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

# FSIS DIRECTIVE	6410.1 Rev. 1	11/3/11

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL DECEMBER 3, 2011.

VERIFYING SANITARY DRESSING AND PROCESS CONTROL PROCEDURES BY OFF-LINE INSPECTION PROGRAM PERSONNEL (IPP) IN SLAUGHTER OPERATIONS OF CATTLE OF ANY AGE

I. PURPOSE

A. This directive is being reissued to provide off-line inspection program personnel (IPP) with information regarding how to verify that cattle slaughter operations are implementing sanitary dressing and process control procedures, and that the procedures they are implementing prevent contamination of carcasses and ensure that insanitary conditions are not created.

B. In addition, this directive provides information describing how IPP are to assess the sanitary dressing and process controls cattle slaughter establishments employ in their food safety systems. Such controls are likely to include decontamination and antimicrobial intervention treatments. Establishments should verify the effectiveness of these controls by sampling and testing for microorganisms of beef manufacturing trimmings, other raw ground beef components (including head meat and cheek meat), and raw ground beef.

KEY POINTS:

- *Defines Process Control Procedures*
- *Defines Sanitary Dressing*
- *Defines Contamination of Carcasses and Parts*
- *Describes the purpose of sanitary dressing and process control procedures*
- *Describes the points in the slaughter process where carcass contamination with food safety hazards, such as Escherichia coli (E. coli) O157:H7, are most likely to occur*

- *Describes how an establishment's failure to properly execute its sanitary dressing and process control procedures can increase the risk of contamination of carcasses and parts at various points in the slaughter operation*

- *Provides instruction to IPP regarding how to verify that cattle slaughter operations are implementing effective sanitary dressing and process control procedures to prevent contamination of carcasses and are properly applying decontamination and antimicrobial intervention treatments to carcasses and parts to address any contamination that my occur*

- *Provides instruction to IPP on how to verify that the establishment is properly assessing any microbial testing results, including results for indicators of process control, at any point during slaughter and at subsequent trim fabrication and grinding operations. Examples of microorganisms used as indicators of process control in raw beef operations include Enterobacteriacae, generic E. coli, E. coli O157:H7, non-O157 STECs, and Salmonella*

- *Provides information regarding slaughter food safety systems and how each aspect of the system (e.g., sanitary dressing and process control procedures, intervention treatments, product sampling, supporting documentation) is a factor to be considered when determining whether there is regulatory compliance*

- *Provides clarification regarding the differences between documenting noncompliance under PBIS procedure code 06D01 and under procedure code 01C02*

- *Provides information regarding supervisory responsibilities, including instructions to Public Health Veterinarians (SPHV), Supervisory Consumer Safety Inspectors (SCSI), the Inspector-in-Charge (IIC), Multi-IPPs Supervisors, and Front Line Supervisors (FLS)*

II. CANCELLATION

FSIS Directive 6410.1, Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age (May 4, 2009)

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to:

1. Add a definition of "Contamination of Carcasses and Parts";

2. Update the instructions related to performing sanitary dressing verification under the Performance Based Inspection System (PBIS);

3. Reformat the directive to include hyperlinks within the document and to resource documents;

4. Provide additional information regarding carcass wash cabinets;

5. Provide information regarding documenting 06D01 and 01C02 noncompliance; and

6. Provide information regarding supervisory responsibilities.

IV. REFERENCES

9 CFR 307.2(g) and (m), 310.3, 310.17(a), 310.18(a), 318.4(b), part 416, part 417
FSIS Directive 5000.1, Verifying an Establishment's Food Safety System
FSIS Directive 5000.2, Review of Establishment Data by Inspection Personnel
Federal Register: November 28, 1997, Volume 62, Number 229, Page 63254-63255
FSIS Directives 6100.1, Ante-mortem Livestock inspection
FSIS Directive 6100.2, Post-mortem Livestock Inspection
FSIS Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations
FSIS Guide for Conducting In-Plant Performance System (IPPS) Assessments

V. DEFINITIONS

Process Control Procedure: A defined procedure or set of procedures designed by an establishment to provide control of those operating conditions that are necessary for the production of safe, wholesome food. The procedures typically include some means of observing or measuring system performance, analyzing the results generated in order to define a set of control criteria, and taking action when necessary to ensure that the system continues to perform within the control criteria. The procedure is likely to include planned measures that the establishment will take in response to any loss of process control. In addition, the procedures can be used as support for decisions made in the hazard analysis.

Sanitary Dressing: Practice of handling carcasses and parts by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, and wholesome meat food product in a sanitary environment.

Contamination of Carcasses and Parts: Carcasses and parts that, based on organoleptic inspection, have been prepared, packed, or held under insanitary conditions that may have caused them to come into contact with filth, or that may have caused them to be injurious to health and are condemnable unless they can be effectively reprocessed. Contamination may occur from:

1. Substances not inherent to the species being slaughtered (e.g. volatile oils, paints, rail dust, rust, unidentifiable foreign material (UFM), condensate, poisons

or gases); or

2. Substances inherent to the species being slaughtered (e.g. digestive tract content, bile). Sanitary dressing procedures minimize this type of contamination.

