



FSIS Directive 6410.1

Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of any Age

Implementation Correlation



Purpose of Correlation

- To address new emphasis' in the directive
- To provide additional information regarding verification
- To provide thought processes to assist IPP when making determinations of noncompliance
- To address the role of sanitary dressing and process control within the food safety system



IPPS Considerations

- Preparing for IPPS visit
 - Review PBIS Data prior to establishment visit
 - 06D01 performance
 - NR review
- During visit
 - Review Weekly Meeting Notes/MOIs
 - Reference to Sanitary Dressing issues discussed?
 - Discuss performance of 06D01/findings/NR



New Emphasis

- Verification of sanitary dressing and process control begins at receiving of cattle, not at the final rail (i.e., a system approach)
- The Agency's expectation is that implemented sanitary dressing and process control procedures are in a written document



New Emphasis

(Continued)

- Noncompliance is not automatic. It will involve consideration of a variety of factors
- FSIS has identified typical locations in the slaughter process where carcass contamination is most likely to occur



New Emphasis - 1

Verification of sanitary dressing and process control begins at receiving of cattle, not at the final rail (i.e., a system approach)



System Approach

- It is the expectation that each time IPP evaluate the sanitary dressing & process control procedures, they look at the *entire slaughter system*, not just one point in the process
- When determining compliance, IPP should consider what they are seeing at that time regarding the system, but also consider what has been *occurring historically* in the operation



Note

Additional information* might also be provided to off-line IPP from on-line IPP, as well as from production areas beyond the final rail. That information can be considered by off-line IPP when determining the compliance of sanitary dressing and process control procedures

**e.g., Information received from IPP in further processing; repetitive on-line contamination incidents; E.coli testing results (either establishment's or FSIS)*



System Approach

- Determining compliance involves deciding if, overall, sanitary dressing operation and process control procedures that are in place, are effective to prevent the creation of insanitary conditions and thereby prevent contamination of carcasses



New Emphasis - 2

It is the Agency's expectation that the implemented sanitary dressing and process control procedures are in a written document and that records be maintained

Note: it is not a regulatory requirement that the procedure be written or that daily records be maintained



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



Definitions

- Process Control Procedures put in place by establishments typically include:
 - observing or measuring system performance
 - analyzing the results to develop measures to ensure the process remains under control
 - taking action when necessary to ensure that the system continues to perform within the control criteria
 - planned measures taken by the establishment in response to any loss of process control



Definitions

- ***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



Written Document

- Establishments *may* employ practices such as:
 - Adequate separation of carcasses, parts and viscera
 - Routinely cleaning/sanitizing equipment used to cut carcasses
 - Good employee hygiene practices
 - Implementing decontamination and antimicrobial intervention treatments
- Implementation of such practices would be beneficial when supporting decisions that the establishment is reducing contamination on carcasses and therefore reducing the likelihood that *E.coli* O157:H7 may be present



Written Document

- HACCP plan
- Sanitation SOP
- SOP
- GMP
- Other Prerequisite program



Written Document

- Regulations require that the hazard analysis include all documentation (i.e., written procedures and associated records) that supports the food safety system
- Written sanitary dressing and process control procedures can be used as support for decisions made in the hazard analysis



Written Document

- If the procedures are not in a written document and if records are not maintained, it may be difficult for the establishment to demonstrate that the slaughter operation, any procedures implemented, and any interventions used, are effective to reduce *E.coli* O157:H7 to below detectable levels



New Emphasis - 3

Determining noncompliance is not automatic and will involve consideration of a variety of factors



Regulatory Basis

- Establishments are expected to slaughter and process cattle in a manner designed to prevent contamination of carcasses
 - 9 CFR 310.18(a) requires prevention of carcass contamination
 - 9 CFR 416.1 requires that establishments be operated such that they do not create insanitary conditions or contaminate product



Determining Noncompliance

- FSRE training thought process:
 - Has not changed for SPS or SSOP issues *other than Sanitary Dressing & Process control*
 - IPP will continue to use the same thought process presented in FSRE training for issues such as lighting, rodent & pest control, ventilation, etc.
 - Compliance for issues other than sanitary dressing and process control will be determined based on the individual incidents observed



Determining Noncompliance

- The thought process for determining compliance of the sanitary dressing and process control procedures is different because it is about a system
- A specific event of finding contamination on a carcass may not be significant as it relates to the system
- Finding contamination on a carcass still may need to be addressed as a specific incident



Determining Noncompliance

Off-line IPP are to determine noncompliance based on their evaluation of the sanitary dressing and process control procedures in relation to the food safety system and not simply in relation to one contamination event



Determining Noncompliance

- Use the information gathered while performing verification procedures to determine compliance
- Document noncompliance in accordance with FSIS Directive 5000.1
- Cite 9 CFR 310.18(a) on Noncompliance Record (NR)



Determining Noncompliance

- The slaughter system, including sanitary dressing and process control procedures, needs to be designed to prevent the creation of insanitary conditions
- If the system is not accomplishing that, the Agency has determined that noncompliance is to be documented as 06D01 noncompliance



New Emphasis - 4

FSIS has identified typical locations
in the slaughter process where carcass
contamination is most likely to occur



Potential Contamination Points

- The points are identified to help off-line IPP focus their verification in order to ensure that:
 - Contamination events are effectively prevented
 - The slaughter process is completed in a timely manner prior to chilling the carcass



Potential Contamination Points

- Live Receiving/holding
- Sticking
- Hide Removal
- Bunging
- Head Removal
- Rodding the weasand
- Evisceration
- Carcass Splitting
- Head and Cheek Meat Processing



Potential Contamination Points

- Questions asked in the directive are:
 - Intended to be thought provoking
 - Not intended to be prescriptive measures that establishments are required to implement
 - Not all inclusive



NOTE

- The potential contamination points listed in the directive are not all-inclusive
- IPP are not required to verify them in any specific order (e.g., sequential, start to finish)



Sanitary Dressing & Process Control's Role in the Food Safety System

- Effective Sanitary Dressing and Process control procedures are integral parts of the food safety system
- Without effective sanitary dressing and process control procedures, carcasses could be overwhelmed with contamination



Sanitary Dressing & Process Control's Role in the Food Safety System

- When contamination overwhelms the decontamination practices and antimicrobial interventions, the establishment may no longer be able to reduce *E.coli* O157:H7 to below detectable levels
- It is essential that slaughter operations also have validated interventions that work in unison with sanitary dressing and process control procedures in order to reduce pathogens



Validated Interventions

- Until the CCP is demonstrated to achieve its anticipated effect under in-plant conditions, the CCP is theoretical and not adequately validated
 - How establishments accomplish this is up to each individual establishment
 - Testing before and after each intervention is one option but not currently a requirement



Summary

- Sanitary dressing and process control procedures are key to preventing insanitary conditions and carcass contamination
- Preventing carcass contamination is essential to ensuring that decontamination practices and validated antimicrobial measures are effective to reduce *E.coli* O157:H7



Summary

(Continued)

- Reducing *E.coli* O157:H7 is a regulatory requirement and is essential to ensuring food safety
- Noncompliances are determined in relation to the food safety system and not in regard to one point in the process or one contamination incident



Summary

(Continued)

- Noncompliance related to sanitary dressing and process control procedures will be documented as SPS/06D01