VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS FOOD SAFETY CONSUMER PROTECTION DIVISION Meat Inspection Service

MONTPELIER, VT Chuck Ross, Secretary



MIS DIRECTIVE

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Adopted from FSIS Directive 6410.3

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

DO NOT IMPLEMENT THIS DIRECTIVE UNTIL OCTOBER 28, 2012.

I. PURPOSE

This directive provides inspection program personnel (IPP) with an inspection methodology and instructions regarding how to verify that poultry slaughter establishments are performing sanitary dressing procedures in a manner that will prevent the creation of insanitary conditions, and the adulteration of product. This directive provides that IPP are to verify that the establishment is operating in a manner that prevents poultry from becoming contaminated throughout the slaughter process, and is not just cleaning contaminated poultry in order to meet visible cleanliness expectations. In addition, this directive provides that IPP are to verify that the establishment's sanitary dressing process results in poultry carcasses that enter the chiller without visible contamination (9 CFR 381.65(e)). Finally, this directive provides that in establishments using air chilling, IPP are to verify that no visible contamination is present on poultry carcasses at the time they enter the cooler or, if packaged before cooling, before packaging.

KEY POINTS:

- Provides definitions for such terms as <u>Process Control Procedures</u>, <u>Sanitary Dressing</u>, <u>Contamination of Carcasses and Parts</u>, and <u>Food Safety System</u>
- Describes <u>points in the slaughter process</u> where carcass contamination with foodborne pathogens, such as Salmonella and Campylobacter, is most likely to occur

DISTRIBUTION: Electronic Subject: Sanitary Dressing

- Explains how IPP are to gather and assess information about the slaughter operation when <u>verify</u>ing that the establishment's sanitary dressing and process control procedures are effectively ensuring sanitary conditions
- Addresses supervisory responsibilities associated with IPP verification activities

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR Part 381 et seq.

9 CFR Part 416 et seq.

9 CFR Part 417 et seq.

Directive 5000.1, Verifying an Establishment's Food safety System

VT Directive 5000.2, Review of Establishment Data by Inspection Program Personnel

Federal Register: February 3, 1995, Vol. 60, No. 23, Pages 6674, 6694, 6695

Federal Register: November 28, 1997, Volume 62, Number 229, Page 63254-63255

Federal Register: February 27, 2006, Vol. 71, No. 38, Page 9772-9777

Federal Register: January 28, 2008, Vol. 73, No. 18, Page 4767-4774

V. Definitions

Free Available Chlorine: The concentration of hypochlorous acid (HOCL) and hypochlorite ions (OCL) existing in chlorinated water.

NOTE: This directive uses the term "free available chlorine" when referring to parts per million (ppm) chlorine. While 9 CFR 381.91 refers to "available chlorine", the more accurate terminology for this directive is "free available chlorine." (Reference: Handbook of Chlorination and Alternative Disinfectants, Geo. Clifford White, Fourth Edition, 1998, Wiley-Interscience).

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, wholesome poultry 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
- Substances inherent to the species being slaughtered (e.g., fecal material, 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.

Poultry Chiller Makeup Water: Water added to the pre-chiller or chiller to replace the water lost by either overflow or absorption. Poultry chiller makeup water may be potable water or reuse water.

Reuse Water: Water, ice, or solutions previously used to chill or wash raw product that may be reused, provided that the establishment takes measures to reduce any physical, chemical, and microbiological contamination of the water, ice, or solution (9 CFR 416.2(g)). In poultry carcass chilling operations, reuse water is also referred to as "red water."

Food Safety System: A systematic approach implemented to prevent foodborne illness. The food safety system includes the development and implementation of a Hazard Analysis and Critical Control Point (HACCP) Plan in accordance with <u>9 CFR Part 417</u> and a Sanitation Standard Operating Procedure (SOP) in accordance with <u>9 CFR Part 416</u>. It also includes any programs or procedures an establishment uses (e.g., prerequisite programs) to prevent food safety hazards from occurring and to support decisions in the hazard analysis.

VI. BACKGROUND

A. Effective sanitary dressing and process control procedures are crucial to an establishment's ability to produce a clean, safe, and wholesome product. Carcass contamination is a vehicle for the transfer of pathogens. As set out in <u>9 CFR 381.65(e)</u>, poultry carcasses contaminated with visible fecal material must be prevented from entering the chilling tank. However, contamination events should be prevented

throughout the dressing process to prevent the creation of insanitary conditions. IPP need to verify, that preventive steps are taken to ensure carcasses and parts, including giblets, are not contaminated, and that contamination events are rare. In addition, before the carcasses enter the chiller, IPP conduct zero tolerance checks to verify that there is no visible fecal contamination on the carcasses.