NOTE: Not all contamination is directly associated with food safety. Sound judgment must be used when determining whether the conditions observed during the slaughter process are part of the slaughter process or are present as an unavoidable consequence of the slaughter process. Evaluation on a case-by-case basis will be needed to determine whether the conditions observed have resulted in either the creation of an insanitary condition or the adulteration of product.

VI. BACKGROUND

A. FSIS is aware that *E. coli* O157:H7 has been found in beef manufacturing trimmings, other raw ground beef components (including head meat and cheek meat), and raw ground beef. The presence of *E. coli* O157:H7 in these products can be attributed, in part, to ineffective sanitary dressing and process control procedures that create insanitary conditions during slaughter. Effective sanitary dressing and process control procedures, coupled with effective decontamination and antimicrobial intervention treatments, are necessary to prevent the creation of insanitary conditions. Establishments that fail to control these procedures and treatments create the potential for the contamination of carcasses and parts in their food safety systems.

B. Effective sanitary dressing and process control procedures underpin the critical control points (CCPs) that an establishment has in place to prevent, eliminate, or reduce to an acceptable level food safety hazards that are reasonably likely to occur in the slaughter process and that support the HACCP system, as a whole, is functioning as intended. FSIS believes slaughter operations should more consistently focus on their sanitary dressing and process control procedures in order to prevent carcass contamination and the creation of insanitary conditions in their operations.

VII. GENERAL INFORMATION

A. The following discussion provides IPP with an introduction to sanitary dressing, its importance, and how an establishment can use it to reduce *E. coli* O157:H7 to below detectable levels.

B. IPP verify that, as set out in 9 CFR 310.18(a), establishments handle beef carcasses, organs, and other parts in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter. Because these sources of contamination, whether visible or not, may contain pathogens, a principal objective of proper sanitary dressing and process control procedures is to reduce the potential for exposure of carcasses and parts to any food safety hazard during the removal of the hide, feet, head, gastrointestinal tract, and other internal organs. IPP need to verify that the design of the establishment's slaughter operation includes a means to measure how well the sanitary dressing and process control procedures accomplish this purpose, and

that the establishment responds if the measure shows that carcasses are being exposed to food safety hazards.

C. In addition, IPP verify that in accordance with 9 CFR 416.1, each official establishment operates, and is maintained, in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. In addition, IPP verify that establishments maintain sanitary conditions as required by 9 CFR 416.1 through 416.5.

D. Thus, IPP are to verify that establishments slaughter and process cattle in a manner designed to prevent contamination from occurring at any step in the process and that responds with use of decontamination and antimicrobial intervention treatments as necessary to address any contamination that (a) may result from the implementation of the slaughter process or (b) may otherwise occur on the carcasses and parts. To meet these requirements establishments employ practices such as:

1. Maintaining adequate separation of carcasses, parts, and viscera during dressing in order to prevent cross contamination;

2. Routinely cleaning and sanitizing or sterilizing equipment and hand tools that are used to remove contamination or to make cuts into the carcass;

3. Designing and arranging equipment to prevent the contact of successive carcasses and parts with contaminated equipment, or not allowing the hide during its removal to flap or splatter which could cause contamination of carcasses;

4. Frequently washing hands and aprons that come in contact with the carcass and parts; and

5. Implementing decontamination and antimicrobial intervention treatments such as washes or sprays on carcasses and parts in accordance with the limits selected by the establishment, and documented to be adequate to address contamination.

E. Establishments may elect to maintain written sanitary dressing and process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other pre-requisite programs. IPP are to use the information regarding verification of these written programs that is included in Section X.D of this document.

F. If IPP determine that the sanitary dressing and process control procedures are used to support decisions in the hazard analysis in accordance with 9 CFR 417.5(a)(1), they are to verify that establishments maintain records addressing the sanitary dressing and process control program. IPP are to assess whether the records demonstrate that the program, as implemented, is effective, and whether the decisions made in the hazard analysis are supported on an on-going basis.

VIII. FSIS VERIFICATION OF SANITARY DRESSING AND PROCESS CONTROL PROCEDURES

NOTE: The verification activities addressed in this directive are to be used in conjunction with, and can be conducted simultaneously with, those addressed in FSIS Directives 6100.1, Ante-mortem Livestock inspection and FSIS Directive 6100.2, Post-mortem Livestock Inspection. Verification of procedures for controlling fecal material, ingesta, and milk in slaughter operations are to be conducted in accordance with FSIS Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations.

