VERIFYING SANITARY DRESSING – A SYSTEMS APPROACH

Introduction

There are two purposes of this module. First, we will provide some background information about sanitary dressing and the procedures in the slaughter processes for cattle and how they may impact sanitary dressing. Second, we will provide guidance on how to verify compliance using the instructions in FSIS Directives 6410.1 and the thought process for using the systems based approach to making compliance determinations.

Resources

FSIS PHIS Directive 5000.1 Verifying an Establishment's Food Safety System

FSIS PHIS Directive 6410.1 Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Slaughter Operations of Cattle of Any Age

9 CFR 310.3, 310.17(a), 310.18(a), part 416, part 417

Objectives

To demonstrate mastery of this module, the student will

1. Define:
    - Process control procedures
    - Sanitary dressing procedures
    - Contamination of carcasses and parts
2. Describe the role of sanitary dressing and process control procedures as part of an establishment's food safety system.
3. Identify points in the slaughter process where contamination is most likely to occur.
4. Explain how to verify that slaughter operations are implementing appropriate sanitary dressing procedures to prevent contamination.
5. Explain how to verify that establishments are properly applying intervention treatments.
6. Describe how to use a system based approach to determining compliance.

Outline

- Definitions
- The Role of Sanitary Dressing Procedures in the Food Safety System
- A Systems Approach to FSIS Verification of Sanitary Dressing and Process Control Procedures
- Potential Contamination Points in the Slaughter Process
- Establishment Interventions
- Determining and Documenting Noncompliance

Definitions

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

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

Contamination of Carcasses and Parts: Carcasses and parts, 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 can originate from two sources:

1. Substances not related to the species being slaughtered like, oils, rail dust, condensate, and unidentified foreign material.
2. Substances related to the species being slaughtered like digestive content, milk, ingesta or bile. Sanitary dressing procedures minimize this type of contamination.

The Role of Sanitary Dressing in the Food Safety System

FSIS continues to find positive *E. coli* O157:H7 results in samples of ground beef and trim, and we continue to have recalls - some associated with human illness. These positive results can be attributed to ineffective sanitary dressing and process control procedures that lead to insanitary conditions during slaughter. Improvement in sanitary dressing and other process controls can reduce the levels of *Salmonella* and other enteric bacteria. FSIS believes that establishments should focus more closely on their sanitary dressing and process control procedures to prevent carcass contamination.

Effective Sanitary Dressing Procedures Prevent Carcass Contamination

Effective sanitary dressing and process control procedures are crucial to an establishment's ability to produce a clean, safe, and wholesome product. Establishments must handle beef carcasses, organs and other parts in a sanitary manner and prevent contamination with fecal material, urine, bile, hair or dirt, or foreign matter in accordance with 9 CFR 310.18(a). Since these sources can contain pathogens, establishments should reduce the potential for exposure to any food safety hazard during removal of hide, feet, GI tract, and internal organs. The design of the establishment's slaughter operation must include a means to measure how well the sanitary dressing procedures accomplish this purpose and actions if contamination does occur. Sanitary dressing procedures must be designed to prevent insanitary conditions and they must prevent the contamination of carcasses.

Sanitary Dressing Procedures are Part of the Food Safety System

Sanitary dressing procedures lay the foundation for an effective food safety system including Critical Control Points (CCPs) designed to prevent, eliminate, or reduce hazards to acceptable levels.

Establishments must operate and be maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure the product is not adulterated, as required by 9 CFR 416.1- 416.5. Examples of means to achieve this include:

- Maintaining adequate separation of carcasses, parts and viscera during dressing.
- Routinely cleaning and sanitizing equipment and hand tools used to remove contamination or to make cuts in the carcass.
- Arranging equipment to prevent the contact of successive carcasses with contaminated equipment.
- Washing hands and aprons frequently.
- Implementing decontamination and antimicrobial intervention treatment such as carcass washes or sprays, to address contamination that could not be prevented in the slaughter process.

The point of sanitary dressing and process control is to prevent the creation of insanitary conditions (i.e., contamination) and to ensure that carcasses are as clean as possible throughout the entire slaughter operation. The establishment should not be waiting until just before the carcasses complete the slaughter process to address sanitary dressing.

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 prerequisite programs. If the sanitary

dressing procedures are used to support decisions made in the hazard analysis in accordance with 9 CFR 417.5(a) (1), establishments must maintain records addressing the sanitary dressing and process control program. The records must demonstrate that the program is effective and thus decisions made in the hazard analysis can be supported on an on-going basis.