B. Salmonella verification testing results have shown reduced Salmonella levels in poultry establishments since FSIS implemented Salmonella performance categories (Category 1, 2, and 3) and other policies designed to lower levels of Salmonella (71 Fed. Reg. 9772 (February 27, 2006), 73 Fed. Reg. 4767 (January 28, 2008) and 75 Fed. Reg. 27288 (May 10, 2010)). However, improvement in sanitary dressing and other process controls can reduce even further the levels of Salmonella and other enteric bacteria on poultry carcasses.

VII. GENERAL INFORMATION

A. The following discussion provides IPP with an introduction to sanitary dressing, its importance, and how an establishment can reduce *Salmonella and Campylobacter*.

B. IPP verify that, as set out in <u>9 CFR 381.65</u>, establishments handle poultry carcasses, organs, and other parts in a sanitary manner to prevent contamination with fecal material, ingesta, 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 a food safety hazard during the removal of the feathers, 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, under the Sanitation Performance Standard (SPS) regulation <u>9 CFR</u> <u>416.1</u>, each official establishment is to be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated. IPP are to verify that establishments maintain sanitary conditions as required by <u>9 CFR 416.1 through 416.5</u>.

D. As set out <u>9 CFR 381.65(e)</u>, establishments are required to prevent fecal material from entering the chilling system. In addition, <u>9 CFR 381.91(a)</u>, requires that carcasses of poultry contaminated by volatile oils, paints, poisons, gases, scald vat water in the air sac system, or other substances that render the carcasses adulterated be condemned. Finally, <u>9 CFR 381.91(b)(1)</u> provides that carcasses accidentally contaminated with digestive tract contents are not to be condemned if promptly reprocessed under the supervision of an inspector, and thereafter found not to be adulterated.

NOTE: <u>9 CFR 381.78</u> allows adulterated carcasses to be reprocessed under supervision such that it is rendered unadulterated and fit for human consumption.

Establishments that demonstrate effective sanitary dressing and process control procedures can propose corrective actions that will render the product wholesome and, at the discretion of the Inspector in Charge (IIC), be allowed to reprocess adulterated carcasses in order to render them fit for human consumption.

E. IPP are to verify that establishments slaughter and process poultry in a manner designed to prevent contamination from occurring at any step in the process, and that establishments respond 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. IPP may see that to meet these requirements, establishments employ practices such as:

- 1. Routinely cleaning and sanitizing equipment, including hand tools that are used to remove contamination or to make cuts into the carcass;
- 2. Designing and arranging equipment to prevent the contact between carcasses and parts;
- 3. Ensuring that employees frequently wash hands and aprons that come in contact with carcasses; and
- 4. Implementing antimicrobial or mechanical intervention treatments, such as carcass washes, sprays, dips, drenches, or brushes, in accordance with the limits selected by the establishment, in accordance with <u>9 CFR 424.21</u> and <u>FSIS Directive 7120.1</u>, and in a manner that has been demonstrated to be adequate to address inadvertent, but rare contamination events of the carcass and associated parts, including the giblets.

F. Establishments may elect to maintain written sanitary dressing and process control procedures as part of their HACCP Plan or Sanitation SOP, Good Manufacturing Practices (GMP), or other pre-requisite program. Establishments can base these written procedures on a variety of sources including, but not limited to, information gathered from in-plant observations or testing or information in the Controlling Salmonella and Campylobacter. IPP are to use the information regarding verification of these written programs that is included in Directive 5000.1.

G. IPP may determine that establishments elect to use their sanitary dressing and process control procedures to support decisions in the hazard analysis in accordance with <u>9 CFR 417.5(a)(1)</u>. If so, IPP are to follow the instructions in this directive to verify that establishments maintain records addressing the sanitary dressing and process control program and to assess whether the records demonstrate that the program, as implemented, is effective and supports the decisions made in the hazard analysis on an on-going basis.

VIII. FSIS VERIFICATION OF SANITARY DRESSING AND PROCESS CONTROL PROCEDURES

A. The verification activities addressed in this directive are to be used in conjunction with, and can be conducted simultaneously with, those addressed in the following directives:

- Directive 5000.1, Verifying an Establishment's Food safety System
- VT Directive 6100.3, Ante-mortem and Post-mortem Poultry Inspection
- FSIS Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Slaughter Operations
- FSIS Directives 7000.1, Verification of Non-food Safety Consumer Protection Regulatory Requirements, Part IV, G

B. IPP that perform slaughter verification duties are to perform the Poultry Sanitary Dressing task to verify that insanitary conditions are not being created. In performing this procedure, IPP are to evaluate the sanitary dressing and process control procedures as they relate to the establishment's food safety system; and not just as a single aspect of the slaughter process. They are to verify that the sanitary dressing, and process control procedures are sufficient to prevent the contamination of carcasses during slaughter operations.

C. IPP are to verify compliance with <u>9 CFR 381.65(e)</u> by determining whether the establishment's sanitary dressing and process control procedures are adequate to ensure that carcasses entering the chiller are not contaminated with fecal material. IPP conduct their verification in accordance with the instructions in <u>FSIS Directive 6420.2</u>. If IPP observe feces during their verification, they are to document the noncompliance using the O3JO2 task.