A. IPP that perform off-line slaughter verification duties are to verify sanitary dressing and the process control procedures conducted by a cattle slaughter establishment in accordance with the instructions in this section. In addition, because verification of sanitary dressing and process control necessarily involves assessing the whole slaughter system, IPP are to evaluate the sanitary dressing and process control procedures as a whole.

B. The 06D01 procedure is used to verify compliance with the sanitation performance standards (SPS) requirements in one or more areas of the establishment. Among the establishment activities to be verified by IPP are the sanitary dressing and process control procedures. To verify that all regulatory requirements associated with PBIS procedure 06D01 are met, IPP are to do the following:

1. Every other week, during the performance of the scheduled weekly 06D01 procedure, IPP are to verify the establishment's sanitary dressing and process control procedures. The verification is to focus on all aspects of the establishment's sanitary dressing and process control procedures. Once verification of sanitary dressing and process control procedures has been completed on that shift, IPP are to verify any additional SPS requirements (e.g. lighting, plumbing, rodent and pest control) in accordance with FSIS Directive 5000.1, as time allows;

2. On the alternate week, during the performance of the scheduled weekly 06D01 procedure, IPP are to focus their verification on one or more of the SPS requirements (e.g., lighting, plumbing, rodent and pest control) in accordance with FSIS Directive 5000.1. Once verification of the SPS requirements has been completed on that shift, IPP are to verify as many of the aspects of the establishment's sanitary dressing and process control procedures, in accordance with this directive, as time allows; and

3. When the information gathered suggests that the establishment has lost process control, IPP are to determine whether the establishment has taken measures to bring the process back under control. Examples of measures an establishment may take include: cleaning of contaminated equipment, removing excessive mud on cattle via washes, or additional checks to verify the process is back under control. If the supervisor determines that it is necessary, IPP are to perform

additional verification of the sanitary dressing and process control procedures to verify that the establishment has brought the process back under control. In such circumstances, it may be necessary for IPP to use the 06D01 procedure code more frequently than once every other week. IPP can perform an additional 06D01 procedure as an unscheduled procedure in lieu of a scheduled 04C03 procedure. If IPP have replaced the 04C03 procedure with a 08S procedure, IPP can conduct an unscheduled 06D01 in lieu of a scheduled 01C02 procedure. The following are examples of the types of findings that can indicate a loss of control:

a. A comparison of the results of current and previous IPP reviews indicates that there has been an increase in contamination. For example, has there been a recent cluster of contamination events following a period of substantial compliance?;

b. Evidence that contamination events are not being effectively prevented (e.g. receiving input regarding on-line verification activities that demonstrate on-line IPP are finding contamination or observing improper dressing procedures more frequently than expected); and

c. Input from FSIS personnel when there is an increase in positive pathogen results in raw beef manufacturing trimmings or raw ground beef samples, from either FSIS or establishment microbiological testing, beyond what is expected, explained, and documented under conditions in which effective sanitary dressing and process controls are implemented.

C. IPP are to gather information using the questions in Section IX.C.Parts 1-10 of this directive to assist them in determining whether an establishment's slaughter operation meets the requirements of 9 CFR 416. The questions provided at each point in Section IX.C.Parts 1-10 below, are not all-inclusive and may vary depending on the type of slaughter operation being conducted (e.g., a high-speed line vs. bed/cradle dressing operation). A response to one of the questions in Section IX.C.Parts 1-10 that suggests loss of control does not automatically mean that there is regulatory noncompliance or a system failure.

D. When verifying the establishment's food safety system as set out in FSIS Directive 5000.1, IPP are to determine whether the establishment has CCPs or other written programs that address any of the potential contamination points identified below in this directive and verify that the establishment properly executes those CCPs or programs.

E. IPP are to gather information using the methodology outlined in Section IX of this directive to assist in the determination of regulatory noncompliance and document noncompliance in accordance with the instructions in Section XI of this directive.

IX. POTENTIAL CONTAMINATION POINTS IN THE SLAUGHTER PROCESS

A. FSIS has identified, through both scientific literature review and best practice guidance created by industry, the points in the slaughter process where carcasses are

most vulnerable to contamination. The steps listed in this directive are not all-inclusive but are those that are most frequently associated with carcass contamination. The steps listed in the directive are in a sequential order (start to finish) for ease of presentation only. IPP are not required to verify them in that same sequential order and are to determine the best sequence for verification based on the specific observations made at a given time.

B. The purpose of identifying and addressing vulnerable points in this directive is to help IPP focus on these points to verify that contamination events are effectively prevented. When contamination occurs, IPP are to verify that the establishment takes steps to minimize recurrence (9 CFR 416.1), and that the establishment effectively addresses the reconditioning of the contaminated carcasses (9 CFR 310.18).

C. When IPP conduct routine verification at the following points in the slaughter process, personal safety is paramount. Verifications are to be conducted from a safe vantage point, especially at the sticking and rodding locations. In addition, when conducting routine verifications, FSIS personnel are to follow good employee hygiene practices in order to ensure that their verification activities do not result in cross contamination of the carcasses.

