UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

5000.1
Revision 3

6/24/08

VERIFYING AN ESTABLISHMENT'S FOOD SAFETY SYSTEM

I. PURPOSE

This directive provides comprehensive direction to Consumer Safety Inspectors (CSIs) on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations.

II. CANCELLATION

FSIS Directive 5000.1, Revision 2, Verifying An Establishment's Food Safety System, dated July 18, 2006

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to include:

A. additional instructions regarding the weekly meeting with establishments and the need to discuss any changes the establishment makes to its processes (section V.C. of this directive);

B. additional instructions for verifying prerequisite programs (Chapter II, IV, B);

C. instructions for verifying the annual HACCP reassessment and the related training requirements for individuals who conduct reassessments (Chapter II, IX, D, E, and F);

D. updated instructions for completing NRs (Chapter IV, I); and

E. instructions to Frontline Supervisors regarding repetitive non-compliances (Chapter IV, VI, B);

This directive also provides an attachment addressing the use of microbial pathogen computer modeling in HACCP plans.

IV. REFERENCES

9 CFR parts 416, 417, and 500
9 CFR 310.25 and 381.94

V. GENERAL

A. Communications with CSIs on New Assignments:

When a CSI rotates into an assignment or is newly assigned to an establishment, the Frontline Supervisor, and, as appropriate, an Enforcement, Investigation and Analysis Officer (EIAO) should discuss with the newly assigned CSI:

1. any previous noncompliance issues, especially those from the last 90 days, that have occurred at the establishment and should discuss the corrective and preventive measures that were provided by the establishment to address the noncompliances;

2. if an enforcement action has been deferred or if a suspension has been held in abeyance at the establishment, the Agency's expectations, as described in the verification plan, for verifying the effectiveness of the corrective and preventive measures that were proffered by the establishment and what led to the decision to defer enforcement or hold a suspension in abeyance; and

3. the findings and outcomes from the most recent Food Safety Assessment that have been conducted at the establishment.

B. Entrance meeting.

When a CSI rotates into an assignment or conducts an inspection at an establishment for the first time, he or she should:

1. review the establishment's Sanitation SOPs, HACCP plan, and prerequisite programs. CSIs are not to take written programs to the inspection office or maintain any copies of the establishment's written programs or data from such programs in the inspection office.

2. have an entrance meeting with the establishment management to familiarize himself or herself with the establishment and inquire about the specific operations of that establishment. Also, if the CSI has questions, based on his or her review of the programs, about specific food safety issues that have been addressed by the establishment, he or she should ask these questions at the meeting.

3. take notes at the entrance meeting and document the notes in a Memorandum of Interview (MOI), maintain a copy of the MOI in the official file, and provide a copy to the establishment.

C. Weekly meeting.

1. CSIs are to have weekly meetings with the establishment to discuss issues of concern. The meetings may involve discussing individual non-compliances, developing trends of non-compliance, or findings on the part of the CSI that are not non-compliances but warrant discussion. Also, the establishment may wish to share information or concerns at the meetings.

2. On a periodic basis, about once a month, the CSI is to ask the establishment at the weekly meeting whether it has made any changes in how it is processing product or that would otherwise affect the safety of the product. If CSI learns that the establishment has made a change in its process, based on the nature of the change, he or she is to perform the appropriate verification activities under this directive. If the CSI is unsure how to proceed, he or she is to contact the District Office through supervisory channels.

3. CSIs are to take notes at the weekly meetings and are to document the notes in a MOI. The CSI is to maintain a copy of each MOI in the official file and provide the establishment with a copy.

CHAPTER I - SANITATION

I. Introduction

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

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

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

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

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

II. Sanitation Performance Standards

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

Section 416.1 states: *Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.*

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

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

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

III. CSI Verification Activities for Sanitation Performance Standards

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

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

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

9 CFR 416.4(c) requires that an establishment have "documentation substantiating the safety of a chemical's use in a food processing environment," 9 CFR 416.2(g) states: "If an establishment uses a municipal water supply, it are to 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 is to make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually." The other SPS regulations do not require that an establishment maintain records of the procedures that it uses to meet these performance standards. Establishments may incorporate SPS procedures as part of its Sanitation SOPs, in which case they would have to meet the relevant recordkeeping requirements for Sanitation SOPs.

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

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

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

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

IV. Verification of the Grounds and Pest Control

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

Section 416.2 (a) states: *The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the*

adulteration of product or the creation of insanitary conditions.

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

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

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

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

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

3. Does the establishment have a pest management program?

4. Does the establishment have a written pest management program as part of the Sanitation SOP?

5. If the pest management program is part of the Sanitation SOP, is the establishment monitoring this program?

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

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

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

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

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

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

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

3. Are the pest control substances being applied as per the conditions and use?

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

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

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

V. Construction

A. What is the regulation related to construction?

Section 416.2 (b) states:

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

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

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

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

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

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

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

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

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

4. Are the walls, floors, ceilings, doors, windows, and other outside openings constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice?

5. Are edible products and inedible products processed, handled, and stored in a manner that prevents product adulteration and the creation of insanitary conditions? Are they processed, handled, and stored separately? If not, is there an opportunity for cross-contamination?

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

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

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

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

VI. Lighting

A. What is the regulation related to lighting?

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

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

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

1. Are the intensity and quality of lighting adequate for the establishment to determine that the products being processed, handled, stored, or examined are unadulterated, and that sanitary conditions are maintained?

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

3. Are the intensity and quality of lighting adequate in the hand-washing areas, dressing and locker rooms, and toilets for the establishment to determine that sanitary conditions are maintained?

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

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

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

VII. Ventilation

A. What is the regulation on ventilation?

Section 416.2 (d) states: *Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.*

B. How may CSIs go about verifying this regulation?

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

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

2. Is the ventilation adequate to control condensation?

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

The CSI observes fog or smoke in the cooked meats cooler. When entering the cooler, it appeared that the ventilation was not adequate to control vapors. The CSI assesses the situation and determines that the establishment has

placed 10 trays of warm product in the area. The CSI observes that the vapor in the room dissipates before forming any moisture on the ceiling. In this situation, there is not noncompliance. If the vapor coming from the warm product does form moisture on the ceiling, creating an insanitary condition, there is noncompliance with this provision.

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

VIII. Plumbing and Sewage

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

Section 416.2 (e) states: *Plumbing systems must be installed and maintained to:*

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

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

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

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

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

(6) Prevent the backup of sewer gases.

Section 416.2 (f) states: *Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.*

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

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

1. Are sufficient quantities of water provided throughout the establishment?

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

3. Does the plumbing system provide adequate floor drainage?

4. Is the plumbing installed to prevent back-flow conditions and cross-connections between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing?

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

6. Is the sewage disposed into a sewage system separate from all other drainage lines or other means to prevent backup of sewage into areas where product is processed, handled, or stored?

7. If the sewage disposal system is a private system requiring approval by a State or local health authority, is the letter of approval available to FSIS upon request?

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

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

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

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

A. What is the regulation related to water supply?

Section 416.2 (g) states: *(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.*

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

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

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

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

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

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

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

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

Section 416.2(g)(2) states: *Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.*

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

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

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

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

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

3. Did the establishment consider water, ice, and solution reuse in the hazard analysis?

4. If the establishment considered water, ice, and solution reuse in the hazard analysis and found a food safety hazard reasonably likely to occur, is there a CCP in the HACCP plan to address this hazard?

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

Section 416.2(g) states: *(3) Water, ice, and solutions to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.*

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

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

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

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

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

1. Is the potable water supply from a municipal source? If not, does the certification or other documentation on file evidence that the establishment's

potable water supply meets the EPA's primary potability requirements for sources of drinking water?

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

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

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

NOTE: The regulations state that water may be reused "for the same purpose." This means that water used to wash or otherwise process raw product may be reused to wash or otherwise process raw product, even at a different point in processing, provided that "measures are taken to reduce physical, chemical, or microbiological contamination." For example, an establishment could reuse poultry chiller water in a scalding tank. Furthermore, water used to process RTE product could be reused to wash or process raw product. But water used to process raw product may not be reused to process RTE product. For example, an establishment could not reuse poultry chiller water for cooking or cooling packaged RTE product.

X. Dressing Rooms and Lavatories

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

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

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

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

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

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

1. Are the dressing rooms, toilet rooms, and urinals sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair?

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

3. Are there lavatories with running hot and cold water, soap, and towels placed in or near toilet and urinal rooms and other places in the establishment as necessary?

4. Are refuse receptacles constructed and maintained in a sanitary manner?

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

The CSI is in an area of the establishment where edible product is being handled. There are several employees working in this rather large room. The CSI observes that there is only one lavatory close by. The CSI thinks that there may be noncompliance with this requirement but decides to evaluate the situation further before making a compliance determination. The CSI observes that the employees are handling product, and when employees' hands are contaminated, they go to the lavatory and wash their hands. The CSI determines that in this situation, there is not noncompliance. If the employees were not washing their hands because the lavatory was not appropriately located in this area, there would be noncompliance with this provision.

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

XI. Equipment and Utensils

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

Section 416.3 states: *(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.*

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

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

storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

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

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

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

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

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

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

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

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

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

XII. Sanitary Operations

A. What is the regulation related to sanitary operations?

Section 416.4 states: *(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.*

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

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

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

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

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

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

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

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

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

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

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

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

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

The CSI observes several vats of meat in the raw product storage area that are not covered. There are several other vats of meat stored in this area that are covered. The CSI thinks that there might be noncompliance with this provision but decides to evaluate the situation further before making a compliance determination. The CSI looks at the overhead in the area and does not observe any conditions that would constitute insanitation or that would cause product adulteration. The CSI observes an employee come into the area and take a vat of product out of this area. The CSI follows the employee to determine whether the product needs to be protected while being transferred to another area. The CSI finds no conditions that would require the product to be covered during transit. Therefore, the CSI determines that there is not noncompliance with this provision. If the CSI had observed that there was a condition in the establishment that could adulterate product during storage or handling, there would be noncompliance with this provision.

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

XIII. Employee Hygiene

A. What is the regulation related to employee hygiene?

Section 416.5 states: *(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.*

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

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other

abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

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

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

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

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

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

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

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

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

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

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

The CSI observes an employee preparing to start to work in the raw product area. The employee puts on an apron. The CSI observes that the apron is dirty from the previous day's production. The CSI thinks that there is noncompliance with this provision but decides to evaluate this situation further before making a

compliance determination. He observes the employee go to the washroom and clean the apron thoroughly before starting to work. The CSI determines that there is not noncompliance with this provision. If the employee does not clean the apron appropriately before going to work, there would be noncompliance with this provision.

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

XIV. Sanitation SOPs

A. What are the written Sanitation SOP Procedures?

The establishment has the responsibility to develop, implement, and maintain written Sanitation SOPs. The basic regulatory requirements are described in 9 CFR 416.12. At the time inspection is granted, the establishment is to have a Sanitation SOP that meets these requirements. The CSI performs the 01A01 procedure to verify that the written procedures meet the basic regulatory requirements. The CSI determines when it is necessary to perform the 01A01 procedure. There are four Sanitation SOP regulatory requirements. The four requirements are: implementation and monitoring, maintenance, recordkeeping, and corrective action. If the CSI determines that the Sanitation SOP does not meet the regulatory requirements specified in 9 CFR 416.12, he or she should contact the DO for direction.

XV. Inspection Procedures

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

There are two Sanitation SOP procedures for pre-operational sanitation verification (01B01/01B02) and two Sanitation SOP procedures for operational sanitation verification (01C01/01C02). The sanitation procedures are performed as scheduled during the approved hours of operations of the official establishment or may be performed as unscheduled during overtime hours or anytime CSIs determine that the establishment is not meeting the requirements of 9 CFR 416.11-416.16. The CSI performs these procedures to verify that the establishment is meeting the Sanitation SOP regulatory requirements. Those requirements are:

1. Implementation and monitoring of Sanitation SOP (416.13);

2. Maintenance of Sanitation SOP (ensuring its effectiveness) (416.14);

3. Sanitation SOP corrective actions (416.15); and

4. Sanitation SOP recordkeeping (416.16)

B. How do CSIs conduct the 01B01 procedures?

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

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

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

C. How do CSIs conduct the 01C01 procedures?

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

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

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

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

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

NOTE: The CSI needs to understand the procedures in the Sanitation SOP that the establishment is implementing to prevent direct contamination or other adulteration of product. The CSI should become familiar with any monitoring

procedures and frequencies that may be included in the Sanitation SOP. Without this knowledge the CSI will not be able to verify regulatory compliance.

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

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

It is possible that the CSI might be performing his or her review and observation procedure at the same time the establishment is monitoring their pre-operational procedures. This provides an excellent opportunity for the CSI to perform the observation part of this procedure. In some cases, the establishment might conduct its monitoring of the implementation of the Sanitation SOP procedures before CSIs arrive at the establishment. In these situations, the CSI should seek direction from supervisory personnel as to how frequently he or she should directly observe the establishment conduct monitoring. The supervisor should consider several factors when making this decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from Sanitation SOP records.

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

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

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

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

1. inspecting one or more areas of the establishment to ensure procedures are effective in preventing direct contamination or other adulteration of product,

2. observing the establishment perform the monitoring procedures, and

3. comparing the findings to what the establishment has documented.

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

observe that activity when it is occurring.

XVI. Implementation and Monitoring

A. What is the implementation and monitoring regulation?

Section 416.13 states: (a) *Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations.*

(b) Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified.

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

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

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

1. Is the establishment implementing the pre-operational procedures in the Sanitation SOP prior to the start of operations?

2. Are direct contamination or adulteration of product or unclean direct product contact surfaces observed by FSIS or the establishment?

3. Is the establishment conducting the procedures in the Sanitation SOP as specified?

4. Does the Sanitation SOP contain monitoring frequencies?

5. If the Sanitation SOP does not contain monitoring frequencies, is the establishment monitoring the implementation of the procedures in the Sanitation SOP daily?

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

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

XVII. Maintenance

A. What is the maintenance regulation?

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

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

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

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

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

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

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

C. What is an example of noncompliance?

- Changes were made in the facilities, equipment utensils, operations, or personnel, and the Sanitation SOP is no longer effective in preventing direct contamination or adulteration of product.

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

XVIII. Corrective Actions

A. What is the regulation on corrective actions?

Section 416.15 states: (a) *Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the*

establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).

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

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

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

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

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

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

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

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

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

C. What are some examples of noncompliance?

- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to ensure appropriate disposition of product.

- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to restore sanitary conditions.