D. In an establishment that uses a process control system, such as Statistical Process Control (SPC), as part of its sanitary dressing and process control procedures, IPP are to verify that the establishment is implementing its SPC system according to its plan, including documenting any actions that it takes in response to any SPC observations and results.

E. To verify that all regulatory requirements associated with the Poultry Sanitary Dressing task are met, IPP are to do the following:

- 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.
- 2. 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, adjusting equipment, or conducting additional checks to verify that the process is back under control.

- F. Conditions that could affect the sanitary dressing and process control system, and thus prompt IPP to investigate further, include but are not limited to, the following:
 - An increased number of positive establishment or VAAFM Salmonella or Campylobacter test results;
 - 2. An increased number of establishment generic *E.coli* or indicator organism test results that exceed either the establishment's or regulatory control limits;
 - 3. An increase in fecal zero tolerance noncompliances; and
 - Documented evidence of carcass contamination that demonstrates a repeated or on-going loss of process control (e.g., incidental contamination documented under SPS, or zero tolerance noncompliances).
- G. IPP are to gather information using the questions in Part IX, Paragraphs A-N, of this directive to determine whether an establishment's slaughter operation meets the requirements of 9 CFR Part 416 or is creating insanitary conditions that may result in product adulteration. The questions provided at each point in Part IX are not allinclusive and may vary depending on the type of slaughter operation being conducted (e.g., a highly automated line vs. traditional hand operated line).

NOTE: The questions in Part IX are not intended to be a check list but are to be considered when gathering information about the establishment's food safety system. It is not necessary for IPP to ask the establishment for information or to examine records or data for every single one of these questions.

- H. A negative response to one of the questions in Part IX of this directive is not an automatic indication of regulatory noncompliance or of a system failure. A negative response may simply mean that additional consideration is needed or other considerations apply. When making determinations of regulatory compliance, IPP performing off-line duties are to consider how all the information they have gathered relates to the food safety system. This assessment could include, but is not limited to, considering the following information:
 - 1. Information regarding sanitary dressing and process control procedures, and decontamination and antimicrobial intervention treatments:
 - 2. Feedback from further processing operations to the slaughter operation on its effectiveness relative to microbial testing on carcasses and parts; and
 - 3. Observations of the plant employees performance of their assigned duties at particular points in the process because appropriate performance by establishment personnel is necessary for adequate process control.
- I. When the information gathered suggests that the establishment has lost control of its process, IPP are to consider whether they should increase the frequency of their

verification of sanitary dressing and process control procedures. They are to consult their immediate supervisor if they need guidance. The following are examples of findings that can indicate a loss of control:

- A comparison of findings (e.g., documented noncompliances, Memorandums of Interview (MOI)) that indicate an increase in contamination. For example, there may have been a recent cluster of documented incidental contamination noncompliance events following a substantial period of compliance; and
- 2. Evidence that contamination events are not being effectively prevented (e.g., IPP are finding contamination more frequently than expected).
- J. When verifying an establishment's food safety system as set out in VT Directive
 5000.1, IPP are to determine whether the establishment has Critical Control Points (CCPs) or other written programs that address any of the potential contamination points identified in Part IX of this directive and are to verify that the establishment is properly executing their CCPs or other programs.

IX. POTENTIAL CONTAMINATION POINTS IN THE POULTRY SLAUGHTER PROCESS

A. FSIS has identified through scientific literature review the points in the slaughter process where carcasses are most vulnerable to contamination. FSIS included information on these vulnerable points in compliance guidelines, FSIS Compliance Guide for Controlling Salmonella and Campylobacter in Poultry, Third Edition, May 2010. The steps listed in this directive are not all-inclusive, but are those that are most frequently associated with poultry carcass contamination. The steps listed in this section are in a sequential order (start to finish) for ease of presentation only. IPP do not necessarily need to verify all the steps every time they perform the poultry dressing verification task. IPP are to determine the best sequence for verification of the listed steps based on the operation and their specific observations at a given time.

- B. The purpose of identifying and addressing the vulnerable points in the slaughter process is to help IPP focus on those points, verify that contamination events are effectively prevented, and make determinations about the establishment's sanitary dressing and process control through chilling. 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 381.91).
- C. When IPP conduct routine verification at the points specified in this directive in the slaughter process, personal safety is paramount. Verifications are to be conducted from a safe vantage point. In addition, when conducting routine verifications, IPP are to ensure that their verification activities do not result in cross-contamination of the carcasses.
- D. Live receiving or hanging: This is the point in the slaughter process where poultry

arrive at the establishment in transport cages, are unloaded, and are hung on shackles before stunning and bleeding. There is a potential for contamination with enteric pathogens such as *Salmonella* and *Campylobacter* because of the presence of these pathogens on the feathers, skin, crop, and cloaca and in the feces of poultry. Transportation to the slaughter facility, and handling during transport and unloading, may cause stress and increased shedding of pathogens and cross-contamination of cages and birds.