1. Live receiving/holding

a. This is the point where cattle arrive at the establishment and are held before slaughter. There is an increased potential for contamination with enteric pathogens such as *E. coli* O157:H7 and *Salmonella* during this time because of their presence on the hide and in feces of cattle. Additionally, transportation to the slaughter facility, handling during transport and unloading, and interaction with other cattle may cause stress and increased shedding of pathogens.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at live receiving/holding include, but are not limited to:

    i. What measures, if any, does the establishment take to reduce the pathogen load on in-coming animals? For example:

        1. Does the establishment take measures, such as periodic cleaning of the unloading areas and pens to reduce the contamination of animals?

        2. Has the establishment elected to conduct cattle washing? If so, do they monitor the process to ensure that washing is adequate to minimize contaminants?

        3. Does the establishment use water mist as a means to reduce airborne dust and dirt particles in the holding area?

4. Has the establishment elected to utilize a “mud-scoring” system (i.e., a system to quantify the amount of mud on live animals) in order to identify cattle that may present an increased likelihood of contamination during hide removal?

5. What measures, if any, does the establishment take to determine the incoming bacterial load on animals?

6. Does the age or type of cattle received (e.g. veal calves) represent a concern related to pathogen load, and does the establishment consider that concern?

2. Sticking

a. This is the point in the process where the animal is bled. Regardless of the slaughter method, it is important for the establishment to minimize contamination of the carcass during any cut conducted at this step.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at sticking include, but are not limited to:

   i. What measures does the establishment use to ensure that contamination of the carcass underlying the hide does not occur during the initial cut? For example:

      1. Does the establishment use the smallest cut possible to accomplish bleeding?

      2. Does the establishment use a one knife system whereby the hand and the knife are cleaned and the knife is sanitized between sticking each carcass, or elect to use a two knife system (i.e., one knife is being used while one knife is being sanitized) and the hand is cleaned between sticking each carcass?

c. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

3. Hide removal (manual and mechanical)

a. This is the point in the process where the hide is removed from the animal. Hides are a significant source of contamination (e.g., dust, dirt, feces, mud). It is important to maintain sanitary conditions when handling the hide.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at hide removal include, but are not limited to:

    i. What measures does the establishment use that minimizes the likelihood of contamination of the carcass during the opening of the hide (other than sticking)? For example:

        1. Has visible contamination been removed at the cut line (e.g., with air knives or by steam vacuuming)?

        2. Does the establishment remove the udder in a manner to prevent contamination of the carcass with milk, as well as to prevent contamination of the exposed carcass by the hide, or by a soiled knife or employee hand?

        3. What measures does the establishment use to limit cross contamination of carcasses during hide removal? For example:

            a. Does the establishment have shields between the carcasses and hide puller to minimize potential contamination?

            b. Does the establishment minimize the possibility that contaminants can become airborne from splattering or flapping of the hide by severing or removing the switch on the tail when hide pullers are used?

            c. Do mechanical hide pullers pull the hide away from the carcass (e.g., downward or backward and not upward), thereby reducing the potential for contamination to drip, splatter, or flap onto the carcass or employees handling de-hided carcasses?

            d. Does the exterior side of the hide touch, slap, or flap the carcass when being removed, potentially allowing the dirty exterior side to touch the carcass?

            e. Is the establishment maintaining clean mechanical hide puller contact points with the hide; hands and garments of the employees handling the hide and the carcass; and knives and other equipment contacting the de-hided carcass?

            f. Do employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled

hands, tools, or garments)?

c. What measures does the establishment have in place to allow for adequate distance between carcasses throughout the slaughter dressing process to minimize carcass-to-carcass contact and cross contamination?

d. Are wash cabinets used at this, or any, point in the slaughter process? If so, what measures does the establishment take to ensure the cabinets do not spread contamination to adjacent carcasses? For example:

i. Does the establishment have measures in place to control overspray of water from the cabinet?

ii. Does the establishment take measures to address conditions such as open abscesses, septic bruises, or the presence of parasites and parasitic lesions before carcasses enter the cabinet?

iii. Does the establishment address pooling of water around anus of the carcass prior to dropping the bung?

iv. Does the establishment ensure that all visible contamination is removed before the carcass enters the cabinet?

v. Does the establishment take measures to ensure that carcasses with excessive contamination do not cross contaminate other carcasses (i.e., create an insanitary condition)?

vi. Does the establishment take measures to ensure that carcasses identified with U.S. Suspect or Retained tags, and that are to be removed from the slaughter line at a further point in the process, do not enter the cabinets unless measures are in place to prevent cross contamination of equipment or other carcasses?