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

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

XIX. Recordkeeping

A. What is the regulation on recordkeeping?

Section 416.16 states: (a) *Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.*

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

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

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

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

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

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

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

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

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

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

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

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

CHAPTER II - HACCP

I. Introduction

The establishment has the responsibility for complying with 9 CFR Part 417 of FSIS HACCP regulations. 9 CFR 417.2(b) requires that every official establishment develop and implement a HACCP plan covering each product produced by that establishment when the establishment's hazard analysis reveals that one or more food safety hazards are reasonably likely to occur in the process of producing the product.

FSIS has the responsibility for verifying that establishments meet the requirements in 9 CFR Part 417. 9 CFR 417.8 describes the FSIS verification functions that are performed to provide a basis for making determinations as to whether the establishment is in compliance. CSIs focus on the execution or implementation of the HACCP plan when performing their verification procedures. In assessing the adequacy of an establishment's HACCP system, CSIs should consider all of the available evidence.

For instance, CSIs should evaluate their observations in conjunction with the results of the microbiological sampling. Has the inspector observed a laxness in the establishment's attention to evisceration and its application of its antimicrobial interventions that is reflected in a higher number of positives in the Agency's *Salmonella* sampling? Has the inspector observed a commitment to food safety that produces good results?

Moreover, establishments may do their own environmental testing, testing for APCs or enterobacteriaceae, or other verification testing. CSIs should review these records in accordance with FSIS Directive 5000.2, Review of Establishment Data by Inspection Program Personnel.

For example, an establishment that makes RTE product decides to undertake some in-plant construction. Because construction increases the risk of *L. monocytogenes* contamination of product, the establishment decides to treat this pathogen as a hazard that is reasonably likely to occur, at least during the construction period. CSIs should seek answers to questions similar to the following to determine whether the establishment's HACCP system is producing safe product.

1. What preventive measures were put in place during the construction to prevent product or product contact surface contamination?

2. Is the plant doing environmental testing during the construction project? If so, do the results indicate any significant micro flora changes during the construction project?

3. Did the establishment implement any additional sanitation procedures during the construction project?

4. Did the establishment do any testing to determine the effectiveness of the special sanitation procedures?

Each situation is different, and CSIs are to use critical thinking in deciding whether there is a basis for concern, or that there is a problem with the establishment's HACCP system that should be addressed. If the establishment is not complying with the regulatory requirements, CSIs should issue an NR or consider recommending other action under the Rules of Practice, 9 CFR part 500 (see Chapter IV).

II. HACCP Verification Methodology

A. How do CSIs perform HACCP verification procedures?

The CSI should understand the regulations in 9 CFR part 417, how to apply these regulations in the plant environment, and the appropriate methodology to use in verifying compliance with these regulations. There are two HACCP procedures, an 01 procedure and an 02 procedure, for verifying that an establishment is meeting the regulatory requirements of 9 CFR Part 417. The number of HACCP plans and the number of products produced within a specific processing category has no impact on the number of HACCP procedures that CSIs are scheduled to perform for that process.

NOTE: An establishment can produce many products within the same processing category with one HACCP plan, or can have a separate HACCP plan for each product within that processing category. In either case, there are only two HACCP procedures for that processing category. If the establishment has a separate HACCP plan for each of the products in the same processing category, the CSI needs to have a method of verifying that the regulatory requirements are met in all of the HACCP plans at some frequency. He or she might verify one of the five requirements (monitoring, verification, corrective action, recordkeeping, and reassessment) in all of the HACCP plans for a particular processing category each time the HACCP 01 procedure is performed. Another method he or she might use is to choose a different HACCP plan each time that procedure is to be performed.

There are two components to each of the HACCP procedures, a recordkeeping component and a review and observation component. The CSI can use either of these components or a combination of these components to verify regulatory compliance.

The CSI may use any of these components or parts, individually or collectively, to verify regulatory compliance with the HACCP regulations. For example, the CSI can review records at one CCP and take a measurement or observe the establishment take a measurement at another CCP to verify that the monitoring requirement is met.

NOTE: When a CSI takes a measurement, he or she is to use the calibrated instrument that the establishment uses for the monitoring or verification activities. The CSI should take measurements at the CCPs using the procedures described in the HACCP plan. For example, a CSI would take a temperature at a CCP using the establishment's thermometer and not his or her own thermometer because the CSIs thermometer may not be calibrated properly.

HACCP 01 Procedure

The HACCP 01 procedure is for verifying, at random, one or more of the HACCP regulatory requirements. There are five regulatory requirements -- monitoring, verification, corrective actions, recordkeeping, and reassessment.

The CSI is to have a method for randomly selecting the requirements that he or she will verify during the performance of this procedure. After this decision is made, the CSI will need to review the HACCP plan to ensure that he or she has full knowledge of what it contains. When noncompliance is found while performing the HACCP 01 procedure, the HACCP 02 procedure is performed on that specific production.

HACCP 02 Procedure

The HACCP 02 procedure is for verifying all applicable regulatory requirements (monitoring, verification, recordkeeping, corrective actions, and reassessment) at all of the CCPs in the HACCP plan for a specific production. This procedure cannot be completed until pre-shipment review has been completed for this product. When the CSI is to perform the HACCP 02 procedure, he or she should verify that all regulatory requirements are met at all CCPs for a specific production. CSIs are to perform the HACCP 02 as scheduled by PBIS and when a noncompliance is found during the performance of a HACCP 01. Inspection program personnel are to link in PBIS the performance of a HACCP 02 that resulted form a HACCP 01 noncompliance.

The CSI can review records, conduct a measurement, and observe the establishment conducting the activities listed in the HACCP plan. However, the CSI are to verify that all the applicable requirements at all of the CCPs have been met for a specific production when performing the HACCP 02 procedure. The CSI can verify corrective actions if there has been a deviation from a critical limit, a deviation not covered by a specified corrective action, or an unforeseen hazard.

When the CSI determines that the establishment does not meet one or more of the regulatory requirements, he or she should document this finding on an NR. If the noncompliance involves the production and shipment of unsafe food, the CSI should initiate the appropriate enforcement actions described in 9 CFR 500.3. If the CSI has documented multiple or recurring noncompliances, he or she should contact the DO and request that an NOIE be issued to the establishment as described in 9 CFR 500.4. In other situations the CSI may

take a regulatory control action to prevent the shipment of adulterated products. The CSI should also keep the Frontline Supervisor informed of developing trends of noncompliance. (see Chapter IV).

III. Hazard Analysis

A. How do CSIs verify that an establishment has performed a hazard analysis?

During the performance of the 03A01 procedure, CSIs verify that an establishment has performed a hazard analysis as part of its basic compliance with the regulations (9 CFR 417.2(a)). The CSIs should use the thought process and methodology described below when verifying that the hazard analysis complies with the regulation. CSIs will verify compliance by reviewing the flow chart, the hazard analysis, the HACCP plan, the establishment's initial validation of the HACCP plan, and HACCP records.

Before reviewing the hazard analysis, the CSIs should understand that a food safety hazard is defined in 9 CFR 417.1 as *any biological, chemical, or physical property that **may** cause a food to be unsafe for human consumption.* The CSIs need to review hazard analysis records to determine whether the analysis considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe. The hazard is to be one that would be identified by a reasonable consideration of the food, how it is processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the plant) does not mean that the hazard analysis is to address that hazard. If the CSI has concerns about whether the relevant hazards have been considered, he or she may decide to discuss issues with the Policy Development Division (PDD) or with the establishment during the weekly meeting. The CSI should ask whether the establishment has considered and addressed the following questions by comparing the hazard analysis to the Basic Compliance Checklist (FSIS Form 5000-1):

1. Did the establishment conduct a hazard analysis or have one conducted for it?

2. Did the establishment's analysis start by identifying all hazards that may occur?

3. Does the hazard analysis identify preventive measures the establishment can apply to the food safety hazards?

4. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment?

5. Does the hazard analysis identify the intended use or the consumers of the finished product?

6. Does the result of the establishment's hazard analysis reveal that one or more food safety hazards are reasonably likely to occur?

7. Does the establishment have a written HACCP plan for each of its products?

8. Has the establishment conducted validation activities to determine whether the HACCP plan will function as intended?

NOTE: Section 417.4 (a)(1) provides more details about the requirement for initial validation, "… 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 CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan." Validation data for any HACCP plan is to include some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. This is necessary because validation is to demonstrate not only that the HACCP plan is theoretically sound, but also that the establishment can implement it and make it work on a day-by-day basis.

9. Do the establishment's records include multiple results that verify the monitoring of CCPs and conformance with critical limits?

10. Does the establishment have subsequent results that support the adequacy of corrective actions in achieving control at a CCP after a deviation from a critical limit has occurred?

B. What happens if the CSI determines that a noncompliance exists?

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. If the CSI determines that the hazard analysis does not meet the regulatory requirements, he or she should notify the DO for direction.

IV. Prerequisite Programs

A. What is the Agency policy regarding prerequisite programs?

Prerequisite programs are conditions and practices that provide the basic environmental and operating conditions that are necessary for the production of safe and wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system. They frequently function across product lines and are often managed as facility-wide programs rather than being process or product specific.

FSIS Directive 5100.1, Enforcement, Investigative, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology, defines

prerequisite programs and sets the decisionmaking criteria that EIAO's are to follow when they assess the design of such programs.

B. How do CSIs verify prerequisite programs?

1. When an establishment references a prerequisite program in its hazard analysis as supporting documentation that a food safety hazard is not likely to occur, the CSI should verify that the establishment:

a. has written procedures that set out the design of the prerequisite program;

b. is executing the program as designed; and

c. has evidence that the program is being executed as designed and continues to support decisions made in the hazard analysis (9 CFR 417.5) (e.g., information on suppliers' interventions, test results from suppliers, results from its own testing, or documents regarding the on-going effectiveness of the program).

NOTE: If CSIs have questions regarding the design of the hazard analysis they should contact the DO.

2. As stated in FSIS Directive 5100.1, "…. deviations from compliance with a prerequisite program usually would not create a food safety concern or necessitate action on the product, whereas deviations from the controls in a HACCP plan cause food safety concerns and generally require action on the affected product." By means of records review and observations and discussions with establishment at the weekly meeting, CSIs are to focus on:

a. the overall program to verify that the establishment is implementing it as designed and consider questions such as:

i. is the establishment implementing the procedures as set out in the program's design?

ii. does the establishment maintain records to support the implementation of the program, including verification records and results from outside auditors?

iii. does the establishment evaluate the implementation of the program?

iv. does the establishment have means to correct implementation problems?

b. any problems that indicate that the prerequisite program may no longer be supporting the decisions made in the hazard analysis that a hazard is unlikely to occur, and consider questions such as:

i. are elements of the program not being implemented?

ii. are adjustments made to the programs when necessary?

iii. do the same implementation problem continue to reoccur?

iv. are there numerous or recurrent mistakes made in the implementation of the program?

C. What happens if the CSI has reason to believe, based on professional judgment, that the overall execution of a prerequisite is not as designed, and that the use of the program may not be continuing to support the decisions made in the hazard analysis?

If a CSI finds, based on records or observations, that the prerequisite program is not continuing to support the decision made in the hazard analysis that a food safety hazard is not likely to occur in the process, they document a noncompliance with 9 CFR 417.5(a)(1), as set out in Chapter IV of this directive, and verify that the establishment:

1. reassesses its hazard analysis as required in 9 CFR 417.4(b) because the decisions made in the hazard analysis may no longer be supported (9 CFR 417.5(a)(1)), and

2. provides data supporting the decisions made during this reassessment required in 9 CFR 417.5(a)(1).

V. Monitoring Requirement

A. What is the regulation that applies to monitoring?

9 CFR 417.2(c)(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*

B. How do CSIs verify the monitoring requirement?

CSIs verify the monitoring requirement by performing the HACCP 01 or HACCP 02 procedures. CSIs should use the thought process and methodology described below when performing either the HACCP 01 or HACCP 02 procedure. CSIs will verify the regulatory requirement by reviewing the HACCP plan, reviewing HACCP records, observing establishment employees performing monitoring activities, and taking measurements at the CCPs. In verifying the monitoring requirement, the CSI should seek answers to the following questions:

1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?

2. Are the monitoring procedures being performed as described in the HACCP plan?

3. Are the monitoring procedures being performed at the frequencies specified for the CCPs listed in the HACCP plan?

When seeking answers to the above questions, the CSI should:

a. Review the HACCP plan to determine whether the HACCP plan design includes the monitoring procedures and frequencies that are used to monitor the critical control points. Since the establishment can modify the HACCP plan without notifying CSIs, the CSI should ensure that he or she is familiar with the monitoring procedures and frequencies in the HACCP plan by reviewing the HACCP plan each time he or she verifies the monitoring requirement. When reviewing the monitoring procedures and frequencies in the HACCP plan, the CSI should be able to understand exactly what the establishment is doing at the CCP. If the CSI does not understand how the establishment is performing the monitoring activity at the CCP, he or she will need to determine whether this is an indication that the monitoring requirement is not being met.

b. Observe an establishment employee performing the monitoring activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan.

c. Based on reviewing the monitoring records or on the basis of observing the establishment performing the monitoring procedures, determine whether the monitoring procedures are being performed at the frequencies specified in the HACCP plan.

C. What are some examples of monitoring noncompliance?

- The establishment is not conducting the monitoring procedures as specified in the HACCP plan.
- The establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.
- The CSI takes a measurement at a CCP and finds that the critical limit is not met.

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

VI. Verification Requirement

A. What are the regulations that apply to verification procedures and frequencies?

9 CFR 417.2(c)(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.*

9 CFR 417.4(a)(2)(i)(ii)(iii) – *Ongoing verification activities include, but are not limited to: The calibration of process-monitoring instruments; direct observations of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with § 417.5(a)(3) of this part.*

B. How do CSIs verify the verification requirement?

CSIs verify the verification requirement by performing the HACCP 01 or HACCP 02 procedures. CSIs should use the thought process and methodology described below when performing either the HACCP 01 or HACCP 02 procedure. CSIs will verify these regulatory requirements by reviewing the HACCP plan, reviewing HACCP records, and observing establishment employees performing verification activities. In verifying the verification requirement, the CSI should seek answers to the following questions:

1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?

2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?

3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

4. Does the HACCP plan list product sampling as a verification activity?

5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?

6. Are direct observation verification activities conducted as per the HACCP plan?

7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?