Questions that IPP are to consider when verifying sanitary dressing and process control procedures at live receiving or hanging include, but are not limited to:

- 1. Is there evidence that the establishment takes measures to determine the incoming bacterial load on birds?
- 2. Does the age or type of poultry received represent a concern related to bacterial load, and is there evidence that the establishment has considered that concern?
- 3. Is there evidence that the establishment takes measures to reduce the bacterial load on in-coming birds? For example:
 - a. Does the establishment take measures, such as periodic cleaning or sanitizing of the unloading areas and cages, to reduce the contamination of birds during transport and unloading?
 - b. Does the establishment have agreements with growers designed to reduce the bacterial load on in-coming birds (e.g., poultry litter treatment plans, vaccination plans or specific feed withdrawal criteria)?
 - c. Does the establishment schedule flocks for slaughter based on their bacterial loads?
- 4. Does the establishment maintain positive airflow from inside the facility to the outside, as a means of reducing the amount of contaminants that enter the facility?
- 5. Does the establishment have measures in place to ensure that poultry that are dead on arrival are disposed of properly (9 CFR 381.95) and not placed on the slaughter line?

E. <u>Stunning and Bleeding</u>: This is the point in the slaughter process where the bird is stunned, cut, and bled. Stunning methods used to make birds unconscious may be electrical, mechanical, or chemical. Bleeding ensures death by slaughter and ensures that poultry have stopped breathing before going into the scalder (9 CFR 381.65(b)).

Questions that IPP are to consider when verifying sanitary dressing and process control procedures at stunning or bleeding include, but are not limited to:

- 1. What measures does the establishment use to ensure that contamination of the carcass does not occur during the initial cut? For example:
 - a. Is the machinery properly maintained to ensure that each bird is adequately bled?
 - b. Are back-up cutters in place in the event that the primary cutters fail to operate?
- 2. Does the establishment employ any decontamination or antimicrobial treatments at this point in the process that are effective in reducing the presence or counts of microbial contaminants?
- F. <u>Scalding:</u> This is the point in the slaughter process where the birds are placed in hot water in order to facilitate feather removal. Scalding is an important step that can reduce levels of *Salmonella* and *Campylobacter* on the carcasses, since much of the dirt, litter, and feces on carcasses is removed at this step. *Salmonella* and *Campylobacter* contamination consistently decrease when scalding is well controlled. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at scalding include, but are not limited to:
 - 1. Does the establishment have control mechanisms, such as pre-scald brushes, to reduce the amount of dirt and organic matter entering the scalder?
 - 2. Does the establishment have measures in place that improve process control in the scalder? For example:
 - a. Does the water in the scalder move in the opposite direction as the carcasses (i.e., counter current)?
 - b. Does the establishment have controls to maintain the optimum pH levels to reduce *Salmonella* (e.g., less than 6.5 or greater than 7.5)?
 - c. Is the water flow rate adequate to agitate the water to flush or dilute dry matter?
 - d. Does the scalder include multi-stage tanks?
 - e. Does the establishment use a post-scald rinse?
 - 3. Does the establishment have controls to maintain water at a temperature that is effective to reduce microorganisms?
 - 4. Does the establishment have adequate support for any water re-use procedure that is in place at this point, or any, in the process?

- G. <u>Feather Removal or Picking:</u> This is the point in the slaughter process designed to remove feathers and, in most cases, the uppermost layer of skin before evisceration. Feather removal (i.e., picking) frequently results in increased microbial contamination of poultry carcasses. Cross-contamination of the carcasses occurs because of contact with contaminated rubber picking fingers and contaminated recycled water. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at picking include, but are not limited to:
 - 1. Are the picker fingers kept in good repair, and are they replaced as needed?
 - 2. Are the picker fingers cleaned or rinsed as needed to prevent feather residue build up?
 - 3. Does the establishment employ any antimicrobial treatments after the picking process that are effective in reducing the presence, or counts, of microbial contaminants?
- H. <u>Evisceration</u>: This is the point in the process where removal of the internal organs, and of any processing defects, from the poultry carcasses occurs in preparation for chilling. Evisceration includes multiple processes. It begins at the transfer point (i.e., rehang) and ends when the carcass enters the chiller. It is the point in the slaughter process where the removal of the viscera (i.e., the edible offal that includes the heart, liver, and gizzard) occurs by automated or manual means. If viscera are not handled properly, or if employee hygiene practices are not followed, an increase in microbial contamination can occur. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at evisceration include, but are not limited to:
 - 1. Does the establishment have a system in place (e.g., water nozzles with appropriate pressure and antimicrobial agent, e.g., chlorine, directed at product contact surfaces of automated evisceration equipment), and does it monitor the system's effectiveness, to determine whether cross-contamination is being controlled at different steps (e.g., venting, opening, eviscerating, viscera removal, and cropping)?
 - 2. Does the establishment have controls in place to prevent cross-contamination (e.g., employee hygiene practices or positive airflow from cleaner areas of the facility to less clean areas), and are those controls effectively implemented and monitored?
 - 3. Does the establishment maintain product contact surfaces on automated evisceration equipment in a sanitary condition to prevent the contamination of carcasses and parts?
 - 4. Does the establishment have controls in place to regularly, and as needed, adjust and maintain equipment (e.g., to accommodate changes in bird size) as a means to reduce carcass contamination and broken bones?