NOTE: U.S. Suspects are to be washed in these cabinets only with permission of the PHV, and in consideration of whether the design of the cabinet prevents cross contamination of other carcasses.

vii. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

viii. Does the establishment employ any type of chlorophyll detection equipment, at this point or later in the dressing process as a means to identify fecal material on carcasses?

ix. Does the establishment include in its HACCP Plan, Sanitation SOP,

Good Manufacturing Practices (GMP), or other prerequisite programs any microbiological testing (e.g., total plate counts, aerobic plate counts) including indicators of process control? Examples of microorganisms used for indicators of process control in raw beef operations include: Enterobacteriacae, generic *E. coli*, *E. coli* O157:H7, or *Salmonella*.

x. Does the establishment have on-going verification to ensure that any re-circulated hot water used in the cabinet meets 9 CFR 416.2 (g)(3)? This regulation states that, "Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product."

xi. Does the establishment have on-going verification of pre and post cabinet microbiological testing of carcasses to ensure that the solution does not contaminate or adulterate the product?

4. Bunging

a. This is the point in the slaughter process where a cut is made around the rectum (i.e., terminal portion of the large intestine) to free it from the carcass, and then it is tied off to prevent spillage of fecal material.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at bunging include, but are not limited to:

i. What measures does the establishment take to ensure that carcass contamination does not occur? For example:

1. Is the establishment putting plastic bags and ties on the bung in a sanitary manner?

2. Do the employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)?

3. Does the establishment employ any validated decontamination or antimicrobial intervention treatment that is effective in reducing presence or counts of microbial contaminants at this point in the process?

5. Brisket opening

a. This is the point in the process where the brisket is split (i.e., cut along the centerline).

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at brisket opening include, but are not limited to:

    i. What measures is the establishment taking to prevent the introduction of contamination into the carcass at this point in the process? For example:

        1. Is the establishment cleaning and sanitizing the brisket saw and knife between each carcass and ensuring that the gastrointestinal tract is not punctured?

        2. Do the employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)?

    ii. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

6. Head removal

a. This is the point in the slaughter process where the head is removed from the carcass. It is important to maintain sanitary conditions because cross contamination can occur if the head comes into contact with insanitary heads, equipment, and employee handling.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at head removal include, but are not limited to:

    i. What measures has the establishment implemented to ensure that contamination of heads, equipment, and employees does not occur? For example:

        1. Are heads removed in a manner that avoids contamination with digestive tract contents or specified risk materials (SRM)?

        2. Is the establishment adequately washing heads, including thoroughly flushing the nasal cavities and mouth, before washing the outside surfaces?

3. Does the establishment limit the splashing of water when washing heads in order to prevent cross contamination and to limit airborne contaminants?

4. Does the establishment properly maintain and clean knives?

5. Do the employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g., touching the carcass with soiled hands, tools, or garments)?

c. If a head wash cabinet is used at this point in the slaughter process, what measures does the establishment use to ensure that excessively contaminated heads do not enter the cabinet, that the equipment holding the head does not contaminate the head, or that spray from the cabinet does not spread contamination to adjacent heads?

d. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

7. Rodding the weasand (esophagus)

a. This is the point in the process where the establishment uses a metal rod to free the esophagus (weasand) from the trachea and surrounding tissues. Weasand meat may be salvaged from the remainder of the gastrointestinal tract for use in raw ground beef production. Typically, the weasand is closed (i.e., tied) to prevent rumen spillage. It is important, at this point in the process, that contamination is not transferred from the exterior of the carcass to the interior or onto the weasand. In addition, if, during the rodding process, the gastro-intestinal tract is punctured, it can cause contamination of the carcass interior and exterior with ingesta content.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at the point of rodding the weasand include, but are not limited to:

i. What measures does the establishment take to prevent the introduction of contamination into the carcass during this point in the process? For example:

1. Does the establishment have a means to close the esophagus to prevent leakage of rumen contents?

2. Do employees maintain proper employee hygiene practices (e.g., wash hands and arms often enough to prevent

contamination of the carcass)?

3. Do employees change or sanitize the weasand rod between each carcass?

c. Is the weasand cleaned and chilled quickly to limit contamination and pathogen multiplication?

d. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

8. Evisceration

a. This is the point in the process where the removal of the viscera (e.g., the edible offal that includes the heart, intestines, paunch, liver, spleen, and kidneys when presented with viscera) occurs. If the viscera are not handled properly, or if employee hygiene practices are not being followed, contamination of the carcass and edible offal can occur.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at evisceration include, but are not limited to:

i. What measures does the establishment take to prevent contamination of the viscera during removal? For example:

1. Do establishment employees remove visible contamination from the area to be cut (e.g., by trimming, by using air knives, or by steam vacuuming) before the cut is made?