A food safety system includes all aspects of the operation, from the beginning of the product flow, receiving; to the end, shipping. Establishment's must consider all potential food safety hazards that may occur. They must consider the animals entering the establishment. How clean or muddy are transport trucks? How often should the holding pens be washed down? Are animals hauled long distances? How many animals can be unloaded before they are subjected to overcrowding? How does the condition of the animals effect or overwhelm establishment antimicrobial interventions? Consider what will happen to the primals or sub primals when they are shipped from the establishment. Consider the testing that product intended for grinding will undergo. How can the establishment ensure product is safely stored at a proper temperature? These are just a few of numerous factors and variables that can impact carcass contamination, effectiveness of antimicrobial interventions, and pathogen testing results.

Systems Approach to FSIS Verification

The thought process for verifying these procedures is to use a systems based approach. Verification activities begin at live receiving and continue through the whole process flow through slaughter, fabrication and grinding operations. This means that the Agency expectation is not to wait until the final rail to verify sanitary dressing and process control procedures.

Verification of a food safety system requires that inspection program personnel (IPP) evaluate production operations by looking at all aspects of those operations and assessing the interactions between them. IPP accomplish this through observation of the implementation of a variety of plans and procedures (e.g., HACCP plan, Sanitation SOP, prerequisite programs, FSIS and establishment testing results) and through the review of documents associated with those plans and procedures.

IPP should think beyond the boundaries of the slaughter floor. FSIS verification does not end when carcasses leave the slaughter area. Carcasses move on to fabrication and become fabricated products like rounds, steaks, trimmings, drums, thighs, and ground beef. Any contamination incidents on the slaughter floor can impact in the microbial quality of the resulting ground product.

The systems approach to conducting verification activities also means considering what has happened in the past. Look at previous NRs for sanitary dressing noncompliance, zero tolerance failures, and evaluate establishment and FSIS microbiological test results. Are there seasons or months that typically cause spikes in positive results or contamination events?

Perform sanitary dressing verification activities in conjunction with ante-mortem and post-mortem inspection, verification tasks for controlling fecal material, ingesta, and milk in slaughter operations (zero tolerance), sanitation performance standards, sanitation SOP, and HACCP verification tasks. You should be familiar with these other tasks as they were discussed previously in our training.

PHIS Sanitary Dressing Task

IPP that perform off-line slaughter verification duties are to use the PHIS (beef) sanitary dressing task to verify compliance with the regulatory requirements. Schedule the task at the frequency identified in the task list. The task does not have to be completed in one day if more time is needed to gather information regarding the sanitary dressing and process control procedures.

Off-line IPP are to verify the establishment's sanitary dressing and process control procedures. The purpose of the task is to focus on all aspects of their dressing procedures in relation to the food safety system and not just one step of the process. Since verification involves assessing the whole slaughter system, IPP are to evaluate the sanitary dressing and process control procedures as a whole.

Possible Indications of Loss of Control

The following examples are types of findings that can indicate loss of control:

- A comparison of results of current and previous IPP reviews indicates there has been an increase in contamination.
- Evidence that contamination events are not being effectively prevented.
- Input indicating there is an increase in positive pathogen results from either FSIS or establishment microbiological testing.

When the information gathered suggests that the establishment has lost process control, IPP are to determine if the establishment has taken measures to restore process control. Examples of measures an establishment may take include: cleaning of contaminated equipment, removing excessive mud via cattle washes, or additional checks to verify process control. IPP may schedule additional directed tasks in the PHIS system if they need to verify that the establishment has brought the process back under control. Certain events that could indicate the need for additional tasks could be: online IPP feedback, muddy conditions on trucks, animals, pens, or cages, and increased fecal findings.

Potential Contamination Points in the Slaughter Process

FSIS has identified the points in the slaughter process where carcasses are most vulnerable to contamination. This was determined through scientific literature review as well as best practice guidance created by industry. The steps listed are

in sequential order for ease of presentation but are not all inclusive. The points listed are most frequently associated with carcass contamination.

When conducting verification at the vulnerable points in the slaughter process, personal safety is paramount. Conduct observations from a safe vantage point, especially at the sticking and rodding locations. In addition, FSIS personnel are to follow good employee hygiene practices to ensure that verification activities do not result in cross contamination.