- 5. Does the establishment have controls in place to maintain conditions of use for pre-chill antimicrobial interventions, such as carcass sprays, drenches, or dips at one or more points along the slaughter line? For example:
 - a. Is the concentration of the antimicrobial monitored, and are corrective actions taken when the concentration is not maintained?
 - b. Does the establishment monitor other physical characteristics or parameters (e.g., pH)?
 - c. Does the establishment monitor and maintain the pressure of antimicrobial sprays and the size of nozzles dispensing the antimicrobial spray?
 - d. Are brushes replaced when worn?
 - e. Has the establishment determined whether bird size affects the effectiveness of the antimicrobial intervention?
- 6. What measures does the establishment take to prevent contamination of the viscera during removal? For example:
 - a. Does the establishment routinely check evisceration equipment for cleanliness and to determine whether it is adequately drawing the viscera?
 - b. Do employees draw and harvest viscera in a manner that prevents contamination of the viscera and carcass?
 - c. What measures does the establishment implement to ensure that employees do not contaminate carcasses during evisceration? What measures does it take to prevent contamination when viscera is removed from the carcass by use of automated evisceration systems?
 - d. Is contamination removed in a timely manner and in accordance with the establishment's reprocessing or reconditioning procedures?
 - e. Do employees maintain proper personal hygiene practices to prevent the creation of insanitary conditions (e.g., do they avoid touching the carcass with soiled hands, tools, or garments)?
- 7. Are Inside-Outside bird washers (IOBW) used at this, or any, point in the slaughter process? If so, does the establishment take measures to ensure the cabinets do not spread contamination to adjacent carcasses? For example:
 - a. Does the establishment maintain adequate pressure of water?
 - b. Does the establishment monitor and maintain the pressure and nozzles dispensing the antimicrobial?

- c. Are there measures in place to control overspray of water from the IOBW, and thus to prevent cross-contamination?
- 8. If a brush washer is used at this, or any, point in the slaughter process, does the establishment take measures to ensure that the brushes do not spread contamination?
- I. <u>On-Line Reprocessing (OLR):</u> This is the point in the slaughter process where contaminated eviscerated carcasses are reprocessed on-line following the provisions of a waiver granted in accordance with <u>9 CFR 381.3(b)</u>. Establishments need to have requested to participate in the <u>Salmonella Initiative Program (SIP)</u> or have a SIP (i.e. a No Objection) letter on file that addresses the alternative procedures or criteria that the establishment must adhere to in order to maintain its waiver.

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

- 1. Is the establishment implementing the alternative procedures, including conditions of use specified in either the 'No Objection' letter or the SIP letter, according to its HACCP plan, Sanitation SOP, or prerequisite program?
- 2. Does the establishment have controls to maintain equipment to accommodate changes in bird size?
- 3. Does the establishment have controls in place (e.g., positive airflow or ventilation, employee hygiene, equipment) to prevent cross-contamination of carcasses?
- 4. Is there evidence that the establishment monitors and controls its antimicrobial interventions to ensure that the OLR system is effectively reducing microorganisms?
- 5. Does the establishment take measures to ensure that carcasses with excessive contamination (i.e., that would create an insanitary condition) are removed from the line for off-line reprocessing?
- J. Off-line Reprocessing and Salvage: This is the point in the evisceration process where internally contaminated carcasses are reprocessed off-line according to 9 CFR 381.91(b) (1) and (b)(2). Questions that IPP are to consider when verifying sanitary dressing and process control procedures at off-line reprocessing or salvage include, but are not limited to:
 - 1. Does the establishment have procedures in place to prevent cross-contamination of product (e.g., employee hygiene practices, sanitation of hand tools and other equipment, or a sufficient number of racks for hanging carcasses or parts to prevent pile up of product), and are the measures being implemented as written?

- 2. Does the establishment address the reconditioning procedure in its Sanitation SOP, a prerequisite program, or the hazard analysis?
- 3. Is contamination removed in a timely manner to ensure that edible products are promptly chilled?
- 4. Does the establishment employ any antimicrobial intervention treatments during the reconditioning process that are effective in reducing the presence or counts of microbial contaminants?