2. Is the uterus removed in a manner that prevents contamination of the carcass and viscera?

c. What measures does the establishment implement to ensure that employees do not contaminate carcasses during evisceration? For example:

i. Do employees properly use knives to prevent damage (i.e., puncturing) to the paunch and intestines?

ii. Is contamination removed in a timely manner and in accordance with accepted reconditioning procedures?

iii. Are footbaths, or separate footwear being used by employees on moving evisceration lines to prevent footwear from contaminating other parts of the operation?

iv. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

9. Carcass splitting

a. This is the point in the process where carcasses are split vertically into two halves.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at splitting include, but are not limited to:

i. What measures does the establishment take to prevent the split carcass from becoming contaminated? For example:

1. Is the establishment cleaning and sanitizing the saws and knives between each carcass?

2. Does the establishment allow for adequate distance between carcasses (i.e., limit carcass-to-carcass contact)?

ii. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

iii. Does the establishment address the removal of spinal cord in accordance with 9 CFR 310.22?

10. Head and Cheek Meat Processing

a. This is the point in the process where the meat is removed from the head and cheek. This meat can be is used in the production of raw beef products, including ground beef. It is important for the establishment to maintain sanitary conditions.

b. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at head meat/cheek meat processing include, but are not limited to:

i. What measures does the establishment take to ensure that head meat/cheek meat is safe to use in raw beef? For example:

1. Does the establishment properly maintain and clean knives?

2. Does the establishment utilize measures sufficient to prevent

cross contamination of heads?

3. Do employees maintain proper employee hygiene practices to prevent the creation of insanitary conditions (e.g. touching the head with soiled hands, tools, or garments)?

4. Is head and cheek meat quickly chilled to limit pathogen multiplication?

5. Does the establishment employ any validated decontamination or antimicrobial intervention treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?

X. ESTABLISHMENT INTERVENTIONS

A. General

1. The following discussion provides an introduction to IPP regarding assessing the measures implemented by an establishment to reduce *E. coli* O157:H7 to below detectable levels.

2. How well the establishment performs its slaughter dressing procedures has a direct bearing on whether the decontamination and antimicrobial intervention treatments in place in an operation will have their intended effects. When contamination overwhelms the decontamination and antimicrobial intervention treatments, reduction of *E. coli* O157:H7 may no longer meet the standard of reduction to an undetectable level. FSIS will have questions about the establishment's ability to support that the food safety system is having the effect that the hazard analysis anticipates, unless the establishment has:

    a. Documentation that supports that the food safety system at slaughter, including sanitary dressing procedures coupled with all intervention treatments is effective under the actual conditions that apply in its operation; or

    b. The establishment has reassessed its system in response to any new or revised procedures or interventions that have been implemented and has determined that no changes are necessary.

3. In accordance with the requirements of 9 CFR 417.4(a)(1), an establishment that has CCPs designed to control contamination during the slaughter and dressing operation is to validate the individual CCPs to ensure that they are effective in preventing, eliminating, or reducing pathogens to an undetectable level under the establishment's operating conditions. Until establishments demonstrate that the interventions employed at each CCP will achieve the anticipated effect under actual in-plant conditions, the effectiveness of the CCP is theoretical.

4. To meet the requirements of 9 CFR 417.5(a)(1), an establishment's hazard analysis must include all documentation that supports the decisions made for the food safety system. Thus, an establishment whose hazard analysis makes the determination that it's SOP, GMP, or other prerequisite program will prevent the creation of insanitary conditions and the occurrence of contamination, including E. coli O157:H7 contamination, during the slaughter and dressing operation needs to include as part of its hazard analysis data and information concerning these prerequisite programs that support that judgment. Unless the establishment demonstrates that the measures implemented through the SOP, GMP or other prerequisite program coupled with the decontamination and antimicrobial intervention treatments will achieve the anticipated effect under actual in-plant conditions, FSIS will view the effectiveness of the food safety system as theoretical.

5. Establishments can demonstrate the effectiveness of their individual decontamination and antimicrobial intervention treatments by ensuring that the interventions used to control hazards at the CCP are implemented in a manner that is consistent with the parameters of any scientific, peer-reviewed, published studies, or challenge studies being used as support for decisions in their hazard analysis. For both the individual treatments and the food safety system, an establishment may elect to demonstrate that their controls achieve their intended effect is testing a representative sample of carcasses for microbial indicators of process control using non-pathogenic indicator organisms. The testing would occur prior to, and after, the application of the interventions to show that the anticipated reduction has occurred.

NOTE: In establishments that elect to test for the pathogen of concern, finding only sporadic positives can be an indication that the system is functioning as designed and is effective. However, failure to find <u>any</u> positives may be an indication that the sampling and testing methods are not sufficient to detect the pathogen of concern and therefore may be failing to provide vital feedback on the food safety system.