Beef Slaughter Process – Potential Contamination Points

A. **Live receiving/holding:** When cattle arrive, there is an increased potential for contamination with enteric pathogens such as *E. coli* O157:H7 and *Salmonella* due to their presence on the hide and in feces. Transport to the slaughter facility, loading and unloading, and commingling with other cattle can cause stress and an increased shedding of pathogens.

B. **Sticking:** This is the point in the process where the animal is bled. The establishment must minimize contamination of the carcass during the cut.

C. **Hide removal (manual and mechanical):** This is the step where the hide is removed from the animal. Hides are known to be a significant source of contamination (e.g., dust, dirt, feces, and mud). It is important to maintain sanitary conditions when handling the hide.

D. **Wash cabinets:** Can be utilized at point(s) in the slaughter process. Measures need to be implemented by establishments to prevent cross contamination during use.

E. **Bunging:** A cut is made around the rectum to free it from the carcass, and then it is tied off to prevent spillage of fecal material.

F. **Brisket opening:** This is the point where the brisket is split.

G. **Head removal:** It is important to maintain sanitary conditions when removing the head because cross contamination can occur if the head comes into contact with insanitary heads, equipment and employees.

H. **Rodding the weasand (esophagus):** The establishment uses a metal rod to free the esophagus from the trachea and surrounding tissues. Weasand meat can be salvaged for use in raw ground beef production. Typically the weasand is tied off to prevent rumen spillage.

I. **Evisceration:** Viscera are removed including edible offal, heart, intestines, paunch, liver and spleen. If viscera are not handled properly or if employee hygiene is poor, contamination of the carcass and edible offal can occur.

J. **Carcass splitting:** This is the point where carcasses are split vertically into two halves.

K. **Head and cheek meat processing:** Meat is removed from the head and cheek. This meat can be used in the production of raw ground beef products.

Gather Information Using Questions

Off-line IPP are to gather information about process control using questions to assist them in determining whether an establishment's slaughter operation meets regulatory requirements and is not creating insanitary conditions resulting in adulteration. The questions provided here are not all inclusive and will vary depending on the type of slaughter operation being conducted. Refer to FSIS PHIS Directive 6410.1 for a complete list of questions. These example questions are for reference purposes only.

From Directive 6410.1 (Cattle)

- What measures if any, does the establishment take to reduce the pathogen loads of in-coming animals?
- What measures if any, does the establishment take to determine the incoming bacterial load on animals?
- What measures do the establishments use to minimize carcass contamination during opening of the hide?
- What measures are taken to prevent cross contamination during hide removal or evisceration?
- Is adequate distance between carcasses maintained to prevent cross contamination?
- What measures has the establishment implemented to ensure that contamination of heads, equipment, and employees does not occur?
- Do the employees maintain proper hygiene practices to prevent the creation of insanitary conditions?
- Do establishment employees remove visible contamination from the area to be cut by trimming or steam vacuuming?
- Is the establishment sanitizing and cleaning knives and saws between each carcass?
- Does the establishment employ any validated decontamination or antimicrobial interventions treatments at these points in the process that

are effective in reducing the presence or counts of microbial contaminants?

Establishment Interventions

An intervention is a process step that has the purpose of eliminating or reducing a hazard to an acceptable level. How well the establishment performs its sanitary dressing procedures directly impacts whether the decontamination and antimicrobial intervention treatments will be effective and accomplish their intended results.

Overwhelming the System

When incoming contamination overwhelms the intervention treatments, reduction of *E. coli* O157:H7 or other pathogens may no longer meet the standard of reduction. So even though the establishment may have validated interventions at strategic locations in the slaughter process, it doesn't afford them any leeway or allowance for sloppy dressing procedures and employee hygiene such as rupturing guts, not cleaning hands, gloves, knives or equipment. The interventions will not achieve their intended effect if the incoming bacterial loads on the hide or feathers are so great that they overwhelm the antimicrobial properties.

Supporting the Food Safety System

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:

- 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,

- The establishment has reassessed its system in response to new or revised procedures or interventions that have been implemented and has determined that no changes were needed.

Validation

In accordance with the requirements for initial validation in 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 only theoretical.

In accordance with the requirements for supporting the hazard analysis in 9 CFR 417.5(a) (1), the hazard analysis must include all documentation that supports the decisions made for the food safety system. If an establishment determines that it can prevent contamination during slaughter through its SOP, GMP or other prerequisite program, then it needs to include support for that judgment in the hazard analysis. 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. The intervention treatments referenced must be able to achieve the anticipated effect under actual in-plant conditions to be considered validated.