K. <u>Product Reconditioning:</u> This is the point in slaughter and further processing where contaminated eviscerated carcasses and parts that have fallen on the floor, or otherwise have become contaminated off-line, are reconditioned in order to restore sanitary conditions. Questions that IPP are to consider when verifying sanitary dressing and process control procedures at product reconditioning include, but are not limited to:

- 1. Does the establishment take measures to limit the amount of incidental contamination that occurs (e.g., prevent product from falling on the floor)?
- 2. Does the establishment have procedures in place to prevent cross-contamination of product (e.g., employee hygiene practices, sanitation of hand tools and other equipment, or a sufficient number of racks for hanging carcasses or parts to prevent pile up of product), and are the measures being implemented as written?
- 3. Does the establishment address the reconditioning procedure in its Sanitation SOP, a prerequisite program, or the hazard analysis?
- 4. Is contamination removed in a timely manner to ensure that edible products are promptly chilled?
- 5. Does the establishment employ any antimicrobial intervention treatments during the reconditioning process that are effective in reducing the presence or counts of microbial contaminants?

L. <u>Chilling</u>: This is the point when eviscerated carcasses are chilled in order to inhibit microbial growth and meet the regulatory requirements of <u>9 CFR 381.66(b)(1)</u>. There are two types of chilling systems: immersion and air. Immersion chilling can result in the spread of bacterial pathogens between carcasses in the chiller because of the dispersal by the chill media and by the carcasses touching. This cross-contamination may occur when sanitary conditions are not maintained in the chiller, or when carcasses entering the chiller carry high levels of pathogens.

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

1. For immersion chillers:

- a. Does the establishment have controls to maintain a high flow rate (e.g., one half gallon per bird or an alternate method)?
- b. Does the water in the chiller move in the opposite direction as the carcasses?
- c. Does the establishment include, and maintain, any water re-use procedure at this point in the process in accordance with 9 CFR 416.2(g)(3)?
- d. Does the establishment have post-chill interventions, and are they monitoring the effective level of the post-chill intervention?
- e. If the establishment has addressed immersion chilling in its HACCP plan or Sanitation SOP or other prerequisite program, are the procedures being implemented appropriately, and is there adequate supporting documentation?

2. For air chillers:

- a. Does the establishment maintain the chiller equipment in good repair as a means of preventing the creation of insanitary conditions during air chilling?
- b. Does the establishment employ any antimicrobial treatments during air chilling that are effective in reducing the presence, or counts, of microbial contaminants?
- c. If the establishment has addressed air chilling in its HACCP plan or Sanitation SOP or other prerequisite program, are the procedures being implemented appropriately, and is there adequate supporting documentation?
- 3. If the establishment is using an antimicrobial intervention during the chilling process (e.g., adding chlorine to water in addition to the limits specified in the U.S. potable water standards), it must be in accordance with the limits identified in FSIS Directive 7120.1. As stated in the directive, the levels of use of antimicrobial chlorine in poultry chiller water are that:
 - Potable water being used to initially fill the pre-chiller, chiller, or red water system, or that is added as makeup water, may contain up to 50 ppm free available chlorine measured at intake (influent) (<u>Federal Register:</u> <u>February 3, 1995, Vol. 60, No. 23, Pages 6674, 6694, 6695</u>); and
 - Water from the red water system that is re-used in the pre-chiller or chiller may contain no more than 5 ppm free available chlorine measured at influent to pre-chiller or chiller.

M. FSIS recognizes that a number of substances can be used as chemical interventions during processing (e.g., chilling, post-chill, cut-up) as part of a multiple hurdle approach to reduce *Salmonella* and other enteric bacteria in poultry products without additional approval from FSIS if used as detailed in <u>FSIS Directive 7120.1</u>, <u>Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products</u>. See Attachment 1 of this directive for the current listing of chemicals that are suitable for use with poultry and poultry products.

NOTE: Quarterly updates to the list will be available in <u>FSIS Directive 7120.1</u>.

N. Questions that IPP are to consider when verifying the establishment's use of chlorine or other antimicrobials as a part of their sanitary dressing and process control procedures include, but are not limited to:

- 1. If the establishment is employing a pre-chill carcass wash that may affect the pH of the chiller water, does the establishment address the effect of the pH of the chiller water on the efficacy of any antimicrobials used in the chiller?
- 2. If the establishment uses a variety of different interventions throughout the slaughter process, does it assess the potential for harmful interaction of the chemicals throughout the process, or the potential for inactivation of one chemical with another?
- 3. Does the establishment address the use of chlorine or other antimicrobials in the chilling system in a HACCP plan, Sanitation SOP, or other prerequisite program?
- 4. Does the establishment maintain records that address and document its use of chlorine or other antimicrobials?
- 5. Does the establishment monitor and record chlorine levels by taking samples of the poultry chiller water before birds have been introduced into the chiller, or of intake water to which chlorine has been added before the water enters the chiller tank, to ensure that there is no more than 50 ppm free available chlorine in the water?

NOTE: When chlorine gas enters from a separate line (i.e. not flowing into the potable water line then into the chiller), the establishment should have a system in place to monitor the chlorine level to ensure that it is dispensed at a rate that provides no more than the equivalent of 50 ppm free available chlorine at the chiller intake.