B. FSIS Verification of Establishment Interventions

1. Once per month when conducting the 03J01 procedure in accordance with the methodology in FSIS Directive 5000.1, IPP are to consider the food safety system when verifying that the establishment is meeting its responsibility to reduce *E. coli* O157:H7 to an undetectable level. In addition, they are to review the establishment's interventions, supporting documentation, and testing records and consider questions such as the following:

    a. Is the establishment effectively using sanitary dressing procedures as a means to minimize contamination and thereby preventing the creation of insanitary conditions?

    b. Has the establishment considered the level of contamination that

may be on the incoming animals?

c. Has the establishment used that information as a measure to demonstrate that its interventions are capable of addressing the expected contamination load?

d. Has the establishment demonstrated that its interventions, as applied within their day-to-day operations, are effective under actual in-plant conditions?

e. Does the establishment use some form of Statistical Process Control (SPC), to demonstrate that its CCPs achieve the intended reduction in organisms?

f. Does the establishment evaluate testing results, including generic *E. coli* and *Salmonella* on carcasses, *E. coli* O157:H7 on beef manufacturing trimmings or other raw beef components, and *E. coil* O157:H7 and *Salmonella* on raw ground beef, to help determine how the results impact the operations?

g. When the establishment conducts multiple operations (e.g., slaughter and processing/trim manufacture in one facility), does the establishment have documentation that describes how, and when, communication between the production departments regarding slaughter/dressing performance and trim testing results are to be recorded and is that documentation available for FSIS review?

h. Does the establishment describe how that information will be used to investigate, and to adjust, the food safety system to ensure that the food safety system is adequate to control *E. coli* O157:H7?

2. When IPP have concerns that the establishment's interventions, as implemented, do not achieve the intended reduction in organisms (e.g., *E. coli* O157:H7), they are to contact the District Office (DO) and request that an EIAO conduct a Food Safety Assessment (FSA). The DO will consider IPP findings based on food safety concerns and risk to the product and prioritize the FSA as necessary.

XI. DETERMINING AND DOCUMENTING NONCOMPLIANCE

A. Using the information gathered during FSIS verification, IPP are to determine whether noncompliance exists. IPP are to use the information gathered during their verification activities as prompts to direct them to points in the slaughter process where further observation may be necessary. Examples of observations that could indicate that sanitary dressing procedures are not being properly implemented, and where insanitary conditions are being created as a result of the loss of process control include but are not limited to:

1. Repeated or ongoing noncompliance related to contamination of carcasses with feces, milk, or ingesta at the final rail (i.e. zero tolerance);

2. Repeated or ongoing loss of process control resulting in failure to prevent contamination of carcasses or parts with fecal material, urine, bile, hair, dirt, or foreign matter; failure to effectively prevent the contamination of carcasses and parts; or failure to remove such contaminants before final inspection;

3. Establishment or FSIS microbial sampling results from carcasses, beef manufacturing trimmings or other raw ground beef components trim (including head meat and cheek meat), or raw ground beef that indicate increasing microbial contamination of carcasses or parts with generic *E. coli*, *Salmonella*, or *E. coli* O157:H7;

4. Increased contamination on carcasses because of environmental conditions (e.g., weather or season), or by other factors affecting the condition of incoming animals that have not been addressed by the establishment;

5. Inappropriate design or use of facilities, equipment, or utensils for the type or size of beef slaughtered;

6. Results of any establishment programs designed to prevent insanitary conditions during dressing procedures that may not support decisions made in the hazard analysis;

7. Feedback from on-line IPP or IIC indicating increased incidents or frequency of carcass contamination (i.e., increased contamination may be an indication that the slaughter line speed is too fast);

8. Feedback from in-plant processing IPP or IIC indicating an increase in positive *E. coli* O157:H7 test results, in testing done by either FSIS or the establishment of beef manufacturing trimmings, other raw ground beef components trim (including head meat and cheek meat), or raw ground beef;

9. Notification through the District Office that the establishment may be implicated in supplying *E. coli* O157:H7 positive beef to another establishment or in an illness-related recall action.

NOTE: When seeking answers to the example questions listed throughout this directive, a negative or adverse response to one question is not an automatic indication of regulatory noncompliance or a system failure. When making determinations of regulatory compliance and process control, IPP are to consider how all the information they have gathered relates to the food safety system.

B. IPP are to document noncompliance using 06D01 procedure code when an insanitary condition has been created as the result of the ineffective implementation of the sanitary dressing procedures.

C. Specifically, IPP are to:

1. Document the creation of an insanitary condition using the 06D01 procedure code and the “p”-- “product based “ noncompliance result code;

2. Cite 9 CFR 310.18(a) to address the contamination of the carcass and also cite any SPS regulation that is appropriate to the situation in order to address the creation of the insanitary condition. For example, cite 9 CFR 416.5 if improper employee hygiene practices have resulted in contamination of the carcass and therefore the creation of an insanitary condition; and

3. Review either the available NRs on file for trends. Link them as necessary in accordance with the instructions in FSIS Directive 5000.1 in order to document that a trend of noncompliance is occurring.

NOTE: As indicated in FSIS Directive 5000.1, Chapter IV, Enforcement, noncompliances with SPS requirements can be linked to Sanitation SOP or HACCP noncompliances if the causes of the noncompliances are the same.