Establishments can demonstrate the effectiveness of their individual intervention treatments by ensuring that they are being used to control hazards at the CCP in a manner consistent with the parameters of any scientific, peer-reviewed, published or challenge studies. One mechanism available for establishments to demonstrate controls achieving their intended effect is testing a representative sample of carcasses for microbial indicators of process control. The testing would occur prior to and after the application of controls to show that the anticipated reduction has occurred.

FSIS Verification of Establishment Interventions

Consider the following questions about establishment interventions:

- Has the establishment considered the level of contamination that may be present on incoming animals?
- Is the establishment effectively using sanitary dressing procedures to minimize contamination to prevent the creation of insanitary conditions?
- Are establishment's interventions proven effective under actual in-plant conditions?
- Does the establishment describe how test results will be used to investigate and adjust the food safety system to ensure it is adequate to control *E. coli* O157:H7 and other pertinent pathogens?

If IPP have concerns that the establishment's interventions do not achieve the intended reduction in organisms, they are to contact the District Office and request that an EIAO conduct a Food Safety Assessment

Determining and Documenting Noncompliance

Compliance determinations will be made using the GAD thought process, gather information by asking questions, assess the information, and determine compliance. Some of the information you could gather includes:

- Conditions observed on trucks, cages and pens during ante-mortem,
- Observations of sanitary dressing procedures at vulnerable points
- Feedback from on-line food inspectors,
- Results from zero tolerance checks, either FSIS or establishment,
- Sanitation performance standards observations
- HACCP verification task results
- Lab sampling results (FSIS or establishment),
- Review of establishment data,
- NRs, MOIs, and weekly meeting notes.

Indications of Potential Noncompliance

Some observation findings such as those listed below should serve as prompts to direct IPP to points in the process where sanitary dressing procedures are not being properly implemented.

- Repeated or ongoing noncompliance related to contamination of carcasses with feces, milk or ingesta at the final rail for livestock (zero tolerance).

- Increased contamination of carcasses or parts due to environmental conditions, like weather or season or other factors affecting the condition of incoming animals that have not been addressed by the establishment.

- Feedback from IPP indicating an increase in positive pathogen results from either FSIS or establishment results.

- Inappropriate design or use of facilities, equipment, or utensils for the type or size of cattle slaughtered.

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

- Feedback from on-line IPP indicating increased incidents of carcass contamination.

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 complete the slaughter process. 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 completing the process.

When assessing information gathered, one individual finding may not necessarily be an indication of regulatory noncompliance or a system failure. For example,

isolated occurrences of fecal contamination observed during the verification of process control procedures is not automatic evidence that establishment has failed to maintain sanitary dressing. When making determinations of regulatory compliance and process control, off-line IPP are to consider how all the information gathered relates to the food safety system.

After assessing the information gathered during FSIS verification off-line IPP are to determine whether noncompliance exists.

Document Noncompliance

When there is evidence that the establishment is not implementing its sanitary dressing procedures, or the procedures are ineffective in preventing the creation of ongoing insanitary conditions, off-line IPP are to document noncompliance.

1. For livestock, cite 9 CFR 310.18(a) to address contamination of the carcass, and 9 CFR 416.1. In the description of the noncompliance, explain the situation(s) which support the determination of noncompliance, and include the appropriate SPS regulation to address the insanitary condition. For example, include 9 CFR 416.5 if improper employee hygiene practices have resulted in contamination of the carcass.

2. Review the NR file in the USDA office to determine if previous noncompliance have been or should be linked to demonstrate a trend of noncompliance. Associate them as necessary in accordance with the instructions in FSIS Directive 5000.1 to document that a trend of noncompliance is occurring.

Summary

Sanitary dressing procedures are a key to preventing insanitary conditions, particularly at the vulnerable points in the slaughter process. Contamination on the carcasses is the result of an insanitary condition caused by ineffective sanitary dressing procedures. Reducing *E. coli* O157:H7, and other pathogens such as *Salmonella*, is a regulatory requirement and ensures food safety. Interventions need to be capable of reducing or eliminating a food safety hazard and not be overwhelmed by the amount of contamination or number of pathogens on the carcass. Noncompliance determinations should be reached using the GAD thought process and systems approach. The slaughter process is a system, so remember to use a system based approach in evaluating the entire slaughter system. Compliance with sanitary dressing and process control procedures is determined in relation to the entire food safety system, not just one contamination incident.