6. Does the establishment add chlorine or other antimicrobials to water that is to be reused as poultry pre-chiller or chiller makeup water? If so, does the establishment monitor and record chlorine levels by taking samples of the reused water before birds have been introduced into the chiller, or of intake water, to which chlorine has been added, before the water enters the chiller tank to ensure that there is no more than 5 ppm free available chlorine in the reuse water?

X. ESTABLISHMENT INTERVENTIONS

A. General information

- 1. The following discussion provides an introduction to IPP regarding assessing the measures implemented by an establishment to reduce pathogens (e.g., *Salmonella* and *Campylobacter*).
- 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, the establishment may need to further reduce pathogens, such as Salmonella and Campylobacter. In order to assess whether the establishment's food safety system is having the effect that the hazard analysis anticipates, IPP are to determine whether the establishment:
 - a. Maintains documentation that supports that its sanitary dressing procedures, coupled with all intervention treatments at slaughter, are effective at addressing pathogens (e.g., *Salmonella* and *Campylobacter*) on carcasses under the actual conditions that apply in its operation; and
 - b. Reassesses its food safety system in response to any new or revised procedures or interventions that have been implemented and determine that no changes are necessary.

NOTE: The reassessment is to be documented in accordance with 9 CFR 417.4(a)(3)(ii). Federal Register, Volume 77, No. 89, Tuesday, May 8, 2012, which was effective June 7, 2012, states the following: 9 CFR 417.4(a)(3)(ii)- Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

- 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. IPP are to verify that the establishment has done so.
- 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 its SOP, GMP, or other prerequisite program will prevent the

creation of insanitary conditions and the occurrence of contamination, including *Salmonella* and *Campylobacter* 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. IPP are to verify that the establishment maintains such data and information.

5. Establishments may elect to demonstrate that the controls in place for both the individual interventions and the food safety system are achieving their intended effect by testing a representative sample of carcasses for microbial indicators of process control using non-pathogenic indicator organisms. Establishments may decide to verify that their interventions are achieving the anticipated reduction of microorganisms through testing prior to, and after, the application of the intervention. IPP are to verify that establishments maintain data that support its food safety system is achieving this effect.

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. Verification of Establishment Interventions

- 1. IPP are to consider the food safety system when verifying that the establishment is addressing *Salmonella* and *Campylobacter*. In addition, they are to review the establishment's interventions, supporting documentation, and testing records and consider whether they address issues 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 routinely may be on the incoming birds?
 - 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 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 or Campylobacter on carcasses and in raw ground poultry, to help determine how the results impact the operations?

- g. When the establishment conducts multiple operations (e.g., slaughter and processing/grinding in one facility), does the establishment have documentation that describes how, and when, communication between the production departments regarding slaughter/dressing performance and grinding testing results are to be recorded, and is that documentation available for regulatory 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 *Salmonella* and *Campylobacter*?
- 2. When IPP have concerns that the establishment's interventions, as implemented, do not achieve the intended reduction in organisms (e.g., *Salmonella* and *Campylobacter*), they are to contact the Meat Inspection Office. The Office 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. IPP are to gather information using the methodology outlined in Part IX of this directive and are to consider how all the information they have gathered relates to the food safety system, and whether noncompliance exists. IPP are to use their findings as prompts to direct them to those points in the slaughter process where sanitary dressing procedures are not being properly implemented, and where insanitary conditions may be present because of loss of process control. Findings that suggest noncompliance include, but are not limited, to the following:

- 1. Repeated or ongoing contamination of carcasses with feces before the carcasses enter the chiller (e.g., zero tolerance noncompliances);
- Repeated or ongoing loss of process control resulting in failure to prevent contamination of carcasses, carcass parts or equipment with fecal material or digestive tract contents;
- Increased contamination on carcasses as a result of environmental conditions (e.g., weather, season) or as a result of other factors affecting the condition of incoming birds that have not been addressed by the establishment;
- 4. Design of, or use of, facilities, equipment, or utensils that are inappropriate for the type or size of poultry slaughtered (e.g., machinery designed for broilers is being used to process spent hens);

- 5. Establishment programs designed to prevent insanitary conditions during dressing procedures that do not support decisions made in the hazard analysis;
- 6. Verbal feedback from IIC to IPP that increased incidents or frequency of carcass contamination are occurring;
- 7. Feedback from either the IIC or in-plant processing IPP indicating an increase in positive generic *E. coli*, *Salmonella* or *Campylobacter* test results, in either establishment results or FSIS verification results;
- 8. Salmonella subtyping in raw products in Salmonella verification sets or establishment testing results that indicate the presence of subtypes that are frequently associated with human illness (e.g., Salmonella Heidelberg).
- B. IPP are to document noncompliance when there is evidence there has been a systemic failure to effectively implement sanitary dressing and process control procedures, resulting in the creation of insanitary conditions. Specifically, IPP are to:
 - 1. Document the creation of the insanitary condition using the O3JO2 procedure on a Noncompliance Record (NR);
 - 2. Cite <u>9 CFR 381.65(a)</u> to address the contamination of carcasses and cite appropriate SPS regulations to address the creation of the insanitary condition. For example, cite <u>9 CFR 416.5(a)</u> if improper employee hygiene practices have resulted in contamination of the carcass; and
 - 3. Review available NRs to determine if a trend is developing. NRs can be associated as necessary in accordance with the instructions in Directive 5000.1, Chapter 5, VII to document that a trend of noncompliance is occurring.