D. If an establishment has elected to include sanitary dressing and process control procedures in its HACCP plan or Sanitation SOP, GMP, or other prerequisite program, failure to implement those procedures as written could also result in noncompliance. IPP are to verify the implementation of the procedures using the verification methodology in FSIS Directive 5000.1 and document any noncompliances observed in accordance with the instructions in FSIS Directive 5000.1, Chapter IV, Enforcement.

E. IPP are to use the 06D01 procedure code to document noncompliance, citing the appropriate SPS regulation when the IIC determines that there is evidence that an insanitary condition has interfered with the inability of the on-line IPP to adequately perform the inspection procedures. The IIC may require a line speed reduction in accordance with 9 CFR 310.1(b)(1).

F. Isolated occurrences of contamination (e.g., fecal, specks, grease) observed during the verification of process control procedures is not automatic evidence that the establishment has failed to maintain sanitary dressing. Contamination on carcasses before to the final rail is typically the result of an insanitary condition caused by ineffective sanitary dressing procedures. When there is contamination on carcasses before the final rail, the establishment still has the opportunity to implement measures to address the contamination before presenting the carcass for final inspection. IPP are to evaluate incidental occurrences of contamination as they relate to the overall slaughter system to determine whether the establishment has failed to prevent the creation of insanitary conditions. If IPP determine that the establishment has failed to prevent the creation of an insanitary condition, they are to document their observations using the 06D01 procedure code, citing 9 CFR 310.18(a). In addition, IPP are to document noncompliance when the establishment is not implementing its sanitary dressing

procedures, or that the procedures are ineffective in preventing the creation of ongoing systematic insanitary conditions.

G**.** IPP are not to use PBIS procedure 01C02 unless the establishment has elected to include its sanitary dressing procedures and process control procedures in its Sanitation SOP.

H. IPP are to verify compliance with 9 CFR 310.18(a) by observing that the establishment's slaughter procedures are adequate to ensure that carcasses presented for inspection are not contaminated. Off-line personnel conduct this verification ***after*** the post-mortem FSIS final rail inspection station (i.e., after the establishment has had an opportunity to implement all of its sanitary dressing procedures). If IPP observe fecal, ingesta, or milk during the performance of zero tolerance verification, they are to document the noncompliance using the HACCP 03J procedure, in accordance with the instructions in FSIS Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations. If IPP observe other kinds of contamination (e.g., rail dust, grease smears) on carcasses ***after*** the final rail, noncompliance may be documented using procedure 01C02.

XII. SUPERVISORY PERSONNEL RESPONSIBILITIES

A. “Supervisory personnel” refers to any Office of Field Operations (OFO) personnel that supervise IPP who conduct off-line verification activities in cattle slaughter operations.

B. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority and Agency policy, and that duties are performed in accordance with prescribed inspection methods and procedures addressed in this directive.

C. FSIS supervisory personnel are to discuss the key points identified in this directive with IPP. In addition, supervisory personnel are to discuss the potential contamination points in the slaughter process addressed in this directive to ensure that IPP understand their role in verifying whether the establishment is initiating measures designed to prevent the creation of insanitary conditions by preventing the contamination of carcasses.

D. FSIS supervisory personnel are to emphasize that IPP are to verify that establishments have documentation, in accordance with 9 CFR 417.5(a)(1), sufficient to support any food safety decisions that they make based on the implementation of sanitary dressing and process control procedures.

E. Supervisors are to discuss how sanitary dressing and process control procedures have an impact on *E. coli* O157:H7 testing results of beef manufacturing trimmings, other raw ground beef components such as trim (including head meat and cheek meat), or raw ground beef. Supervisors are to emphasize that IPP in the slaughter areas are to conduct a purposeful evaluation of the establishment’s sanitary dressing and process

control procedures and are to correlate with IPP in processing areas whenever poor implementation of the procedures could lead to positive results in beef manufacturing trimmings, other raw ground beef components trim (including head meat and cheek meat), or raw ground beef testing results.

F. Supervisory personnel are to ensure that IPP are correctly applying the inspection methodology, are making informed decisions, are properly documenting findings, and are taking the appropriate enforcement actions as instructed in this directive.

G. Supervisory personnel are to refer to the current version of the FSIS Guide for Conducting In-Plant Performance System (IPPS) Assessments for additional guidance and instructions.

XIII. DATA ANALYSIS

PBIS tracks the inspection activities used to verify an establishment's food safety system. Directive 5000.1 Verifying an Establishment's Food Safety System states that Office of Data Integration and Food Protection (ODIFP), Data Analysis and Integration (DAIG) will analyze PBIS data on inspection activities on a biannual basis. The analysis will include data from Sanitation Performance Standard (SPS) procedures. The final report will identify trends in noncompliance by activity.

Refer questions regarding this directive to the Policy Development Division through *askFSIS* at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development