When seeking answers to the above questions, the CSI should:

a. Review the HACCP plan to determine whether it lists direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring calibration verification procedures and frequencies. Since the establishment can modify the HACCP plan without notifying CSIs, the CSI should ensure that he or she is familiar with the verification procedures and frequencies in the HACCP plan by reviewing the HACCP plan each time he or she verifies the verification requirement.

b. Observe an establishment employee performing the verification activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan.

c. Review the HACCP records or observe the establishment performing the verification procedures to determine whether the verification procedures are being performed at the frequencies specified in the HACCP plan.

d. If the establishment has included an alternative generic *E. coli* sampling frequency into the HACCP plan (see 9 CFR 310.25(a)(2)(iv) or 381.94(a)(2)(iv)), the CSI will verify that the alternative is an integral part of the establishment's verification procedures for its HACCP plan.

e. If product sampling is included in the HACCP plan, the CSI should observe an establishment employee taking samples and review the results as part of the HACCP 01 or 02 procedures. If the establishment received positive results, the CSI should verify the corrective action requirements of 9 CFR 417.3 are met.

NOTE: The CSI should use good judgment in recognizing that there are times when a HACCP plan might not contain all three ongoing verification activities listed in 9 CFR 417.4(a)(2)(i)(ii)(iii). If an establishment has a CCP that is monitored without the use of process monitoring equipment, there would be no need for process monitoring equipment calibration verification procedures. If an establishment only has one employee, it would not be possible for that person to conduct a direct observation of the monitoring activity. In this situation, the HACCP plan would not need to list a direct observation of the monitoring activities. The direct observation ongoing verification activity should be designed for the plant verifier to directly observe the plant employee conducting the monitoring activity. A plant verifier conducting the same activity as the monitor does not meet the regulatory requirement for the direct observation verification activity described in 9 CFR 417.4(a)(ii).

C. What are the regulatory requirements related to on-going verification and direct observation of corrective actions?

9 CFR 417.4(a)(2)(ii) requires that establishments have ongoing verification activities that include direct observations of monitoring activities and corrective actions. 9 CFR 417.5(a)(2) requires that establishments have decisionmaking documents associated with the selection and development of CCPs and critical limits and documents that support both the monitoring and verification procedures selected and the frequency of those procedures.

It is important that the establishment implement corrective actions that meet the requirements of 9 CFR 417.3(a) each time that a deviation from a critical limit occurs, and the requirements of 9 CFR 417.3(b) each time an unforeseen hazard occurs. Since it cannot be predicted when a deviation from a critical limit or an unforeseen hazard will occur, it would be counterproductive

to require that the establishment have specific procedures and frequencies in its HACCP plan for directly observing corrective actions. It is necessary, however, for an establishment to directly observe corrective actions frequently enough to verify that these actions are being performed in a manner that meets the applicable regulatory requirements. Under the regulation, the establishment is to document these direct observations in the same manner that it documents other verifications.

D. What are some examples of verification noncompliance?

- The HACCP plan does not, at a minimum, list records review verification procedures; direct observation verification procedures; or calibration of process-monitoring instruments verification procedures.

- The HACCP plan does not list the frequencies at which the verification procedures will be performed.

- The establishment is not performing the direct observation verification procedures as specified in the HACCP plan.

- The establishment is not performing the records review verification procedures as specified in the HACCP plan.

- The establishment is not performing the process monitoring verification procedures as specified in the HACCP plan.

- The establishment is not performing one or more of the verification procedures listed in the HACCP plan at the frequencies specified in the HACCP plan.

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

VII. Recordkeeping Requirement

A. How do CSIs verify the recordkeeping requirements?

The CSI verifies that the establishment is meeting the recordkeeping requirements. The CSI will verify these requirements by reviewing the HACCP plan, hazard analysis, HACCP records, supporting documentation, and decisionmaking documents. The CSI verifies some of the recordkeeping requirements when performing the HACCP 01 procedure. For example, the CSI uses an 01 procedure to verify that the establishment has supporting documentation for the monitoring procedures in the HACCP plan. Other recordkeeping requirements are verified when performing the HACCP 02 procedure. Preshipment review is verified by performing 02 procedures. The majority of the time the CSI will verify the recordkeeping requirement by reviewing only records (recordkeeping component of the HACCP procedures).

An occasion when a CSI may use the review and observation component to verify a recordkeeping requirement is when the CSI observes the establishment actually performing the pre-shipment review. The HACCP procedures that should be used for verification of the recordkeeping regulatory requirements will be specified throughout this section.

B. What is the regulatory requirement for recordkeeping?

9 CFR 417.2(c)(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.*

C. How do CSIs verify compliance with 9 CFR 417.2(c)(6)?

The CSI should review the HACCP plan to verify that it lists the records the establishment will use to document the monitoring of the CCPs. The CSI should review the HACCP records to verify that the establishment is recording actual values and observations that were obtained during the monitoring activities. The CSI should verify these requirements when performing the HACCP 01 procedure and HACCP 02 procedure. In verifying this requirement, the CSI should ask the following questions:

1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?

2. Do the records contain actual values and observations obtained during monitoring?

D. What are some examples of noncompliance?

- The HACCP plan does not provide for a recordkeeping system that documents the monitoring of the CCPs.

- The establishment is recording results with a check mark, rather than recording actual values and observations.

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

E. What are the requirements for supporting documentation?

9 CFR 417.5(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;*

(2) – The written HACCP plan, including decisionmaking documents associated with the selection and development of CCPs and critical limits, and documents

supporting both the monitoring and verification procedures selected and the frequency of those procedures.

NOTE: As part of the requirement above, establishments will have documentation that addresses the requirement in 9 CFR 417.4(a) that "every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis." The CSI should determine whether there is compliance with this regulation by verifying that the establishment has the documentation required in 9 CFR 417.5(a)(2).

F. How do CSIs verify compliance with these regulations?

CSIs should verify that there is compliance with these requirements by performing the HACCP 01 procedure. The CSI will verify these requirements by reviewing the hazard analysis, supporting documents for the hazard analysis, HACCP plan, decisionmaking documents associated with the selection and development of the CCPs and critical limits, supporting documentation for the verification procedures and frequencies, and supporting documentation for the monitoring procedures and frequencies. The CSI should use professional judgment on how much supporting documentation to request. The CSI should not just arbitrarily ask for supporting documents. The CSI should request supporting documents when he or she questions whether a decision made by the establishment is the appropriate one.

There are three possible outcomes for the verification of these requirements. Those three outcomes are compliance with the requirements, noncompliance with the requirements, and an inability to determine whether there is compliance because more information is needed.

1. The HACCP 01 procedure is documented as performed when the requirements are met.

2. The CSI issues an NR when there is noncompliance with the requirements.

3. The CSI provides the establishment with a 30-day letter when he or she is not able to determine whether there is compliance. In the 30-day letter, the CSI is to explain what information he or she needs the establishment to supply so he or she can determine whether there is compliance. The CSI is to provide the Frontline Supervisor with a copy of the 30 day letter. If the establishment fails to provide the CSI with the requested information within 30 days, the CSI is to contact the District Office, via supervisory channels, for instructions on further actions.

In verifying these recordkeeping requirements, the CSI should seek answers to the following type questions:

1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis?

2. Does the establishment have the decisionmaking documents associated with the selection of each CCP?

3. Do the documents explain why the establishment selected that location for the CCP?

4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?

5. Does the establishment have scientific, technical, or regulatory support for the critical limit?

6. Does the support appear credible?

7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?

a. If the CSI questions the monitoring frequencies, he or she should perform a monitoring check between the scheduled performances of the establishment's monitoring procedure.

b. If the CSI finds deviations, and the establishment has not, he or she should verify that the establishment addresses this issue.

8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?

9. If the establishment has supporting documents for these decisions, does the documentation support the decisions?

G. What are some examples of noncompliance?

- The establishment has no supporting documentation to support why it is not necessary to establish controls for food safety hazards identified in the hazard analysis.

- The establishment has no decisionmaking documents associated with the selection of the CCPs.

- The establishment has no scientific, technical, or regulatory support for the critical limit.

- The establishment has no documentation supporting the monitoring procedures and frequencies.

- The establishment has no documentation supporting the verification procedures and frequencies.

- The establishment has documentation, but the documentation does not support the decisions made.

NOTE: There are situations when the CSI needs more information to determine whether the establishment is meeting the requirements of 9 CFR 417.2. If the establishment is monitoring its critical limit every hour, and the only supporting documents that are available are the monitoring records for the past year, the CSI might need more information to determine whether the HACCP plan complies with 9 CFR 417.2. The CSI has not been trained in assessing the scientific and technical information that an establishment might have to support the HACCP system. The CSIs have resources available to assist them in evaluating this information. He or she can contact the PDD, or can contact the DO and request assistance from an EIAO.

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

H. What is the regulatory requirement for HACCP records?

9 CFR 417.5(a)(3) – *The establishment shall maintain: Records documenting the monitoring of CCPs 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.*

I. How do CSIs verify compliance with 9 CFR 417.5(a)(3)?

CSIs should verify these requirements by reviewing HACCP records that document the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit, a deviation not covered by a critical limit, or an unforeseen hazard. These requirements can be verified performing the HACCP 01 and HACCP 02 procedures. In verifying these requirements, the CSI should seek answers to the following questions:

1. Do the records document the monitoring of CCPs and their critical limits?

2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?

3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the

date the record was made?

4. Are the verification procedures and results of those procedures documented?

5. Is the time recorded when the verification activity was performed?

6. Does the record contain the date the record was made?

7. Are the process-monitoring calibration procedures and results being recorded?

J. What are some examples of noncompliance?

- The records do not have the monitoring results recorded.
- The records do not include actual times that monitoring or verification activities are performed.
- The records include entries such as “acc”, “ok”, or check marks rather than actual values for monitoring results.
- The monitoring entries do not include product identification or code.
- The records do not include the date the record was completed.
- Initials being recorded rather than the verification procedures and results.
- The corrective actions taken in response to a deviation from a critical limit, other deviation, or unforeseen hazard are not recorded.
- The results of the calibration of process monitoring instruments are not recorded.

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

K. What is the regulatory requirement for record authenticity?

9 CFR 417.5(b) – *Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*

L. How do CSIs verify compliance with 9 CFR 417.5(b)?

CSIs should verify this regulatory requirement by reviewing HACCP records documenting the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit or deviation not covered by a critical limit or unforeseen hazard. When verifying this regulatory requirement, the CSI should seek answers to the following questions when performing the HACCP 01 or HACCP 02 procedure:

1. Was each entry on the record made at the time the event occurred?

2. Does each entry include the time?

3. Was each entry on the record signed or initialed by the establishment employee making the entry?

M. What are some examples of noncompliance?

- Some entries on the records do not contain the time the event occurred.
- The records do not include the signature or initials of the person performing the activity.
- There is no date on the records.
- Results are not being recorded when the events occur.

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

NOTE: The HACCP monitoring records only need to have the date entered once on the form for all the entries made on that date.

N. What is the regulatory requirement for computerized records?

9 CFR 417.5(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.*

O. How do CSIs verify compliance with 9 CFR 417.5(d)?

The CSI can verify this recordkeeping requirement by performing the HACCP 01 or HACCP 02 procedure. The CSI should verify this requirement by requesting that the establishment demonstrate the controls that it has in place to ensure the integrity of the records. When verifying this requirement, the CSI should seek the answer to the following question:

Are appropriate controls provided to ensure the integrity of electronic data

and signatures?

P. What are some examples of noncompliance?

- The establishment does not have controls in place to ensure the integrity of the electronic records.

- The establishment has controls to ensure the integrity of the electronic records but is not following those controls, e.g., passwords and electronic signatures are not kept secure.

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

Q. What is the regulatory requirement for record retention and availability?

9 CFR 417.5(e)(1)(2)- *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 products, 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.*

R. How do CSIs verify compliance with 9 CFR 417.5(e)(1)(2)?

The CSI should verify that the records are being maintained the required amount of time by reviewing the HACCP records. The CSI should not routinely request past records to verify that HACCP records are being maintained for the appropriate time. If the CSI suspects that records are not being maintained for the required amount of time, he or she should contact the Frontline Supervisor for instructions. The CSI might request records stored off-site one time to ensure they can be provided, but it would not be necessary for the CSI to routinely request records that are stored off-site to verify this requirement. When verifying this recordkeeping requirement, the CSI should seek answers to the following questions performing the HACCP 01 or HACCP 02 procedure:

1. Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products?

2. Are the records kept on-site for 6 months?

3. If the records are stored off-site after 6 months, can they be retrieved in 24 hours?

S. What are some examples of noncompliance?

- The establishment is not maintaining records for the required length of time.

- The records are not being maintained on premises for 6 months.

- The establishment cannot retrieve the records within 24 hours when stored off-site.

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

T. What is the regulatory requirement for pre-shipment review?

9 CFR 417.5(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.

U. How do CSIs verify compliance with 9 CFR 417.5(c)?

FSIS considers product to be "produced and shipped" when the establishment completes pre-shipment review. Verifying that the establishment has completed pre-shipment review enables CSIs to know whether the company has taken full and final responsibility for applying its HACCP controls to the product that it has produced. The CSI should occasionally perform a verification check by observing the establishment employee perform the pre-shipment review. This type of observation is particularly important if the CSI is new to the establishment. Once the observation verification has been performed, this regulatory requirement can be verified using the recordkeeping component of the HACCP 02 procedure. The CSI should understand that pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment.

When verifying an establishment's pre-shipment review of its records by performing the HACCP 02 procedure, the CSI should seek answers to the following questions:

1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?

V. What are some examples of noncompliance?

- The establishment ships the product without conducting a pre-shipment review.

- The establishment performs pre-shipment review but does not sign and date the records.

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

VIII. Corrective Actions

A. What is the regulation that applies to corrective actions taken in response to a deviation from a critical limit?

9 CFR Part 417.3(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.*

B. How do CSIs verify compliance with 9 CFR 417.3(a)?

In every situation where there is a deviation from a critical limit, it is necessary for an establishment to take actions that meet the requirements of 9 CFR 417.3 and it is necessary for the CSI to verify that these requirements are met. CSIs are to verify that the required actions are taken by comparing the corrective actions taken by the establishment to the requirements of the regulation. The CSI should verify that the corrective action requirements are met as part of the HACCP 01 and HACCP 02 procedures. The CSI can verify these requirements by using the recordkeeping component or the review and observation component of the procedures. The corrective action requirements should be verified every time a deviation occurs. To verify compliance with the corrective action regulatory requirements, the CSI seeks answers to the following questions:

NOTE: When there product adulteration related to a deviation from a critical limit, a deviation not covered by a specified corrective action, or an unforeseen hazard, CSIs should only take a control action if the establishment fails to prevent adulterated product from entering commerce.

