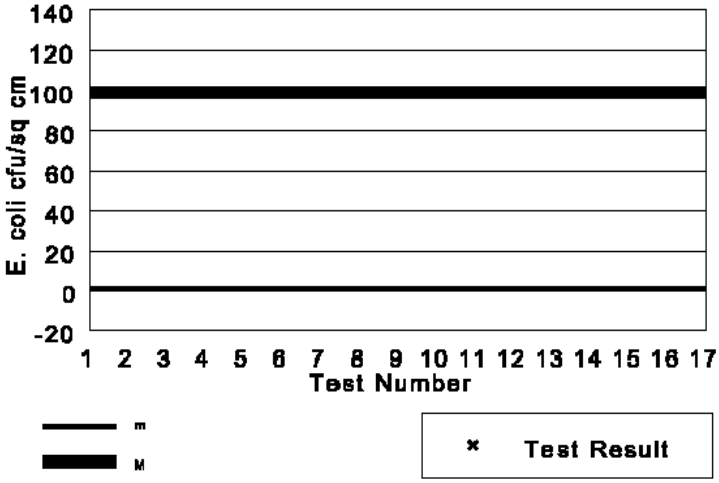
- acceptable, marginal (represented by “m”)
- unacceptable (represented by “M”)

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 above example is a control chart. The E. coli test results are plotted vertically using the E. coli CFU/cm^2 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/cm^2) represents the upper limit of the marginal range or big “M”. The lighter dark line (at 0 CFU/cm^2) 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							
10							
11							
12							
13							

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 thru 13, 2 thru 14, 3 thru 15, 4 thru 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. The column "Result unacceptable" is marked "yes" if the upper control limit ("M") has been exceeded and the column "Results marginal" is marked "yes" if the result of the *E. coli* sample is above the lower control limit ("m"), but not above "M". The "number 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

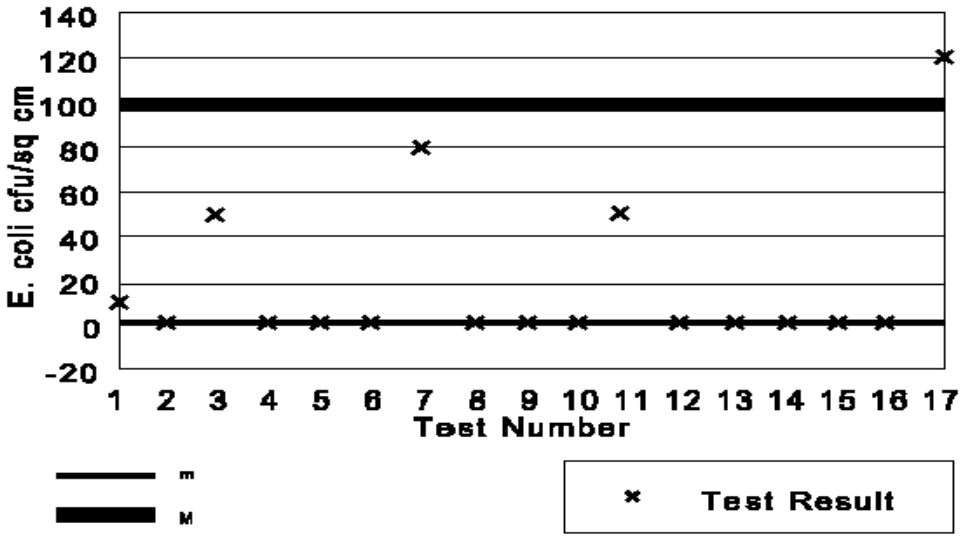


Figure 2

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 establishment 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/cm^2, the "M" value for cattle. Any result

over 100 cfu/cm^2 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 an establishment 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 establishments using statistical process control, when *E. coli* test results do not meet *E. coli* limits set by the establishment, corrective action to regain process control must be taken.

Although the establishment 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 §310.25(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.