Verifying Sanitary Dressing Workshop

Scenario:

Open Beef is a one shift cattle slaughter establishment in Petaluma, CA. The establishment slaughters approximately 500 head of cattle per day. It produces carcass halves and quarters, primal and sub-primal parts, edible offal, beef trimmings, head meat and cheek meat. Open beef applies lactic acid as an antimicrobial intervention spray to carcasses at the final wash step. The cheek meat, head meat and beef trimmings are intended for use in ground beef products.

After stunning, the carcasses are hoisted on a chain driven rail. The head and tongue are removed for head inspection. The viscera are removed onto a moving line for viscera inspection.

Robert Allen is a GS-8 CSI, and has just come back to the office from conducting ante-mortem inspection on a truckload of cattle just arriving. It's been raining for the last 3 days and he wonders if it will clear up before the weekend

He has already received some feedback from on-line inspectors regarding contamination on heads and carcasses. The establishment has recently employed a mud scoring system in response to some zero tolerance failures last month. He determines that a directed sanitary dressing procedure is appropriate to add to the task calendar based on feedback and observations.

Answer the following questions using your notes and module content.

1. What are some FSIS records to review while performing the task?

2. What are some establishment records to request?

3. Define the “systems based approach” for verifying sanitary dressing. Does the systems based approach prescribe a time frame for completing the task, a sequential order?

Based on the following information below, please arrive at a compliance determination using the systems based approach covered in the module.

Upon initiation of the beef sanitary dressing task on 2/04/16, CSI Allen reviews FSIS records and several establishment documents that address sanitary dressing and process control procedures. The following prerequisite programs serve as support for decisions made in the hazard analysis.

- GMP 01 Employee Hygiene Practices
- Prerequisite program for cabinet hot water reuse

On 2/04/2016, CSI Allen observed repeated instances within a 5 minute period, where establishment employee hygiene practices associated with the removal of hide from the hind legs were not being implemented as written, resulting in carcass contamination. The applicable section of the written GMP requires that the employee must sanitize the knife each time a cut is made through the hide. The employee in question did not sanitize the knife between cuts and only occasionally sanitized between carcasses. The slaughter foreman was notified of the findings and a Sanitation performance Standard (SPS) noncompliance record would be documented.
On 2/05/16, CSI Allen observed an establishment employee inspecting the filters of the recirculation tanks for the wash cabinet. Employee cleaned the filters but did not flush the cabinet tank as described in the establishment prerequisite program. Management was notified of their failure to properly implement their prerequisite program.

On 2/06/2016, CSI Allen observed repeated instances of establishment employees not sanitizing knives during removal of udders between carcasses resulting in carcass contamination. The employee hygiene GMP for knife trimming requires that team members sanitize knives during udder removal between each carcass. An employee was observed removing udders of three carcasses before sanitizing the knife. The slaughter foreman was notified and an SPS NR was documented.
On 2/06/2016, CSI Allen observed the establishment conducting a zero tolerance CCP check. The result was a failure at the CCP due to fecal contamination on the shank. The establishment immediately initiated corrective actions to include trimming and re-inspection of affected parts. Establishment determined the cause of the failure was an employee who failed to properly clean their apron resulting in cross contamination during evisceration. A review of establishment records indicated that there were two zero tolerance failures during the four previous production shifts for the same cause.
On 2/07/2016, on-line CSI Wilson working on the final rail advised me that there had been contamination on the leading foreshanks of several carcasses. Each carcass had been railed out for trimming. After further investigation, I saw contamination on three of the next ten carcasses. I immediately conducted a zero tolerance verification check which failed. The slaughter foreman was notified and a zero tolerance NR was documented.
On 2/08/2016, I was advised by CSI Jones, processing inspector in the Fabrication department at Open Beef, that FSIS results for trim produced on 2/04/16 had tested positive for *E. coli* O157:H7, and was currently retained pending the implementation of corrective actions in accordance with 9 CFR 417.3.
On 2/08/2016, I reviewed FSIS noncompliance records for the last two weeks, 1/24/15 through 2/06/16 since the last sanitary dressing task had been performed. I observed 4 SPS noncompliances were documented and associated citing the establishment's inability to implement company GMPs as written resulting in carcass contamination. Additionally two zero tolerance NRs had been documented by FSIS.

4. What are your conclusions regarding compliance? Is there regulatory noncompliance with the sanitary dressing task? Why or why not? If so, what are the relevant regulations verified and cited?

5. What additional actions would you take?