NOTE: As indicated in Directive 5000.1, SPS noncompliances can be associated with Sanitation SOP or HACCP noncompliances if the noncompliances resulted from the same or a related cause.

C. If an establishment has elected to include sanitary dressing procedures in its HACCP plan or in its Sanitation SOP, GMP, or other prerequisite program, failure to implement those procedures as written could also result in documentation of noncompliance with HACCP system requirements. IPP are to verify the implementation of the HACCP system procedures using the verification methodology in Directive 5000.1 and document any noncompliances observed in accordance with the instructions in Directive 5000.1, Chapter V. In some cases, an establishment's loss of sanitary dressing process control may interfere with the ability of on-line inspectors to conduct postmortem inspection. IPP are to use the Poultry Sanitary Dressing task to document noncompliance, citing the appropriate SPS regulation, when the IIC determines there is evidence that the insanitary condition created has resulted in the inability of on-line IPP to adequately perform the inspection procedures. The IIC may require a line speed reduction in accordance with 9 CFR 381.67, 9 CFR 381.68(c), or 9 CFR

381.76(b)(3)(ii)(a) until the establishment regains control of the sanitary dressing process.

- D. Incidental contamination (e.g., ingesta, feces, UFM, rail dust) does not automatically represent an insanitary condition. Even if there are observations of contamination on carcasses during the slaughter process, the establishment still has the opportunity to implement measures that will address the contamination before the carcasses enter the chiller. IPP must assess the available information and evaluate each occurrence of incidental contamination to determine whether the establishment has failed to prevent the creation of insanitary slaughter conditions prior to carcasses entering the chiller. If IPP find that insanitary conditions exist as a result of incidental contamination, they are to document their findings using the SPS Verification task citing 9 CFR 381.65(a), and the appropriate SPS regulations related to incident.
- E. There may be limited situations in which IPP might need to use the 01C01/02 task to document carcass contamination (e.g., if the sanitary dressing and process controls are part of the Sanitation SOP); however, this determination will typically need to be made on a case-by-case basis.
- F. Documentation of incidental noncompliances, while they address specific issues observed at specific points in time, may be indicative of a failure somewhere within the food safety system as a whole. If IPP determine that the incidental noncompliances indicate a systemic problem that has led to the creation of insanitary conditions, IPP are to use their observations, and the tools available to them (e.g., associated NRs, MOI), as the basis for developing a concise, supportable position that explains how they made their determination. IPP are to document the noncompliance in accordance with the instructions in Part XI.B above.

XII. SUPERVISORY RESPONSIBILITIES

- A. "Supervisory personnel" refers to any Office of Field Operations (OFO) personnel that supervise IPP who conduct off-line verification activities in poultry slaughter operations.
- B. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with statutory authority and Agency policy, and that duties are performed in accordance with prescribed inspection methods and procedures addressed in this directive.
- C. Supervisory personnel are to discuss the <u>key points</u> identified in this directive with IPP. In addition, supervisory personnel are to discuss the <u>potential contamination points</u> 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. Supervisory personnel are to emphasize that IPP are to verify that establishments have documentation, in accordance with <u>9 CFR 417.5(a)(1)</u>, 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 pathogens such as *Salmonella and Campylobacter* testing results or raw ground poultry. 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 *Salmonella* set sampling and in raw ground poultry testing.
- 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 <u>FSIS Guide for Conducting In-Plant Performance System Assessments</u> for additional guidance and instructions.

XIV. SUBMITTING QUESTIONS REGARDING THIS DIRECTIVE THROUGH askFSIS

- A. Please refer questions through askFSIS at http://askfsis.custhelp
- B. When submitting a question via askFSIS, log into askFSIS then, using the **Submit a Question** tab, enter the following information in the fields provided:
 - Subject Field: Enter FSIS Directive 6410.3 or Poultry Sanitary Dressing
 - Question Field: Enter your question, including as much detail as possible.
 - Product Field: Select **General Inspection Policy** from the drop-down menu.
 - Category Field: Select Regulations/Agency Issuances from the drop-down menu.
 - Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.
 - When all fields are complete, press the **Submit** button.

C. Questions can also be referred to the Policy Development Division through <u>askFSIS</u> or by telephone at 1-800-233-3935.

Head of Service

VT Meat Inspection Service

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