REGULATIONS – POULTRY

§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 establishments to conduct microbial testing for generic E. coli, Biotype 1, a specie 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 establishments 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 establishments 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 establishments.

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.

§ 381.94 (a)(1) Continued

> ***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.***
> ***(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.***

§ 381.94 (a)(2)(i) requires that the establishment identify the employee(s) who will collect samples. The establishment 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 establishment, 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 establishment 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 establishment. 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 establishments 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 establishment 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 §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 establishment 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 establishment. 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	Loweer 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/cm^2) for sponging results.

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

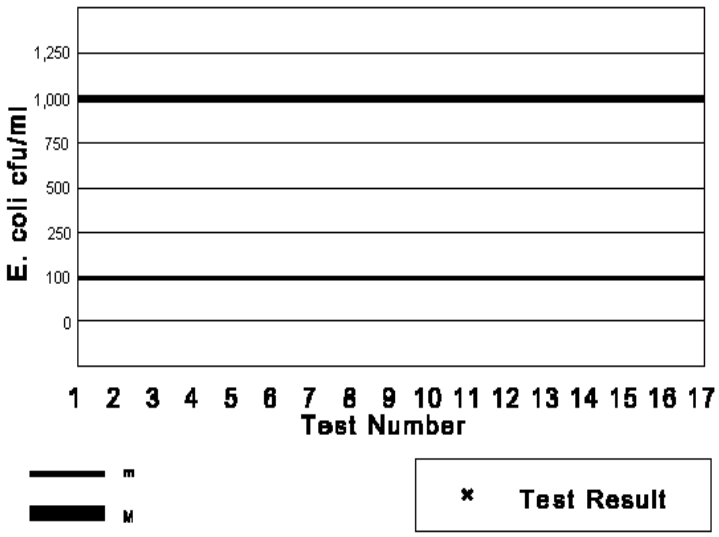
- acceptable, marginal (represented by “m”)
- unacceptable (represented by “M”)

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 follow.



Above is an example of a control chart. In this type of control chart, the *E. coli* test results are plotted vertically using the *E. coli* CFU/ml axis. For each sample the results are plotted starting at "1" in the Test Number horizontal axis and moving right as more samples are taken and plotted on the control chart. The heavier dark line (at 1,000 CFU/ml) represents the upper limit of the marginal range or "M". The lighter dark line (at 100 CFU/ml) represents the lower limit of the marginal range or "m".

Test #	Date	Time Collected	Test Result (cfu/ml)	Result unacceptable?	Result marginal?	Number marginal or unacceptable in last 13	Pass/Fail ?
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							

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 thru 13, 2 thru 14, 3 thru 15, 4 thru 16, etc., would be used to determine if the *E. coli* test results met the guidelines ensuring process control. With each new test result recorded the window would move ahead one result so that a set of thirteen samples is maintained at all times. The column "Results unacceptable" is marked "yes" if the upper control limit or "M" has been exceeded and the column "Results marginal" is marked "yes" if the results of the *E. coli* sample is above the lower control limit ("m"), but not above the upper control limit or "M". The "number of marginal or unacceptable in the last 13" column tracks the number in the marginal range of the last thirteen test results.

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 both forms is from an establishment that slaughters chicken and samples were taken using the whole bird rinse method (Figures 1 and 2).