1. Did the establishment identify the cause of the deviation?

2. Did the corrective action eliminate the cause?

3. Did the corrective actions ensure that the CCP is brought under control?

4. Were measures implemented to prevent recurrence of the deviation?

5. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?

When seeking answers to these questions, the CSI should:

a. Review the corrective action records associated with the deviation from the critical limit and observe the establishment executing the corrective actions.

b. Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(a) to determine whether the corrective actions taken in response to the deviation from the critical limit meet all of these requirements.

c. Observe the establishment executing the corrective actions to verify that the establishment has identified the appropriate affected product.

d. Observe the establishment executing the corrective actions to verify that the establishment has identified and eliminated the cause of the deviation.

e. Observe the establishment executing the corrective actions to verify that the establishment's corrective actions have the CCP under control after the actions are taken.

f. Observe the establishment executing the corrective actions to verify that preventive measures are established.

g. Observe the establishment executing the corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering into commerce.

C. What are some examples of noncompliance?

- The establishment did not identify the cause of the deviation from a critical limit.

- The establishment identified the cause of the deviation from the critical limit, but did not take appropriate actions to eliminate that cause.

- The establishment did not implement appropriate measures to ensure that the CCP is under control after the actions were taken.

- The establishment did not implement measures to prevent the recurrence of the deviation.

- The establishment did not take appropriate measures to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce.

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

D. What regulation applies when there is a deviation not covered by a specific corrective action or an unforeseen hazard occurs?

9 CFR 417.3(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)…*

E. How do CSIs verify compliance with 9 CFR 417.3(b)(1)-(3)?

If an unforeseen hazard occurs, the CSI is to verify that the regulatory requirements of 9 CFR 417.3(b) are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR 417.3(b). The CSI should verify that these requirements are met each time there is a deviation not covered by specific corrective actions, or an unforeseen hazard occurs. These requirements should be verified as part of the HACCP 01 or HACCP 02 procedures. The CSI should answer the following questions to determine whether the corrective action requirements have been met:

1. Did the establishment segregate and hold **all** affected product?

NOTE: To determine what product is affected, consider such factors as the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?

3. Did the establishment take necessary action 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. Was a reassessment conducted to determine whether the newly

identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?

When seeking answers to these questions, the CSI should:

a. Review the corrective action records associated with the deviation or unforeseen hazard and observe the establishment executing the corrective actions.

b. Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(b)(1)(2)(3)(4) to determine whether the corrective actions taken meet all of these requirements.

c. Observe the establishment segregating and holding the affected product to verify that the establishment segregated and held **all** affected product.

d. Observe the establishment evaluating the affected product to verify that only acceptable product is released.

F. What are some examples of noncompliance?

- The establishment did not hold **all** affected product.
- The establishment held product, but it was not the product that was affected.
- The establishment did not evaluate the product to determine whether it was acceptable for distribution.
- The establishment evaluated the product and found it to be unacceptable for distribution, but did not take the necessary action to ensure that no product injurious to health or otherwise adulterated, as a result of this deviation, enters commerce.
- A reassessment was not conducted to determine whether the newly identified deviation or unforeseen hazard should be incorporated into the HACCP plan.

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

G. What is the regulation that applies to reassessment when a deviation not covered in the HACCP plan, or an unforeseen hazard occurs?

9 CFR 417.3(b)*(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.*

H. How do CSIs verify compliance with 9 CFR 417.3(b)(4)?

The reassessment requirement cannot be randomly verified because reassessment occurs when something triggers it, e.g., a deviation not covered by a specific corrective action or an unforeseen hazard, etc. The establishment is required to document its reassessment when it is triggered by a deviation not covered by a specific corrective action or unforeseen hazard. The CSI should verify that the establishment is meeting the reassessment requirement by reviewing the corrective action records when a deviation not covered by a specific corrective action or unforeseen hazard occurs. When verifying compliance with 9 CFR 417.3(b)(4), the CSI should seek to address the following type questions:

1. Was a reassessment conducted as a result of an unforeseen hazard?

2. Does the establishment have supporting documentation for the decisions made during the reassessment?

I. What are some examples of noncompliance?

- A deviation not covered by a specific corrective action or an unforeseen hazard occurred, and a reassessment was not conducted.

- The establishment conducted a reassessment in response to a deviation not covered by a specific corrective action or an unforeseen hazard and determined that the newly identified deviation or unforeseen hazard should not be incorporated into the HACCP plan, but had no supporting documentation for that decision.

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

IX. Reassessment Requirement

A. What is the regulation that applies to reassessment of the HACCP plan?

9 CFR 417.4(a)(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.

B. How do CSIs verify compliance with 9 CFR 417.4(a)(3)?

The establishment is not required to document reassessments that it conducts as a result of changes in its process, unless the reassessment reveals that modification of the HACCP plan is necessary. If the reassessment reveals that modification of the HACCP plan is necessary, the HACCP plan is to be modified immediately, and the HACCP plan is to be signed and dated. The establishment is also required to sign and date the HACCP plan to demonstrate that the annual reassessment has been conducted. The CSI is to review reassessment records, if available, and the HACCP plan to verify these requirements. When verifying compliance with 9 CFR 417.4(a)(3), the CSI should consider the following questions:

1. Did the establishment reassess?

2. Did the establishment consider all significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?

3. Has change occurred that could affect the hazard analysis or HACCP plan?

4. If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, did the establishment modify the HACCP immediately?

C. What are some examples of noncompliance?

- Reassessment revealed that the HACCP plan no longer meets the requirements of 9 CFR 417.2(c), and the plan was not immediately modified.

D. What are the regulatory requirements regarding the individuals who develop and reassess HACCP plans?

Under 9 CFR 417.7(b), the individual who performs the annual reassessment, as well as any person who develops a HACCP plan for an establishment under 9 CFR 417.2(b), or who modifies a HACCP plan, is to have completed a course of instruction in the application of the seven principles of HACCP to meat or poultry product processing, including a segment on the development of a

HACCP plan for a specific product and on record review. Also, the individual does not have to be an employee of the establishment (9 CFR 417.7(a)).

E. How do CSIs verify that the reassessments are conducted by trained individuals?

1. If CSIs determine during the performance of their duties that an establishment has implemented a new HACCP plan or hazard analysis, then he or she is to ask establishment management at the next weekly meeting after they determine that the new plan is in place whether the individual who prepared the plan met the training requirement in 9 CFR 417.7.

2. CSIs are to document the discussion from the weekly meeting in the weekly meeting notes:

NOTE: The establishment is not required to have documentation that the individual attended HACCP training. If the establishment does not maintain such documentation, CSIs should rely on information from establishment management.

3. CSIs are to verify the training requirements by asking such questions as:

- has the individual who prepared the plan successfully completed a course or training in the seven principles of HACCP to meat or poultry product processing?

- did the course or training include a segment on the development of a HACCP plan for a specific product?

- did the course or training include a segment on the review of records?

3. Whenever an establishment does not use an individual having the training required by 9 CFR 417.7 to develop, modify, or reassess its HACCP plan, CSIs are to document the noncompliance under 03A01 with the ‘M” basic noncompliance classification indicator and enter it as unscheduled under 03A01 in PBIS.

F. How do CSIs verify that an establishment has conducted the annual reassessment?

1. Once a year, as close as possible to the anniversary of the date that FSIS implemented HACCP (January 25-26th), CSIs are to verify that the establishment has:

a. performed its annual reassessment, at some point during the prior year, by reviewing its HACCP plans to verify that they have at least been dated and signed sometime during the previous calendar year, as required by 9 CFR 417.2(d)(2)(iii); and

b. complied with the training requirement for each of its HACCP plans at reassessment, including the annual reassessment, and when it made any modifications in its HACCP plans during the preceding year. CSIs are to perform this task using Performance Based Inspection System (PBIS) procedure 03A01. Because the verification of the training requirement will coincide with the verification of the annual reassessment, a separate ISP 03A01 is not recorded just for the training component of this verification activity.

2. CSIs are to record only one 03A01 procedure on the PBIS Procedure Schedule for each PBIS HACCP processing category (for example, 03B, 03C, 03D, 03E) that covers product the establishment produces, regardless of how many HACCP plans the establishment has under that HACCP processing category, or how many HACCP Systems – Basic Compliance checklists (FSIS Form 5000-1) CSIs complete.

NOTE: For example, if the establishment has a slaughter HACCP plan (03J), three raw ground product HACCP plans (03B), and two raw not ground product HACCP plans (03C), CSIs would record a total of three unscheduled 03A01 procedures in the PBIS procedure results screen. This number represents each of the three HACCP processing categories that cover products the establishment produces, even though the establishment has six HACCP plans. If the establishment has one HACCP plan that FSIS verifies using two PBIS HACCP processing categories (03J and 03C), then CSIs are to record two unscheduled 03A01 procedures in the PBIS procedure results screen.

3. CSIs are to:

a. complete, on FSIS Form 5000-1, HACCP Systems – Basic Compliance Checklist, for each HACCP plan the following applicable information:

i. Establishment Name;

ii. Establishment No.;

iii. Process;

iv. Reassessment Date; and

v. The last block, “4. Dated Signature,” if the establishment does not perform its annual reassessment. CSIs are to check the yes column of the form if the responsible establishment official did not sign and date the HACCP plan for the annual reassessment or when modified.

b. document this activity as “A” (performed) if there is compliance. If the establishment is in compliance, file the completed FSIS Form 5000-1 in the official file for three fiscal years; and

c. document noncompliance on a noncompliance record (NR) if the establishment has not signed and dated each of its HACCP plans during the calendar year or met the training requirement under 9 CFR 417.7 for each of its HACCP plans, using the noncompliance result code “M - Basic” and citing:

i. 9 CFR 417.7 for not meeting the training requirement;

ii. 9 CFR 417.2(d) and 9 CFR 417.4(a)(3) for not meeting the annual reassessment requirement; or

iii. all three regulations if the establishment has not reassessed and does not meet the training requirement.

NOTE: If the IIC has concerns regarding the design of the HACCP plan, he or she is to contact the District Office for direction.

d. attach the completed FSIS Form 5000-1 to the copy of the NR and maintain a copy in the official file.

D. What regulation applies to reassessment of the hazard analysis?

9 CFR 417.4(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.*

E. How do CSIs verify compliance with 9 CFR 417.4(b)?

1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur?

2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?

3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

F. What are some examples of noncompliance?

- The establishment has a process with no HACCP plan, changes occurred that could affect whether a food safety hazard exists, and the establishment did not conduct a reassessment of the hazard analysis.

- Changes occurred that could affect whether a food safety hazard exists, reassessment was conducted, the reassessment revealed that a food safety hazard exists, and no HACCP plan was developed.

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

CHAPTER III - PATHOGEN REDUCTION ACTIVITIES

I. *E. coli* Testing

The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter facilities. The following discussion explains how CSIs are to verify that the establishment is maintaining such controls.

A. What is the general requirement for *E. coli* testing?

Section 310.25 states: (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. The establishment shall:

(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 locations(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedures shall be made available to FSIS upon request.

(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."

B. How will Frontline Supervisors verify the basic requirement of these regulations?

At the time an establishment is granted inspection, the Frontline Supervisor will verify that the written *E. coli* testing procedures meet the basic regulatory requirements. The Frontline Supervisor completes the *E. coli* Basic Compliance Checklist (FSIS Form 5000-3) when performing the 05A01 procedure. This procedure is only performed once. When the procedure is performed, the Frontline Supervisor should use this checklist to verify the written procedures meet the regulatory requirements:

1. Do the written procedures contain procedures for collecting samples for *E. coli* testing?

2. Do the written procedures identify the establishment employee designated to collect the samples for *E. coli* testing?

3. Do the written procedures address the location of sampling?

4. Do the written procedures describe how sampling randomness is achieved?

5. Do the written procedures describe how the samples are handled to ensure sample integrity?

6. Is the establishment collecting samples for *E. coli* testing?

7. Is the establishment recording the analytical results of *E. coli* tests on a process control chart or table?

NOTE: If the Frontline Supervisor performs the 05A01 procedure and determines that the *E. coli* written procedures do not meet regulatory requirements, he or she should meet with establishment management to inform them that they need *E. coli* testing procedures. If the establishment fails to adequately respond to the Frontline Supervisor's request, he or she should contact the DO to inform them of the situation. If there are changes to existing procedures, CSIs are to notify the Frontline Supervisor.

C. What general procedures will CSIs follow?

Each official establishment that slaughters livestock or poultry is required to test for *Escherichia coli* Biotype 1. There are 2 procedures (05A01 and 05A02) that CSIs use to verify that these establishments meet the *E. coli* regulatory requirements. The basic regulatory requirements are in 9 CFR 310.25(a)(1) – (4) for livestock slaughter establishments. The basic regulatory requirements for poultry slaughter establishments are set out in 9 CFR 381.94(a)(1) – (4). The regulatory requirements for livestock will be used in this document when the livestock and poultry regulations are the same. When there are differences in the regulations, both regulations will be listed. If CSIs find noncompliances while carrying out the methodologies below, they are to follow the noncompliance determination and documentation instructions in Chapter IV of this document.

D. How will the CSI verify the on-going compliance with 9 CFR 310.25(a)?

The CSI will verify all other requirements when performing the 05A02 procedure. The CSI will utilize FSIS Form 5000-4 to verify that these regulatory requirements are met.

E. How do CSIs verify that establishments are collecting samples from the correct type of livestock or poultry?

When verifying the sample collection requirements, the CSI will seek an answer to the following question: Is the establishment collecting samples from the type of livestock or poultry that it slaughters in the greatest numbers?

F. What is an example of noncompliance?

- The establishment slaughters pork in the greatest numbers but is collecting samples from beef carcasses.

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

II. Sample Collection

A. What regulations apply to sample collection?

Paragraph 310.25(a)(2)(ii) states: *Sample collection. The establishment shall 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.*

Paragraph 381.94(a)(2)(ii) states: 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 colleted 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.

B. How will the CSI verify these regulations?

When verifying these requirements, the CSI will seek answers to the following questions:

1. Is the establishment collecting samples at the required location in the process?

2. Is the establishment collecting samples by sponging or excising tissue from the required sites on a livestock carcass, or whole-bird rinsing a chicken or turkey carcass, or sponging a turkey carcass?

C. What are some examples of noncompliance?

- The establishment is not collecting samples from chilled carcasses, and the establishment is not hot boning.

- The establishment is sponging tissue from areas of the carcass other than the flank, brisket, and rump.