Figure 1

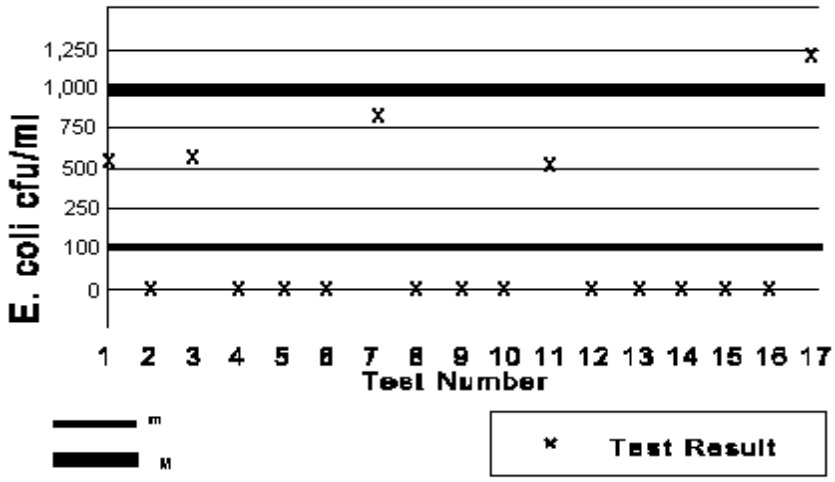


Figure 2

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 establishment 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 establishment 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 establishments using statistical process control, when *E. coli* test results do not meet *E. coli* limits set by the establishment, corrective action to regain process control must be taken.

Although the establishment 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.

Salmonella Performance Standards – Livestock and Poultry

Introduction

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* in July 1996, as part of the *Pathogen Reduction; Hazard Analysis Critical Control Point (PR/HACCP) Systems; final rule.*

In May 2010, FSIS published a Federal Register Notice (Docket No. FSIS-2009-0034) posting new performance standards for the pathogenic microorganism *Salmonella* and *Campylobacter* for chilled carcasses in young chicken (broiler) and turkey slaughter establishments. These new performance standards were based on data collected during recent Nationwide Microbiological Baseline Data Collection Programs (July 2007 – June 2008). A follow-up Federal Register notice was published in March 2011 (Docket No. FSIS-2010-0029) stating that the updated performance standards for young chickens and turkeys would take effect with FSIS verification sample sets scheduled for July 2011.

In 2011, there were two multi-state outbreaks, one was linked to *Salmonella* Hadar in ground turkey products (turkey burgers and ground turkey) and the other outbreak was associated with *Salmonella* Heidelberg in ground turkey. Therefore, FSIS published a Federal Register Notice (Docket No. FSIS-2012-0007; December 6, 2012) informing establishments that produce not ready-to-eat (NRTE) ground or otherwise comminuted chicken and turkey products that they have to reassess their HACCP plans due to the *Salmonella* outbreaks associated with the consumption of comminuted NRTE turkey products (FSIS Notice 17-13). The Federal Register notice also announced that FSIS will expand its *Salmonella* Verification Sampling program to include all non-breaded, non-battered comminuted NRTE poultry products, in addition to ground chicken or turkey products. The intent of this exploratory sampling program is to use the collected data to determine the prevalence of *Salmonella* and *Campylobacter* in NRTE comminuted poultry product produced at federally inspected establishments. FSIS expects to establish a pathogen reduction performance standard for the above mentioned pathogens for NRTE comminuted poultry products (chicken and turkey) based on the results of this sampling program.

In September 2013, the Agency published FSI Directive 10,250.1 where it incorporates into one document all instruction that FSIS has issued to inspection personnel regarding *Salmonella* and *Campylobacter* verification activities for raw meat and poultry products.

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 products, and it can easily be tested for in a variety of products. Furthermore, 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.

Campylobacter species, specifically *C. jejuni* and *C. coli*, are most often isolated from the intestinal tract of poultry as well as in poultry products. *Campylobacter* bacteria are the

second most frequently reported cause of food borne illness, and *Campylobacter jejuni* is the most common strain causing illness.

Salmonella and *Campylobacter* can be transmitted to humans by eating foods contaminated with animal feces. The goal of the newly revised *Salmonella* and *Campylobacter* testing program is to protect the consumer from contaminated products, especially from fecal contamination, by verifying that each establishment's performance meets the new performance standards for poultry as well as the *Salmonella* performance standard for meat products as codified in 9 CFR 310.25(b). In addition to reporting individual *Salmonella* and *Campylobacter* sample results to establishments, FSIS posts nationwide *Salmonella* and *Campylobacter* data on its website on a quarterly basis.

FSIS collects raw meat and poultry products samples from establishments and test the samples for *Salmonella* and *Campylobacter* to verify that establishments are meeting the pathogen reduction performance standards. Pathogen reduction performance standards for raw products are an essential component of FSIS 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 establishments by inspection program personnel is a significant Agency priority.

Salmonella and *Campylobacter* Verification Testing

FSIS IPP conducts the *Salmonella* and *Campylobacter* verification sampling by collecting both carcass and ground product samples. Samples from raw products include carcasses of cows/bulls, steers/heifers, and market hogs; and ground products include beef, chicken, and turkey products. These samples are analyzed for *Salmonella* only. Samples for young chicken (including roasters and Cornish game hens) and turkey (young breeders) carcasses will be analyzed for both *Salmonella* and C*ampylobacter*.

Note: As per FSIS Directive 10,250.1, FSIS is not currently sampling and testing for *Salmonella* in steers or heifers, cows or bulls, or market hogs

Samples are collected from beef, swine, and turkey carcasses using the sponge technique. Specifically, turkey carcasses will be sampled using two sponges, one to be analyzed for *Salmonella* and the other for *Campylobacter*. Sponge sites are the same as those used for generic *E. coli* sampling. Chickens are sampled using whole bird rinses.

Sponge Sample Sites	
Beef	flank, brisket, and rump
Swine	belly, ham, and jowls
Turkey	back and thigh

Ground products (beef) are sampled by taking 25 grams of the ground product. A sterile ring of a standard size is filled level with the top of the ring with product. The ring is ***not*** sent to the lab, only the ground product.

NRTE comminuted poultry products (under the NCPESP project) are sampled by collecting sufficient product to fill the two provided Whirl-Pak bags up to the fill-line indicated on each

bag, following the instructions as described in Notice 35-13. This larger sample size will provide consistency as the Agency moves toward analyzing each sample for two pathogens.

In establishments which produce more than one type of product subject to testing, such as both carcass and ground product, only one type of product sampling is conducted at a time.

The pathogen reduction performance standards apply to establishments, not to individual products. Products are not tested to determine their disposition, but rather to measure the effectiveness of the slaughter and grinding process in limiting contamination. Establishments do not have to hold product or recall product based on results of the *Salmonella* or *Campylobacter* samples.

Samples are taken in sets and the results of an entire set are used to determine if an establishment is meeting the performance standards. So failure to meet *Salmonella* or *Campylobacter* performance standards is based on whether or not a set passes, not on individual samples. A *Salmonella* or *Campylobacter* test is positive when any *Salmonella* or *Campylobacter* organisms are found.

Circumstances in Which Sampling is not Warranted

Even though most raw meat and poultry products are subject to *Salmonella* testing, there is a narrow set of circumstances in which sampling is not warranted. According to FSIS Directive 10,250.1, when an establishment processes all its products into ready-to-eat (RTE) product or diverts all of its raw products to another federally-inspected establishment for further processing into a RTE product, FSIS will exclude the establishment from the *Salmonella* verification testing program.

If an establishment claims that all products are processed into RTE product, IPP are to verify this during the performance of a HACCP procedure, by observing that all the products are actually further processed into RTE product in the establishment, or by reviewing records to ensure that all products are further processed into RTE products in the establishment.

The Performance Standards

The tables below shows the number of samples required to complete a verification sample set for the different livestock and poultry species, and the maximum number of positive results allowed before a set fails to meet the regulatory standards. Here's how to use this chart. Consider young chicken (broilers) carcasses. To meet the *Salmonella* performance standard an establishment can have no more than five positive sample results (c) out of every set of 51 carcasses (n) sampled. If the sample set meets the *Salmonella* performance standards or baseline guidance results, it passes. Sets that exceed the standards or guidance fail. Just as a reminder, the performance standards for ground pork have not been published; however, OPHS may request samples.