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

III. Sampling Frequency

A. What are the regulations that apply to sampling frequency?

Paragraph 310.25(a)(1)(i) states: Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

Paragraph 310.25(a)(2)(iii) states: 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:

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

Swine: 1 test per 1,000 carcasses, but at a minimum of one sample during each week of operation.

Paragraph 381.94(a)(2)(iii) states: Sampling frequency. Slaughter establishments except very low volume establishments 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:

Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation.

Turkeys, ducks, geese, and guineas: 1 sample per 3,000 carcasses, but a minimum of one sample during each week of operation.

Paragraph 310.25(a)(2)(iv) states: 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.

Paragraph 310.25(a)(2)(v) states: 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.

Paragraph 381.94(a)(2)(v) states: 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.

B. How do CSIs verify compliance with these regulations?

When verifying these regulatory requirements, the CSI should seek answers to questions similar to the following:

1. Is the establishment collecting samples at the frequency specified in 9 CFR 310 (a)(2)(iv)?

2. If an establishment is operating under a validated HACCP plan that has substituted an alternative frequency, is the alternative frequency an integral part of the HACCP plan verification procedures?

3. Has FSIS notified the establishment in writing that the alternative frequency is inadequate to verify the effectiveness of process control?

4. If the establishment is sampling based on very low volume, does the volume of animals slaughtered meet the criteria for that sampling rate?

C. What are some examples of noncompliance?

- A swine slaughtering establishment that does not qualify as a very low volume plant is not sampling at the rate of 1 per 1,000 slaughtered or a minimum of one sample each week of operation.

- A chicken slaughtering establishment that does not qualify as a very low volume plant is not sampling at the rate of 1 per 22,000 slaughtered or a minimum of one sample each week of operation.

- An establishment that does not qualify as a very low volume plant is sampling at the rate specified for very low volume rate of slaughter.

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

IV. Sample Analysis

A. What are the regulatory requirements for sample analysis?

Paragraph 310.25(a)(1)(ii) states: *Obtain analytic results in accordance with paragraph (a)(3) of this section.*

Paragraph (a)(3) states: 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.

B. How do CSIs verify compliance with these regulations?

When verifying these regulatory requirements, the CSI will seek an answer to the following question: Is the laboratory analyzing the samples using an AOAC Official Method or another method that meets the criteria in paragraph (a)(3)?

C. What is an example of noncompliance?

- The laboratory analyzing the samples is not using an AOAC-approved method to obtain analytic results of the *E. coli* samples.

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

V. Recording of Test Results

A. What are the regulatory requirements for recording test results?

Paragraph 310.25(a)(1)(iii) states: *Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.*

Paragraph (a)(4) states: 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.

B. How do CSIs verify compliance with this regulation?

When verifying these requirements, the CSI should seek answers to the following questions:

1. Does the establishment's process control chart or table show at least the most recent 13 *E. coli* results?

2. Does the establishment's process control chart or table express *E. coli* results in terms of CFU/cm^2 of surface area sponged or excised by type of livestock slaughtered, or CFU/ml of fluid by type of poultry slaughtered?

3. Is the establishment retaining records of test results for 12 months?

C. What are some examples of noncompliance?

- The establishment's process control chart or table does not show the most recent 13 *E. coli* results.

- The establishment's process control chart or table does not express *E. coli* results in CFU/cm^2 of surface area sponged or excised by type of livestock slaughtered, or CFU/ml of fluid by type of poultry slaughtered.

- The establishment is not retaining records of test results for 12 months.

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

VI. Evaluation of Results

A. What is the regulatory table for the evaluation of results?

Table 1 – Evaluation of *E. coli* Test Result

Type of Livestock	Lower limit of marginal range	Upper limit of marginal range	Number of sample tested	Maximum number permitted in marginal range

	(m)	(M)	(n)	(c)
Cattle	Negative	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000CFU/cm^2	13	3
*Chickens	100 CFL/ml	1,000 CFU/ml	13	3
*Turkeys	N.A.[a]	N.A.	N.A.	N.A.

[a] Not available; values for turkeys will be added upon completion of data collection program for turkeys.
* This portion of the Table 1was extracted from Table 1of § 381.94(a)(5).

B. How do CSIs verify compliance with this regulation?

If an establishment is sampling for *E. coli* by excising tissue, CSIs should verify that the results comply with the table above. If an establishment is sampling for *E. coli* by sponging carcasses, CSIs should verify that the establishment is evaluating the test results using statistical process control techniques. The CSI should verify that establishments that slaughter turkeys evaluate *E. coli* test results using statistical process control techniques. When verifying these regulatory requirements, the CSI should seek answers to the following questions:

1. If Table 1 does not include applicable m/M criteria, is the establishment using statistical process control techniques to determine what variation in test results is within normal limits?

2. If Table 1 includes applicable m/M criteria, is the establishment determining whether it is operating within these criteria?

C. What are some examples of noncompliance?

- The establishment is sponging livestock carcasses and is not using statistical process control techniques to evaluate *E. coli* test results.

- The establishment slaughters turkeys and is not using statistical process control techniques to evaluate *E. coli* test results.

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

CHAPTER IV - ENFORCEMENT

I. FSIS Form 5400-4, Noncompliance Record (NR)

A. The NR and NR Continuation Sheet are to be completed in the Performance-Based Inspection System (PBIS) Electronic format following the instruction in the User's Guide for PBIS 5.1.8.

B. Grouping of Noncompliance

1. Food Safety
   Any 01 - SSOP
   Any 03 - HACCP
   06D01 - Sanitation Performance Standard

2 Other Consumer Protection
   Any 04 - Economic/Wholesomeness
   05B01 - Economic Sampling- Scheduled
   06D02 - Inspection Requirements

3, FSIS Verification Sampling
   05A01 - micro. sampling for *E*. *coli*
   05A02 - micro. sampling for *E*. *coli*
   05A03 - micro. sampling for *Salmonella*
   05B02 - Directed sampling
   05C01 - Residue

BLOCK #

1. -3. Automatically completed in PBIS 5.1.8. (note if for some reason PBIS is not operational, a paper copy of the Noncompliance Record generated from PBIS may be utilized).

2. **To (Name and Title)**—PBIS 5.1.8 will provided a list of names from the PBIS Establishment profile Contact tab information to select from or enter the name and title of the responsible establishment official if not listed. For a HACCP system noncompliance, always enter the name of the person who signed the HACCP plan. For a Sanitation SOP regulation noncompliance, always enter the name of the person who signed the Sanitation SOPs. For SPS noncompliance, the CSI should enter the name of the establishment official responsible for responding to the NRs.

3. ***Personnel Notified***—PBIS 5.1.8 will automatically fill this field. If a different person was notified, enter the name of the establishment management personnel who was/were notified about the noncompliance.

4. ***Relevant Regulations***—PBIS 5.1.8 will provide a listing of potential regulatory citations. Select all the specific regulatory requirements that the

establishment did not meet. For example, if the establishment did not take corrective action in response to a deviation from a critical limit and the product in question contained Specified Risk Materials (SRMs), then the CSI would select 417.3 (a) and 310.22(b). CSIs are to use the window found in PBIS 5.1.8.

5. **Relevant Section/Page of Establishment Procedure/Plan**—Enter the section or page of the establishment's procedure or plan when the noncompliance represents the failure to comply with the written provisions of their procedure or plan. For example, if the monitoring frequency listed in the HACCP plan is hourly, and the establishment performs the procedure every two hours, there is monitoring noncompliance. CSIs record the section or page of the HACCP plan that lists the monitoring frequency. Place an "X" in the appropriate box to reference the type of procedure or plan. *E. coli* and alternate processing procedure noncompliance are considered "other." When the noncompliance is not related to a procedure or plan, enter N/A.

6. **ISP Code**—In PBIS 5.1.8, the procedure code is selected or added as an unscheduled procedure and will be automatically entered on the electronic NR. See the PBIS User's Guide for detailed information on the procedure codes.

7. **Noncompliance Classification Indicators**--In PBIS 5.1.8 the trend is entered in the procedure results screen. The Proc Detail tab will provide the classification trend indicators for each procedure. Enter the letter that best describes the noncompliance.

8. **ISP Code**—In PBIS 5.1.8, the procedure code is selected or added as an unscheduled procedure and will be automatically entered on the electronic NR. See the PBIS User's Guide for detailed information on the procedure codes.

9. **Noncompliance Classification Indicators**--In PBIS 5.1.8 the trend is entered in the procedure results screen. The Proc Detail tab will provide the classification trend indicators for each procedure. Enter the letter that best describes the noncompliance.

10 **Description of Noncompliance**—

CSIs are to include in Block 10 of a noncompliance record the following:

- A description of each noncompliance in clear, concise terms, including the exact problem, time of occurrence, location, and effect on the product, if any.

- An explanation of how they notified establishment management of the noncompliance.

- When there is a developing trend of noncompliance, the number of the previous NR with the same cause and a description of how the NR derived from the same cause. Also, CSIs are to describe any

unsuccessful further planned actions taken by the establishment to address the noncompliances. Additionally, CSIs are to indicate whether they have discussed the developing trend of noncompliance with establishment management.

- Any applicable deadlines.

- Whether a regulatory control action (US Retain/Reject tag) was applied, and if so, the number on the tag(s).

NOTE: In most cases, it is not necessary to include in Block 10 references to the Acts or to quote the applicable regulation in full.

Examples of information to be included in Block 10:

- At approximately 0410 hours, after the establishment's pre-operational inspection and before the start of production, I performed procedure 01B02. I observed the following noncompliances: Rust on the auger and auger throat of the #2 grinder; rust on the auger and blender arms of the small Hobart grinder; rust on the crossbar on top of the hopper to the stuffer; and dried residue on the blade guides and the bottom of the pulley on both band saws. I applied U.S. "Reject" tags # B 1469277, B 1469278, B 1469279, B 1469280, and B 1469281 to the #2 grinder, the small Hobart grinder, the stuffer, and both band saws, respectively. I informed the foreman who immediately had the equipment appropriately cleaned to restore sanitary conditions. Verbally the foreman provided the following preventive measure: increasing the amount of time spent conducting pre-op monitoring and giving instructions to the cleaning crew to be more observant. A similar noncompliance was documented on NR 05-07, dated February 13, 2007. The preventive measures of modifying the Sanitation SOPs to include a procedure for cleaning the saw blades in a manner that will prevent rust formation and a procedure for soaking the cuber in an acid solution were not implemented or were ineffective in preventing recurrence. Continued failure to meet these regulatory requirements could result in additional regulatory or administrative action.

- At approximately 1425 hours, I observed condensation dripping from pipes in the ceiling onto chicken parts on belt #1 in the processing boning room. Belt #1 was U.S. "Rejected" with tag #578688. Approximately 30# of product was U.S. "Retained" with tag #578689. Ms. Jane Doe was notified of the direct contamination of product and the insanitary condition of belt #1. She was informed that the regulatory control actions would remain in effect until the establishment meets the requirements of 9 CFR 416.15 and 416.2.

- At approximately 0940 hours, I observed the QA technician taking the temperature of 5 chicken filets exiting the oven on line #1 for CCP 2. After taking the temperature of the 5 chicken filets, I observed the QA technician record the temperatures in the establishment's HACCP

records. The QA technician then left the processing area. I reviewed the HACCP records for that CCP for that day and found that only 5 filets per each hourly check were recorded for that shift starting at 0530. The establishment's monitoring procedures and frequency for CCP 2 require the QA technician or designee to record the temperature of 10 chicken filets exiting the oven on line #1 every hour. The temperature of the product recorded for that day has met the critical limit of ≥ 160oF. I retained the product with U.S. "Retained" tag #687423 and rejected the belt and oven with U.S. "Rejected" tag #687424. Ms. Jane Doe was notified of the noncompliance. She was informed that the regulatory control actions would remain in effect until the establishment demonstrated product safety.

11. ***Signature of Inspection Program Employee****--The IIC or CSI signs the NR after the NR has been finalized and printed.* A NR can only be made final by printing a hard copy.

12 & 13. **Plant Management Response**—On the printed NR, the "immediate action" and "further planned action" blocks are completed by the establishment. When the establishment elects to respond, the "immediate action" is the action the establishment is taking to correct the noncompliance including appropriate product disposition. The "further planned action" is the action to prevent recurrence. CSIs should document an oral response by the plant management.

14 & 15. **Signature of Plant Management and Date**--If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the NR.

16 & 17. **Verification Signature of Inspection Program Employee and Date** – To indicate that an NR is closed, the IIC or CSI is to sign these lines. Then open the "Manage NR" screen, select the NR number to be closed and change the status block from open to closed. Only a final NR can be closed.

NOTE: The NR can only be closed after CSIs have verified that the establishment has brought itself into compliance with the regulatory requirement that was not met and resulted in the issuance of the NR. If the non-compliance necessitates the establishment to take actions as required by 9 CFR 416.15 or 417.3, the NR can only be closed after CSIs have verified that the establishment has met the requirements of 9 CFR 416.15 and 417.3. Remember, the establishment is not required to indicate its corrective and preventive measures on the NR and CSIs may need to verify corrective actions by reviewing establishment records.

C. How is the continuation sheet completed?

In addition to the NR, there is a Continuation Sheet, FSIS Form 5400-4a, that is used only when the CSIs need extra space, or when multiple CSIs conduct verification of pre-operational sanitation inspection procedures in elements 01B and 01C. When using the NR Continuation Sheet for extra space, CSIs can just

check the box next to the word “Attachment” in the top right corner of the sheet, and complete blocks 1-3,10,11 and 12.

II. Documentation of SPS Noncompliance

A. What are the general procedures for documenting the SPS verification activities?

The CSI performs ISP procedure 06D01 to verify compliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements. Every time the CSI finds that the establishment is not meeting the SPS requirements, he or she should document the noncompliance on the NR. If the noncompliance is failure by the establishment to comply with the SPS, the Food Safety block is checked on the NR.

There are four trend indicators associated with procedure 06D01. Those trend indicators are lighting, structural, outside premises, and product based. Only one of these trend indicators can be used for each NR issued. If more than one trend indicator applies, the CSI should use the most appropriate one to describe the noncompliance. If the determination has been made that there is regulatory noncompliance, the CSI should include the regulation citation in Block 6 of the NR.

B. When is the lighting trend indicator used?

The lighting trend indicator is used when there is noncompliance with lighting requirements. If inadequate light causes the quality or intensity of lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether the product is not adulterated, the lighting trend indicator should be marked on the NR (see Chapter I, Part IV).

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

C. When is the structural trend indicator used?

The structural trend indicator is used when structural regulatory requirements are not met. The CSI should use the structural trend indicator when structural noncompliances are observed, such as holes in the wall, cracks or holes in the floor, or condensation on overheads that create insanitary conditions or could result in product adulteration. (see Chapter I, Part III).

D. When is the outside premises trend indicator used?

The outside premises trend indicator is used when the CSI finds that the regulatory requirements for outside premises are not met. For example, the CSI should use the outside premises trend indicator when he or she observes an accumulation of trash or rubbish outside the establishment that permits harborage and breeding of pests. (see Chapter I, Part II).

E. When is the product based trend indicator used?

The product based trend indicator is used when there is noncompliance involving product that does not result in misbranding, mislabeling, or direct product contamination that is covered by the Sanitation SOPs. For example, the CSI observes product from the previous day's production on a wall before the start of operations that creates an insanitary condition, he or she should use the product based trend indicator. (see Chapter I, Part XII).

F. What actions should be taken when noncompliance with the SPS regulations is observed?

If an establishment has not complied with a sanitation performance standard, and product is not directly contaminated, CSIs need to determine whether the noncompliance requires a regulatory control action to prevent contamination or adulteration of product.

1. If there is an imminent probability that the noncompliance will result in product adulteration if not addressed immediately, CSIs will take a regulatory control action such as tagging product or rejecting equipment and complete a NR.

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

If an establishment has not complied with a sanitation performance standard, and product is directly contaminated, CSIs will verify that the establishment addresses the noncompliance by meeting the requirements of 9 CFR 416 or 9 CFR 417 as described below. CSIs will write an NR using the appropriate 01 (Sanitation SOP) or 03 (HACCP) ISP procedure code.

1. If direct product contamination occurs, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 416.15. The establishment may need to re-evaluate the effectiveness of its Sanitation SOPs and modify them if they are no longer effective in preventing direct contamination or adulteration of product.

2. If the direct product contamination poses a food safety hazard, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 417.3(b). These corrective

actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the HACCP plan.

III. Documentation of Sanitation SOP Noncompliance

A. What do CSIs document?

The CSI performs the Sanitation SOP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 416.12 – 416.16. When the CSI determines that the establishment does not meet one of these regulatory requirements, he or she should document the noncompliance on an NR, marking the most appropriate trend indicator and the food safety box.

The four trend indicators for Sanitation SOP are:

1. monitoring,
2. implementation,
3. recordkeeping, and
4. corrective actions.

NOTE: Only one trend indicator should be used for each NR issued.

B. When is the monitoring trend indicator used?

The CSI should mark the monitoring trend indicator on the NR when he or she determines that the plant fails to monitor its pre-operational or operational sanitation procedures daily or at the frequency specified in the Sanitation SOP. When the CSI observes contaminated product or contaminated direct contact surfaces that the establishment monitor did not detect, the monitoring trend indicator is used. (see Chapter I, Part XIV).

C. When is the corrective action trend indicator used?

The CSI should mark the corrective action trend indicator when the establishment does not meet the corrective action requirements. This trend indicator should be marked on the NR when the establishment does not take corrective actions to meet the requirements in 9 CFR 416.15. This trend indicator should be used when FSIS determines that the corrective actions taken are not adequate to restore sanitary conditions. It would be the appropriate trend indicator to use if the establishment did not implement measures adequate to prevent recurrence. If the establishment did not implement corrective action to ensure appropriate disposition of contaminated product, this would be the appropriate trend indicator. (see Chapter I, Part XVI).

D. When is the recordkeeping trend indicator used?

The CSI should use the recordkeeping trend indicator when there is noncompliance with 9 CFR 416.16. This trend indicator would be marked when the records are not being maintained daily or retained for the required period of time, or the plan fails to record the results of the monitoring check. This is the appropriate trend indicator to use when the establishment is not documenting the corrective actions taken when FSIS or the establishment determines the Sanitation SOP did not prevent direct contamination or adulteration of product. This trend indicator would also be marked on the NR when the records have not been initialed and dated. (see Chapter I, XVII).

E. When is the implementation trend indicator used?

The CSI uses the implementation trend indicator when he or she finds two regulatory requirements that have not been met during the performance of one procedure. For example, if the CSI is performing the 01C02 procedure and finds that the establishment is not monitoring the operational procedures at the stated frequency and did not initial and date the daily sanitation records, the appropriate trend indicator to use is implementation.

F. What actions do CSIs take when noncompliance with the Sanitation SOPs is observed?

1. When the CSI is performing a PBIS scheduled 01B02 or 01C02 Sanitation SOP procedure and observes direct contact surfaces or product that is contaminated, he or she should take a regulatory control action on the equipment or product. He or she should not remove the regulatory control action until the establishment has proposed corrective actions that 1) ensure appropriate disposition of products, 2) restore sanitary conditions, and 3) prevent recurrence of direct contamination or adulteration of products. The CSI documents the noncompliance on the NR. If the CSI is performing the 01B01 or 01C01 Sanitation SOP procedure and observes that the establishment official responsible for the implementation and monitoring of the Sanitation SOP did not initial and date the record, the CSI documents the noncompliance on the NR, although no regulatory control action would be required.

2. When the CSI is performing an unscheduled 01B02 or 01C02 Sanitation SOP procedure and observes noncompliance, during overtime hours or after they have performed a scheduled 01B02 or 01C02 Sanitation SOP procedure, they are to document that noncompliances on a separate NR.

NOTE: If the establishment has found the noncompliance and taken the corrective actions required, there is no noncompliance. The CSI should verify that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces. If the establishment finds that the responsible individual did not initial and date the record and implemented immediate and

further planned actions and records these actions, the CSI should not document this as noncompliance.

G. What actions do CSIs take when noncompliance is found with both SPS and Sanitation SOP regulatory requirements?

If the CSI is performing one of the sanitation procedures (06D01, 01B02, 01C02) and observes noncompliance with the SPS and Sanitation SOP regulatory requirements, all of the findings would be documented under the appropriate Sanitation SOP procedure. If the CSI is performing the 01B02 or 01C02 procedure and only observes noncompliance with the SPS regulations, he or she should document the Sanitation SOP procedure as performed on the Procedure Schedule, and issue a NR under the 06D01 procedure. If the CSI is performing the 06D01 procedure and only observes Sanitation SOP noncompliance, he or she should document the 06D01 procedure as performed and issue a NR for the Sanitation SOP noncompliance using the appropriate procedure (01B02 or 01C02).

IV. HACCP Noncompliance Determinations

A. What is the difference between a deviation from a critical limit and HACCP noncompliance?

A deviation from a critical limit is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take actions in accordance with 9 CFR 417.3.

A HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR part 417, monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance.

B. What should CSIs consider before making a noncompliance determination?

Before making a determination that there has been noncompliance, consider the following questions:

1. Has the establishment already identified the failure to meet the regulatory requirements or deviations from critical limits?

2. If product is involved, has the establishment ensured product safety?

3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken the 9 CFR

417.3 corrective and preventive measures to address the deviations?

4. Is a trend developing (i.e., has the establishment repetitively carried out the actions in 1 through 3 above for similar situations)?

NOTE: In answering these questions, it may be necessary to consider additional records.

If the answer is no to questions 1, 2, or 3, or yes to question 4, then a noncompliance exists. CSIs will write an NR and perform a HACCP 02 procedure.

If the answer is yes to 1 through 3 and no to question 4, then there is no noncompliance because the establishment has already identified and addressed the situation. The HACCP 01 should be considered performed, and no other action is necessary. Because the establishment's response provides the further planned actions and preventive measures for the noncompliance or deviation, not writing an NR does not adversely affect an inspection program employee's ability to track developing trends. However, an establishment's failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant NRs in recurring situations.

C. What are some situations that CSIs may encounter that will require a determination as to whether there is a noncompliance?

NOTE: For purposes of consistency, all the examples below use a monitoring example. The methodology applies to problems with verification, recordkeeping, reassessment and corrective actions as well.

EXAMPLE 1*:* While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check. The inspector then finds that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate corrective and preventive measures for the noncompliance by re-training the employee. Also, the inspector looked at previous NRs and determined that the establishment had not missed a monitoring check in over three months. In this situation no NR is necessary even though there was a missed monitoring check, and the HACCP 01 procedure is marked as performed. However, if the inspector finds that adequate preventive measures were not in place, and that the missed monitoring check and correction had occurred several times within the month, he or she may determine that a trend for monitoring noncompliance has developed. In this case he or she will issue an NR and discuss this trend with establishment management during the weekly meeting.

EXAMPLE 2: While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check and finds no indication that the establishment identified the missed monitoring check. He or she writes an NR for the HACCP 01 procedure. Then

he or she performs a HACCP 02 procedure and finds that the product was shipped without a pre-shipment review. In this situation the inspector writes an NR that explains this noncompliance. Next he or she determines whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, the inspector would take action under the Rules of Practice, 9 CFR part 500.

EXAMPLE 3: While performing the HACCP 01 procedure records review, an inspector observes that an establishment employee recorded a deviation from a critical limit on the monitoring record. The inspector verifies that the corrective actions taken by the establishment meet the requirements of 9 CFR 417.3(a). There is no regulatory noncompliance, and an NR is not necessary.

EXAMPLE 4: While performing the HACCP 02 procedure records review for a single lot of product, an inspector sees in the records that an establishment employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. The inspector continues to review the records and finds that at pre-shipment review the establishment identified the deviation and took the proper 9 CFR 417.3 corrective and preventive measures but failed to address the monitoring error. In this situation the inspector writes an NR for the monitoring error and determines whether the establishment can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the establishment cannot support product safety, the inspector should take action in accordance with the Rules of Practice, 9 CFR part 500.

D. How do CSIs document a HACCP noncompliance?

The CSI performs the HACCP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 417.2 – 417.7. The five requirements that the CSI verifies when performing these procedures are **monitoring, verification, corrective actions, recordkeeping, and reassessment**. When the CSI performs one of the HACCP procedures and determines that there is regulatory compliance, he or she documents that the procedure is performed on the procedure schedule. When the CSI determines that the establishment does not meet one of the regulatory requirements, he or she documents the noncompliance on an NR, marking the appropriate trend indicator. The four trend indicators for HACCP are monitoring, corrective action, recordkeeping, and establishment verification. Only one trend indicator should be used for each NR issued.

E. When do CSIs use the monitoring trend indicator?

A CSI should use the monitoring trend indicator when he or she determines that there is noncompliance with the monitoring requirement. This trend indicator should be marked: 1) if the CSI determines the establishment is not monitoring the critical limit at the frequency stated in the HACCP plan; 2) if the CSI determines the establishment is not monitoring the critical limit using the procedures described in the HACCP plan; or 3) if the CSI finds a deviation from the critical limit that the establishment has no way of detecting.

F. When do CSIs use the verification trend indicator?

The CSI should use the establishment verification trend indicator when: 1) the establishment is not conducting the verification activities as described in the HACCP plan, or 2) the establishment is not conducting the verification activities at the frequencies described in the HACCP plan.

G. When do CSIs use the corrective action trend indicator?

The corrective action trend indicator should be used when a deviation or an unforeseen hazard occurs, and the corrective action taken by the establishment does not meet the regulatory requirements. The CSI should use the corrective action trend indicator if the corrective actions taken in response to a deviation from a critical limit did not: 1) appropriately address identifying and eliminating the cause of the deviation; 2) include measures to ensure that the CCP is under control; 3) include measures to prevent the deviation or unforeseen hazard from recurring; or 4) include appropriate disposition of the product.

NOTE: For this trend indicator, the CSI is only to document an establishment's failure to meet the requirements of 9 CFR 417.3. If the establishment finds the deviation or unforeseen hazard and takes the corrective action necessary to meet the regulatory requirements, there is no noncompliance.

H. When do CSIs use the recordkeeping trend indicator?

The CSI should use the recordkeeping trend indicator when: 1) The monitoring records do not include the actual times, temperatures, or other quantifiable values, the calibration of process-monitoring instruments, corrective actions, verification procedures and results, product identity, signature or initials of the person making the entry, or the date the record is made; 2) the establishment does not have the decisionmaking documents associated with the selection and development of the CCPs and critical limits, and documents supporting both the monitoring and verification procedures and frequencies; 3) the establishment did not conduct pre-shipment review; or 4) the establishment is not retaining HACCP records for the required length of time.

V. *E. coli* Noncompliance Determination

A. How do the CSIs determine noncompliance?

When the CSI performs the 05A02 procedure (see Chapter III), noncompliance exists if he or she determines:

1. The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number.

2. The establishment is not collecting samples at the location in the slaughter process required by the regulations.

3. The establishment is not collecting samples by sponging or excising tissue from the required sites on a livestock carcass, whole-bird rinsing or sponging on the required sites of a turkey carcass or whole-bird rinsing chickens.

4. The establishment is not collecting samples at the required frequency.

5. The establishment is not sampling randomly as per its written procedure.

6. The establishment is not having the samples analyzed at a laboratory using an AOAC Official Method or another method that has been approved and published by a scientific body.

7. The establishment's records of test results do not include at least the most recent thirteen test results.

8. The establishment's records do not express *E. coli* test results in terms of colony forming units per square centimeter when excision tests are used for cattle and swine or sponge tests are used for cattle, swine, or turkeys; or test results are not expressed in colony forming units per milliliter when the whole bird rinse method is used.

9. The establishment is not retaining records of test results for twelve months.

10. Table 1 in the regulations does not include applicable m/M criteria, and the establishment is not using a statistical process control technique to determine how much variation in test results is within normal limits.

11. Table 1 in the regulations includes applicable m/M criteria, and the establishment is not determining whether it is operating within these criteria.

B. How will the CSI document findings?

When the CSI makes the determination that one or more of the above requirements are not met, the CSI should document the noncompliance on an NR. The "other" trend indicator is always used with the 05A02 procedure.

VI. Linking NRs

A. When should NRs be linked?

The CSI should only link NRs when the noncompliances are from the same cause. For example:

- If repetitive condensation findings are occurring, the CSI should be linking NRs together to document that there is a trend occurring. This trend may be because the preventive measures are either not implemented or are

ineffective in preventing this noncompliance. However, a CSI should use professional judgment in making the determination whether NRs should be linked. If the establishment has shown a substantial period of compliance, the CSI should not link the NR to previous NRs with the same cause, unless there is a compelling circumstances that justifies doing so, for example, the exact same circumstance that brought about the initial NR has reoccurred.