***SALMONELLA* PERFORMANCE STANDARDS**		
Class of Product	Number of Samples Tested (n)	Maximum Number of Positives Allowed to Achieve Standard (c)
Steers/heifers	82	1
Cows/bulls	58	2
Ground beef	53	5
Hogs	55	6
Fresh pork sausages	N/A	N/A
Young chickens/broilers*	51	5
Ground chicken	53	26
Ground turkey	53	29
Turkeys*	56	4

*** Note:** The maximum number of positives allowed to achieve the standard for young chicken/broilers and turkeys in the table reflects the new *Salmonella* performance standards published in the March 21, 2011 Federal Register Notice that have been in effect since July 2011.

***CAMPYLOBACTER* PERFORMANCE STANDARDS**		
Class of Product	Number of Samples Tested (n)	Maximum Number of Positives Allowed to Achieve Standard (c)
Broilers carcasses	51	8
Turkey carcasses	56	3

Note: The *Campylobacter* sample set criteria for tracking and reporting the performance standards are from the smaller of the two lab sample portions (1 ml) which detects the higher levels of contamination.

Sets and Categories

At the completion of each set, the District Office (DO) sends an "End of Set Letter" (EOS) to the establishment explaining the establishment's status with respect to the risk-based *Salmonella* and *Campylobacter* testing program and strategy (combination of an establishment's overall process control and individual *Salmonella* subtype results). The EOS letters are organized into the following sections:

- Process control
- Public Health-focused evaluation of isolates by serotype
- Discussion of compiled set results

An establishment's process control status determines into which category the establishment is placed. There are 3 categories. The establishment's last consecutive sample sets define the establishment's category. Sets that exceed the standards fail.

Category 1: (Consistent Process Control) indicates process control which is 50% or less of the performance standard or baseline guidance. For example, the turkey's carcasses standard is 4. If a turkey carcass set had a total of 1 positive samples, this is less than half (2) of the maximum number of positives allowed to still meet the standard (4).

Category 2T: The establishment was not able to maintain consistent process control over the previous *Salmonella* verification testing set but maintained consistent process control over the most recent set (The most recent set is at or below 50% of the performance standard and any result in the prior set.)

Category 2: (Variable Process Control) indicates that the establishment had 51% or higher of the performance standard or baseline guidance, but did not exceed the maximum number of positives. Establishments in this category demonstrate intermediate process control.

Category 3: (Highly Variable Process Control) shows that the set failed and the establishment was not able to maintain consistent process control over the past two *Salmonella* verification testing sets and showed highly variable process control over the most recent set (The most recent set does not meet the performance standard and any result in prior set).

For establishments whose process control is questionable, and who have had a high percentage of positives, FSIS will intensify its scheduling of Agency verification sample sets. The Agency will also post the test results and names of establishments that fail to effectively control this pathogen on the FSIS Web site.

(http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program/)

Establishments in Category 3 will be sampled at a higher frequency than those in Categories 1 or 2.

When a set fails and the establishment is in Category 3, the District Manager may determine that an Enforcement, Analysis and Investigation Officer need to conduct a Food Safety Assessment (FSA) at that establishment since its controls are questionable.

Salmonella Regulations, Livestock, 310.25(b) and Poultry, 381.94(b)

Sec. 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(b) Pathogen reduction performance standard; *Salmonella*. (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 2:

Table 2--Salmonella Performance Standards

Class of product	Performance Standard (percent positive for Salmonella)[a]	Number of samples tested (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……..	[b] N.A.	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.

[b] Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) Enforcement. FSIS will sample and test raw meat 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 such 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[3].

[3] A copy of FSIS's ``Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

(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.

(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.

(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.

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

(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 (per cent positive for Salmonella)[a]	Number of samples tested (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.....	[b] N.A.	N.A.	N.A.
Squabs.....	[b] N.A.	N.A.	N.A.
Ratites.....	[b] N.A.	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; baseline targets for turkeys, squabs, or ratites will be added upon completion of the data collection programs for that product.

(2) Enforcement. FSIS will sample and test raw 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 such 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[3].

[3] A copy of FSIS's ``Sample Collection Guidelines and Procedure for Isolation and Identification of Salmonella from Raw Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

(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.

(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.

(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.