- An NR under procedure 06D01 for condensation can be linked to an NR written for condensation under procedure 01B02 or 01C02 as the cause is the same. However, an NR written for condensation under 06D01 should not be linked to an NR written for water dripping from the ceiling, from a roof leak, under 06D01. They are both noncompliances and both are water dripping from the ceiling. Both are documented under the same procedure code and the same trend indicators. However, the noncompliance for condensation is from a different cause than the noncompliance for the roof leak.

When the CSI links one NR to another, he or she should reference the previous NR number and date as well as the further planned action that was ineffective in preventing recurrence of the noncompliance. For example:

- The CSI issued NR 25-02 on July 1, 2002, for condensation and the establishment's further planned action was to install fans. On July 8, 2002, the CSI again observes condensation. If the CSI links these NRs, he or she should document in Block 10, that the same or similar noncompliance was documented on July 1, 2002, on NR 25-02. The further planned action of installing fans was ineffective in preventing the condensation noncompliance.

When the CSI starts linking NRs, he or she should be discussing these linkages with plant management during the weekly meetings. The CSI should also include in Block 10 of the NR that these discussions were held.

The purpose of linking NRs is to provide notification to the establishment that the further planned actions are ineffective in, or were not implemented in a way that is, preventing the noncompliance from recurring, and that if the trend continues, the repetitive NR supports an enforcement action under the Rules of Practice.

The CSI should also include a statement in Block 10 of the NR stating that continued failure to meet regulatory requirements can lead to enforcement actions described in 9 CFR 500.4.

The CSI should continue to link NRs together that derive from the same or a related cause until he or she determines that an enforcement action is necessary to bring the establishment into compliance with the regulations. When the determination is made by the CSI that enforcement action is necessary, he or she should contact the DO and to discuss the issuance of an

NOIE to the establishment, as described in 9 CFR 500.4. The CSI should always keep his or her supervisor apprised of the situation.

NOTE: It is important to note that noncompliance with SPS requirements can be linked to Sanitation SOP or HACCP noncompliance if the cause of the noncompliance is the same. It is inappropriate for the CSI to have several NRs documenting noncompliance without linkage and then determine there is a trend occurring and list all of the individual NRs to serve as linkage. The NRs should be linked as they are issued, and the concern communicated to the establishment at the weekly meetings.

The CSI should use good judgment in making the determination which NRs to link together. For example:

- If the CSI observes condensation on an overhead that is not contaminating product and makes the determination there is SPS noncompliance, he or she should then determine whether there is a need to link that NR to a previous NR.

- One of the decisions that the CSI needs to make when trying to reach this determination is whether the second noncompliance is an isolated incident or a trend of noncompliance developing. Some of the questions that might assist the CSI to make this decision are:

1. How much time has lapsed since the previous NR was written?

2. Was this noncompliance from the same or related cause as the previous NR?

3. Were the establishment's further planned actions implemented?

4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?

5. Is the establishment continuing to implement better further planned actions?

- An establishment might have several hundred pieces of equipment that are cleaned daily prior to operation. The procedures have been implemented as per the Sanitation SOP, the monitoring of the procedures have been conducted, but there may still be a small amount of residue on a contact surface somewhere in the plant at some frequency that was not found during the establishment's monitoring. To determine whether a trend is developing, the CSI would ask:

1. Are the noncompliances occurring due to the same or related cause?

2. Why are the noncompliances occurring? (Negligence, ineffective method, incomplete execution by the plant, or some other reason)

NOTE: The CSI can contact the supervisor for assistance in making this decision. The in-plant inspection team can also contact the PDD for assistance, if needed.

B. What questions should Frontline Supervisors ask regarding repetitive noncompliance violations?

1. Do the NRs indicate that the noncompliances are from the same or related causes?

2. How much time has elapsed between linked NRs?

3. Are there NRs over the past three months that should be linked to other NRs?

4. Do the NRs establish that there is a persistent problem in the plant's approach to addressing noncompliances (e.g., the establishment's procedures led to repeated noncompliances)?

Based on the answers to these questions, the Frontline Supervisor and IIC are to determine whether the NRs should be linked, and whether a Food Safety Assessment should be recommended.

Rules of Practice

PART I -- Enforcement Actions

A. What are the three types of enforcement actions defined in the Agency's Rules of Practice?

9 CFR 500.1 defines three types of enforcement actions. They are:

1. A "regulatory control action," is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product;

2. A "withholding action," is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process; and

3. A "suspension," is an interruption in the assignment of program employees to all or part of an establishment."

B. Although similar, what are the differences between a withholding action and a suspension?

Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

Both withholding and suspension actions are different from a withdrawal of a Federal grant of inspection or a refusal to grant inspection. Withdrawal actions are initiated by the FSIS Administrator according to the Department of Agriculture's Uniform Rules of Practice, a different set of procedures, found at 7 CFR Subtitle A, part 1, subpart H.

PART II -- Regulatory Control Action

A. What are the regulatory provisions for a regulatory control action?

9 CFR 500.2 lists the reasons for which FSIS may decide to take a regulatory control action. They are:

1. insanitary conditions or practices;

2. product adulteration or misbranding;

3. conditions that preclude FSIS from determining that product is not adulterated or not misbranded; or

4. inhumane handling or slaughtering of livestock.

B. What is the purpose of a regulatory control action?

A regulatory control action covers a wide variety of inspection procedures.

A regulatory control action is a limited focus action that is to be used to address specific problems that CSIs come upon in the course of their activities.

A regulatory control action permits CSIs to identify regulatory noncompliance and prevent the movement of the product involved or use of the equipment or facility involved until the noncompliance has been corrected. CSIs are not required to give the establishment prior notification that they are about to execute a regulatory control action.

C. What are some examples of regulatory control actions?

- A regulatory control action may be warranted for direct product contamination with a contaminant that does not result in a food safety hazard.

- A regulatory control action may be warranted with respect to product that is economically adulterated.

- A regulatory control action may also be warranted as a result of regulatory noncompliance even when there is no product contamination or adulteration.

- A regulatory control action should be taken when inspection program personnel are assessing sanitary conditions of the establishment prior to operation and observe product residue from the previous day's production on a contact surface.

- A regulatory control action would be warranted if CSIs determine that packaged product does not meet the net weight requirements.

- CSIs could initiate a regulatory control action when there is noncompliance with the SPS regulations, if control is needed to prevent contamination of product.

NOTE: Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

D. What procedures are to be used when CSIs take a regulatory control action?

After determining that a regulatory control action needs to be taken, CSIs will notify, as specified in 9 CFR 500.2(b), the establishment orally or in writing of the action and the basis for it. The written notification will be a NR.

As specified in 9 CFR 500.2(c), an establishment may appeal a regulatory control action by following the procedures described in 9 CFR 306.5 and 381.35. These simple procedures direct establishments that want to appeal to bring the appeal to the next level of supervision.

F.What do CSI do if an establishment violates a regulatory control action or removes a retain or reject tag?

1. When an establishment violates a regulatory control action by removing a reject or retain tag, they are in violation of 9 CFR 500.3(a)(5). The existing policy for a situation where a US retain/reject tag is removed by someone other than a program employee is for the CSI to immediately meet with the establishment management to discuss this issue, document the conversation in an MOI.

2. CSIs are to provide a copy of the MOI to the establishment, put a copy in the government file and email a copy through the supervisory channels to the District Office.

3. The DM or their designee will then decide whether this violation requires the initiation of a suspension under 9 CFR 500.3(a)(5).

a. If the DM or designee makes that determination, the establishment will be notified as per 9 CFR 500.5(a). The establishment is then afforded an opportunity to provide adequate statements as to what happened to the tag, who removed it, and what its proposed actions are to prevent it from occurring in the future.

b. If the DM or designee decides not to initiate a suspension, a letter will be provided to the establishment regarding the serious nature of a US reject/retain tag violation. The DM or designee is to consider the public health signification of the original noncompliance that resulted in the inspection program employee needing to use a regulatory control action (US reject or US retain tag) when deciding not to take a suspension or withholding action.

PART III -- Withholding Actions and Suspensions

A. When is prior notification not necessary before taking a withholding or suspension action?

9 CFR 500.3, states that *"FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because*

1. The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 601;

2. the establishment does not have a HACCP plan as specified in 417.2;

3. the establishment does not have Sanitation SOPs as specified in 416.11-416.12;

4. sanitary conditions are such that products in the establishment are or would be rendered adulterated;

5. the establishment violated the terms of a regulatory control action;

6. an establishment representative assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

7. the establishment did not destroy a condemned meat or poultry carcass, or part or product thereof in accordance with part 314 or part 381, subpart L of this chapter, within three days of notification.

NOTE: As a suspension only under 9 CFR 500.3(b), the establishment is handling or slaughtering animals inhumanely.

B. Why is prior notification not necessary?

The situations in paragraph III A necessitate prompt action to protect the public health or the safety of FSIS personnel. When this is the case, but only in such cases, a withholding action or suspension action may be taken without prior notification.

CSIs taking withholding actions without prior notification need to be able to document the imminent threat to public health or to the safety of CSIs that made prior notification infeasible.

NOTE: Multiple instances of economic adulteration do not justify taking a withholding action without prior notification to the establishment and the opportunity to achieve compliance.

C. When is prior notification necessary before taking a withholding action or a suspension action?

9 CFR 500.4 states that *FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:*

1. The HACCP system is inadequate under 417.6 of this chapter, due to multiple or recurring noncompliances;

2. The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in 416.13 through 416.16 of this chapter;

3. The establishment has not maintained sanitary conditions as prescribed in sections 416.2 – 416.8 of this chapter due to multiple or recurring noncompliances;

4. The establishment did not collect and analyze samples for E. coli Biotype I, and record results in accordance with 310.25(a) or 381.94(a) of this chapter; or

5. The establishment did not meet the Salmonella performance standard requirements prescribed in 310.25(b) or 381.94(b) of this chapter.

D. What is the purpose of the prior notification?

The purpose of prior notification, with an opportunity for the establishment to respond, is to provide the establishment with due process procedures.

For paragraph C above, the determinations require that the Agency compile extensive information and analyze it with care and good judgment. This makes it reasonable to provide the establishment with this information in advance. The establishment will have an opportunity to point out any factual errors made by the Agency, identify scientific or technical disagreements, and articulate differing interpretations of regulatory requirements. All this information is useful to FSIS in determining how to proceed. The plant also has an opportunity to present corrective actions.

PART IV -- NOIE

A. What is an NOIE?

An NOIE is a notice of intended enforcement action. It provides notification to an establishment that there is a basis for FSIS to withhold the marks of inspection or to suspend inspection as specified in 9 CFR 500.4. The information in the NOIE meets the notification requirements of 9 CFR 500.5 that states: *If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in*

writing. The written notification will:

a. state the effective date of the action(s);

b. describe the reasons for the action(s)

c. identify the products or processes affected by the action(s)

d. provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and

e. Advise the establishment that it may appeal the action as provided in section 306.5 and section 381.35 of this chapter.

A DM issues an NOIE to an establishment for noncompliances that do not pose an imminent threat to public health but that may warrant the withholding of the mark of inspection or suspension of inspection if not corrected. In addition to informing an establishment about noncompliances warranting a withholding or suspension, the NOIE provides an establishment three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved. Based on discussion with the establishment, the DM may extend the three business days if he or she believes this is necessary.

B. What should a DM do when he or she receives an establishment's response to an NOIE?

The DM should assess and evaluate the establishment's response and decide whether inspection should be withheld or suspended. The DM determines whether the establishment's proposed action plan addresses the problem and, if implemented, is likely to provide an acceptable solution. The DMs should consider any decisionmaking documents as required by the appropriate regulations. Also, the DM should consider the establishment's history of implementing its operating procedures and its planned corrective and preventive actions and determine whether the establishment is likely to implement its proposed actions effectively. DMs are encouraged to contact staff members from the PDD, the Office of Public Health and Science, and the Office of Policy and Program Development for assistance in making decisions.

Upon assessing and evaluating the establishment's response, the DM may decide to accept the establishment's plan, implement the appropriate enforcement action, or defer his or her decision. The following provides the DM guidance on what procedures to follow:

1. Under what circumstances should a DM accept the establishment's response?

If the establishment responds within the specified time frame, has demonstrated that compliance has already been achieved, or provides a

description of acceptable corrective and preventive actions from which the DM can find that compliance will be achieved upon implementation, the DM can accept the response, notify the establishment of the decision, ensure that the establishment implements the corrective and preventive actions in a timely manner, and close the matter with a letter to the establishment.

2. Under what circumstances could a DM implement an enforcement action?

If the establishment does not respond or, based on the DM's assessment and evaluation of all pertinent information, the DM finds that compliance cannot or will not be achieved upon implementation, the DM will implement the enforcement action. In those instances involving:

- withholding actions, the DM instructs the IIC to impose the withholding action and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification are to include the basis for his or her decision.

- suspension actions, the DM instructs the IIC to suspend inspection and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification is to include the basis for his or her decision.

C. Under what circumstances can a DM defer an enforcement decision?

A DM may defer an enforcement decision when he or she has substantial reason to believe that the establishment's proposed corrective and preventive actions are adequate to eliminate the noncompliance but lacks the substantive and supporting evidence that he or she needs to make a definite decision. For example, a plant may submit an apparently adequate proposed plan and have a good history of executing its HACCP plan, but not include sufficient documentation to enable the DM to find that the proposed plan, once executed, will prevent recurrence. In this situation, a DM may choose to defer his or her enforcement decision and allow the establishment to implement the plan until it can be determined whether the plan is effective. The DM is expected to make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM should not defer a decision for more than 90 days without cause. The DM is to notify the establishment in writing as to why he or she deferred a decision.

If, at any time, during a period of deferral, the establishment fails to adhere to the proposed action plan, and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension in accordance with 9 CFR 500.4. The DM will immediately notify the establishment management of this decision and the basis for it in accordance with 9 CFR 500.5.

PART V -- Abeyance

A. What is an abeyance, and when is it used?

9 CFR 500.5(e) states that *FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.*

B. Under what circumstances could the DM hold a suspension in abeyance?

When a DM has suspended inspection, he or she may subsequently decide to hold that suspension in abeyance as specified in 9 CFR 500.5 if:

1. the establishment presents a plan that demonstrates to the satisfaction of the DM that the establishment has designed corrective and preventive actions that are appropriate to meet the regulatory requirement and ensure that it will not recur; and

2. it is necessary to allow the establishment to operate after implementing these corrective and preventive actions so the DM can determine whether the establishment is able to adequately execute the plan. The DM should not hold a suspension in abeyance until the corrective and preventive actions are implemented, and the abeyance should not be for more than 90 days without cause.

If the establishment has a history of failing to meet the criteria discussed above, the DM may decide not to accept the establishment's plan.

If the DM decides to put the suspension in abeyance, and the establishment fails to either meet regulatory requirements or maintain regulatory compliance, during the abeyance period, the DM may lift the abeyance and put the suspension back in effect. If this occurs, the DM will instruct the IIC to suspend inspection in accordance with 9 CFR 500.4 and immediately notify the establishment management in accordance with 9 CFR 500.5(a). The DM will also contact the Acting Regional Investigation Manager.

PART VI -- VERIFICATION PLANS

A. Verification Plan Design

A verification plan (VP) is to be developed by the EIAO in conjunction with the in-plant inspection team when the District Manager decides to defer enforcement following the issuance of a NOIE or to hold a suspension in abeyance following the suspension of the assignment of inspection personnel. The VP provides a systematic means for inspection program personnel to verify that an establishment is effectively implementing the corrective measures that

were proffered to FSIS. The EIAO has the primary responsibility for preparing the written verification plan. However, the EIAO is to work with the in-plant inspection team, including the Frontline Supervisor, in the development of the VP.

The VP is to:

1. describe the verification activities that will be performed by inspection personnel based on the establishment's corrective measures.

2. list the ISP procedure codes associated with each verification activity that will be carried out by the inspection team.

3. list the regulatory provisions associated with each verification activity.

4. be developed so that the verification activities identified in the VP are performed by in-plant inspection program personnel as part of scheduled and unscheduled PBIS procedures.

The EIAO has primary responsibility for communicating and discussing the final verification plan to the IIC. The Front-line Supervisor, and appropriate district office personnel, should also participate in the discussion. If a new IIC is assigned to the facility at any time during the deferral or abeyance periond (e.g, due to a scheduled rotation), the EIAO and Front-line Supervisor should ensure that the IIC understands how to implement the verification plan.

B. Verification of Establishment's Corrective Measures

1. On at least a bi-weekly basis, the in-plant team is to report via e-mail to the Front Line Supervisor, and the District Office, the results of the activities it has conducted under the VP.

2. The in-plant inspection team has the flexibility to increase the frequency of the verification activities based on its findings, and should notify the Front-line Supervisor if they do so. The in-plant team, through the Front-line Supervisor, may request that the EIAO conduct a follow-up visit to an establishment that has had an enforcement action deferred or is under a suspension action that is held in abeyance to determine the overall effectiveness of the establishment's corrective measures.

3. The EIAO is to revisit an establishment operating under a verification plan at 30, 60, and 90-day intervals as long as the verification plan is in place. The EIAO should assess the adequacy of the plant's corrective and preventive actions that resulted in the deferral or abeyance and should provide a recommendation to the District Office as to the appropriate next steps. Recommendations made by the EIAO could include continuing to hold the action in abeyance, close the action, or to initiate further enforcement in the event that the establishment's corrective and preventive actions are found not to be effective.

4. When the in-plant inspection team believes it appropriate that a deferral or abeyance action be closed, the in-plant team may request that an EIAO visit the establishment to review the effectiveness of the corrective and preventive measures implemented by the establishment. When such requests are made and throughout the course of the EIAO visit, the in-plant inspection team should continue with their daily verification responsibilities.

Analysis of Data

PBIS tracks inspection activities that are used to verify an establishment's food safety system. The Office of Food Defense and Emergency Response, Data Analysis and Integration Group will analyze PBIS data on a monthly basis to track whether inspection activities have been completed. The analyses will include identifying trends in noncompliance by the type of activity.

Refer questions to the Policy Development Division at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

USE OF MICROBIAL PATHOGEN COMPUTER MODELING (MPCM) IN HACCP PLANS

1. What is an MPCM program?

An MPCM program is computer-based software that, based on such factors as growth, lethality, and survival in culture broth and food products, estimates the growth or decline of foodborne microbes in food samples in production.

2. How can the MPCM programs be used?

MPCM programs can be valuable tools for establishments to use in supporting hazard analyses, developing critical limits, and evaluating the relative severity of problems caused by process deviations. They can also be used to help predict the expected effectiveness of corrective actions.

3. What are the limitations of MPCM programs?

It is not possible or appropriate to rely solely upon a predictive modeling program to determine the safety of foods and processing systems. Determining pathogen growth or survival and controlling it in food products requires complete and thorough analysis by an independent microbiology laboratory, challenge studies, and surveys of the literature. MPCM programs do not replace these types of activities or the judgment of a trained and experienced microbiologist.

4. How should CSIs verify the use of MPCM programs?

A. Establishments are responsible for validating their HACCP plans and must justify the use of the conclusions reached by the use of MPCM programs. CSIs should verify that establishments document the use of MPCM programs as specified in 9 CFR 417.5. Generally, an MPCM program would not be the only documentation relied upon to support an element of a HACCP plan. However, in certain circumstances, a microbiologist or other trained process authority professional may determine the MPCM program is the most appropriate source of data to support HACCP decision making. For example, the control of *Clostridium botulinum* in low acid canning technology has long been established and documented in scientific and other technical reference literature. Provided that the control parameters for *C. botulinum* are incorporated into an MPCM program and accurately reflect the process under review, then the MPCM program may be relied upon as the sole source for decision making for a HACCP element. In such cases, the microbiologist or other trained professional on the HACCP Team is to document their decision to use the MPCM as part of the HACCP records.

B. CSIs should verify that the parameters used in the predictive model match the ones used by the establishment in its process, and that the data produced by the MPCM program were taken into account by the establishment in its decision making process during the HACCP plan development or implementation.

(**NOTE**: CSIs should not use or place on Agency computers an establishment's MPCM program. In the future, CSIs may have access to an Agency issued MPCM program.)

C. If CSIs have questions regarding an establishment's use of an MPCM program, they should contact PDD. If necessary, a Enforcement Investigation Analyst Officer may respond to the concerns about the establishment's use of the MPCM programs.

APPENDIX A - SLAUGHTER PROCESS VERIFICATION METHODOLOGY

Hands-on verification of the pre-operational (pre-op) procedures component of a slaughter establishment's Sanitation SOP's will include utilization of a Pre-op Sanitation Inspection Plan. The development of a plan is necessary to provide uniformity in conducting pre-op sanitation inspection by identifying areas and units for random sampling. Plans will differ with the size of the establishment: Establishments that have 15 or more units will be subdivided into areas and have a certain time allotment as compared to establishments that have 14 or less units, which will not be divided into areas and thus will have a shorter time allotment.

Pre-op Sanitation Inspection Plans for Slaughter Establishments Having 15 Units or More

A. Pre-op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignments, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time for each assignment:

a. The pre-op start time will be determined by an inspection program employee based on the Inspection Units (IU's) selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

b. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate areas and identify units in each area:

a. An area is a major portion of an establishment designated in the Pre-op Sanitation Inspection Plan for hands-on pre-op sanitation inspection. Examples of an area include the picking area, the eviscerating area, or major equipment groupings or systems. The inspection program employee will determine the boundaries of each area. One to five areas will be covered during a pre-op inspection assignment.

b. Each area is divided into units. The size of an area may vary from 15 to 50 units. A unit is a numbered three-dimensional section within an area. Each unit is to be sufficiently identified so that inspectors who rotate into a pre-op sanitation inspection assignment can easily identify each unit. A unit may have irregular boundaries that are

usually identified by landmarks such as an individual piece of equipment, utensils, associated floors, walls, drains, or other vertical structures and overhead structures. A hand-drawn schematic of the area will be used to identify units. The schematic will include major landmarks in the area such as walls, doors, and posts, and an outline of the principal equipment. The boundaries of the units will be drawn on the schematic and the units numbered. To the extent practical, units should be numbered in the order of product flow for each area. Large, complex equipment may be divided into smaller units. For example, a designated unit might be an individual piece of equipment, such as a picker, and the floor, gutter, drain, posts, walls, and overhead structures in the vicinity of that piece of equipment. The picker may also be divided down the middle and each half included in a different unit. Other examples of units include portions of the area with identifiable boundaries, such as the hide puller, including the floors, drains, walls, and overhead structures and a traffic lane through which products and personnel move.

c. Portable equipment and other equipment that is displaced during cleaning may not always be located entirely within a unit at the time of inspection. Such equipment will be inspected when it is within the boundaries of a unit.

d. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and is to be divided into 1 minute units. Physical boundaries are to be specified for each unit in the Pre-op Sanitation Inspection Plan.

e. Inspection Units (IU's) will be randomly selected from units in an area:

(1) Upon receipt of the Procedure Schedule (i.e., the week before), an inspection program employee should select the random IU's for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but is to be completed at least the day before hands-on verification is scheduled. This information is to be kept in a secure location where it is viewable only to inspection personnel. This will allow determination of the lockout/tagout verification time based on the IU's selected. The selected IU's should remain under security. The amount of time for lockout/tagout verification should be communicated to the inspector(s) responsible for performing pre-op sanitation.

The number of IU's to be selected for area sampling is according to the following schedule:

Units Per Area	Number of IU's
15 to 30	3
31 to 40	4
41 to 50	5

(2) The IIC will authorize a method of randomly selecting IU's for inspection. The following method may be used:

(a) Number cardboard chips to correspond with the inspection unit numbers and place them in a container large enough to permit thorough mixing of the chips.

(b) Before each inspection, mix and then select the specified number of chips from the container.

(c) Write the IU numbers that have been selected for inspection on a piece of paper.

(d) Return the chips to the containers.

Pre-op Sanitation Inspection Plans for Slaughter Establishments Having 14 Units or Less (small establishments)

Pre-op sanitation inspection in small establishments will differ from pre-op sanitation inspection in larger facilities. The Pre-op Sanitation Inspection Plan consists of two sections:

1. Section One identifies the inspection assignment, sets the time allotted for pre-op inspection, including lockout/tagout procedures, and sets the pre-op start time:

a. The IIC will create a Pre-op Sanitation Inspection Plan. The plan will be filed in the inspector's office or in a file designated for the inspector's use in those establishments that are not required to maintain an inspection office.

b. The pre-op start time will be determined by an inspection program employee based on the IU's selected, establishment pre-op record availability, and the amount of time the establishment will need to perform lockout/tagout on the selected equipment. (The procedure time is independent of the lockout/tagout verification time.)

c. The inspector's tour of duty may not always begin at the same time as the scheduled pre-op start time. The inspector's tour of duty should not be confused with the pre-op start time.

2. Section Two contains schematics that designate units:

a. A unit takes approximately 1 minute to physically observe. If a section identified as a unit takes longer than 1 minute to observe, it is too large to be a unit and is to be divided into 1 minute units. Physical boundaries need to be specified for each unit in the Pre-op Sanitation Inspection Plan.

b. Small establishments will not be subdivided into areas.

c. An inspection program employee will select 3 IU's at random for pre-op sanitation inspection as scheduled by the PBIS.

d. An inspection program employee should select the random IU's upon receipt of the Procedure Schedule (i.e., the week before) for those days a hands-on verification procedure is scheduled to be performed. This can be done the week before, but are to be completed at least the day before hands-on verification is scheduled.

SUPPLEMENTARY INSTRUCTIONS REGARDING ENFORCEMENT ACTIONS

When noncompliance with regulatory requirement(s) is found, CSIs will take action as outlined in FSIS Directive 5400.5 and FSIS Directive 5000.1, Revision 1, Chapter I, Sanitation, and consistent with applicable regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").

NOTE: Hands-on verification includes a records review component. Prior to performing the hands-on verification, the inspector will review the establishment's records for that day, if available at that time. CSIs will document findings on an NR. When determining if noncompliance exists, CSIs are to take into account what is known for a fact.

The regulations on Sanitation SOP's require the establishment to implement procedures sufficient to prevent direct contamination or adulteration of product(s), and pre-op procedures in the Sanitation SOP's are to address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils. Therefore, contaminated product and violative facilities, equipment, and utensils, in addition to requiring official control actions, will be considered Sanitation SOP failures. Official control action consists of retention of products and rejecting equipment, utensils, and rooms and/or areas to prevent their use in the production of products until a failure is remedied.

FSIS CSIs will determine whether official control action is appropriate. When the Agency seeks to take further regulatory or administrative action, it is to be able to rely on NR information. Therefore, documenting failure to comply with regulatory requirements as specified above is essential (whether or not official control action was taken).

APPENDIX B - COMPLETING FSIS FORM 5400-4 WHEN MORE THAN ONE INSPECTOR PERFORMS SANITATION ISP PROCEDURES IN LARGE ESTABLISHMENTS

When multiple inspectors perform an individual ISP procedure, that is 01B or 01C, each inspector will document individual findings. This can be accomplished by one inspector, as consulted on the local level, documenting on the NR, while the remaining CSIs utilize an NR Continuation Sheet for documentation purposes. ALL noncompliance with regulatory requirements are to be documented. The NR Continuation Sheet(s) should have the same number as the NR.

The NR should include a statement to indicate the number of the NR Continuation Sheets that are attached. The NR Continuation Sheets will be attached and all the documentation will be provided to the plant manager. It is essential that the failure to comply with regulatory requirement(s), whether documented on the NR or the NR Continuation Sheet, include all information related to the noncompliance. It is important that both are written in a manner to allow "visualization" of the noncompliance. Both the NR and NR Continuation Sheet need to contain the provision(s) of the regulation(s) with which the establishment failed to comply as well as the section or page of the establishment's Sanitation SOP procedures not followed. Previous noncompliance for the same or related cause are to be included in the documentation and, as instructed in FSIS Directive 5400.5, noncompliance trend information provided. Also, the failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration as documented previously should be included.

Because NR information will form the basis of further Agency actions, it will be essential for each person documenting noncompliance with one or more regulatory requirements to include all of the above information.

For example: There are three inspectors at Est. 38 who perform Pre-op verification.
Two inspectors will document their findings on individual NR Continuation Sheets. One inspector documents failure to comply with regulatory requirement(s) on the NR. The NR and NR Continuation Sheets are put together, and the appropriate noncompliance and trend indicator blocks are marked on the NR and the Procedure Schedule. The NR will include a statement that there are two NR Continuation Sheets attached.

In the example, one of the inspectors documenting on an NR Continuation Sheet is responsible for pre-op verification on the slaughter floor. If this inspector finds repeated noncompliance for the same cause on the slaughter floor, he or she is responsible for including this information on the NR Continuation Sheet (including previous NR numbers and dates). This inspector should also include failure of the establishment's corrective actions to prevent recurrence of direct product contamination or adulteration, as previously documented, and any notification he or she has previously provided to the

establishment pertaining to the repeated failure to comply with regulatory requirements.