

# FSIS DIRECTIVE 6410.3

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

### *A Systems Approach*

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Omaha, Nebraska  
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# OBJECTIVES

- Discuss a 'system' as it relates to sanitary dressing and process control
- Role of sanitary dressing and process control as a part of the establishment's food safety system
- Directive 6410.3
  - Locations in the slaughter process where carcass contamination is most likely to occur
  - FSIS Verification
  - Establishment Interventions
  - Determining compliance



# NOTE

We will not be addressing the Facilitator and Participants handouts that were provided to supervisory personnel during this presentation.

Those documents will be discussed at the local level by the immediate supervisor.



# BACKGROUND

- Establishments are expected to slaughter and process poultry in a manner designed to prevent contamination of carcasses
  - **9 CFR 416.1** requires that establishments be operated such that they do not create insanitary conditions or contaminate product
  - **9 CFR 381.65(a)** requires prevention of carcass contamination
  - **9 CFR 381.65(e)** requires prevention of carcasses contaminated with feces from entering the chiller



# BACKGROUND

- Effective sanitary dressing and process control procedures are crucial to an establishment's ability to meet those regulatory requirements
- In addition, sanitary dressing is a mechanism that assists in the reduction of *Salmonella* and *Campylobacter* by ensuring that the *creation of insanitary conditions (i.e., contamination of carcasses) is prevented*





Sanitary dressing noncompliances are determined based on cumulative information reflecting the food safety system

Sanitary Dressing noncompliance is not likely to be documented in regard to one contamination incident or one single point in the process



# FOOD SAFETY SYSTEM

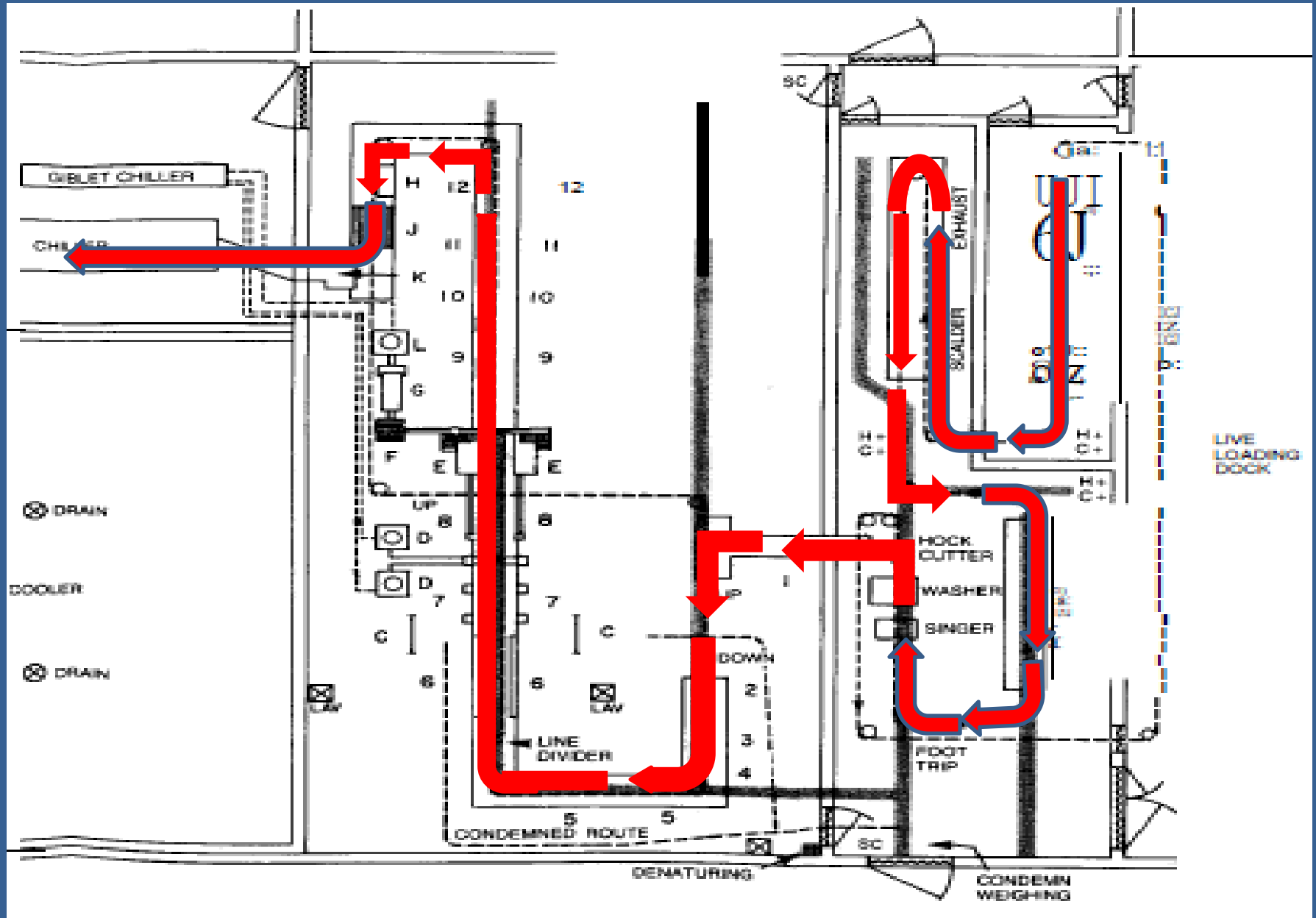


# FOOD SAFETY SYSTEM

- A food safety system includes all aspects of the operation
- For example:
  - Slaughter
  - Fabrication and Grinding
  - Product storage
  - Product Testing
  - Control Programs
  - Customer feedback







# SYSTEM APPROACH

- It is the expectation that each time IPP evaluate the sanitary dressing & process control procedures, they look at the **entire slaughter system, and beyond**, not at just one point in the process

NOTE: When determining sanitary dressing compliance, IPP should consider what they are seeing at that time regarding the **system**, but are to also consider what has been **occurring historically** in the operation (i.e., consider cumulative information)



# It's a puzzle



# NOTE

IPP have an opportunity to gather  
information about the system

*every time*

they walk out onto the slaughter floor  
regardless of whether or not they are  
conducting the PHIS Poultry Sanitary  
Dressing task



# ROLE OF SANITARY DRESSING AND PROCESS CONTROL



# 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.



# Process Control Procedures

- 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.
- 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



# NOTE

*The point of sanitary dressing and process control is to prevent the creation of insanitary conditions (i.e., contamination) and to ensure that poultry carcasses are as clean as possible throughout the entire slaughter operation.*

*The establishment should not be waiting until just before the birds falls into the chiller to take care of contamination*





# WHY IT'S IMPORTANT

- Preventing carcass contamination is essential to ensuring that decontamination practices and validated antimicrobial interventions are effective to reduce *Salmonella* and *Campylobacter*
- Being **proactive** is better for food safety than being **reactive**





# FSIS DIRECTIVE 6410.3



# FSIS DIRECTIVE 6410.3

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



# FSIS DIRECTIVE 6410.3

- Explains how IPP are to gather and assess information about the slaughter operation when verifying that the establishment's implementation of sanitary dressing and process control procedures are effectively preventing the creation of insanitary conditions



# DEFINITIONS

- ***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, are condemnable unless they can be effectively reprocessed.



# 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.*



# DEFINITIONS

- ***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 9 CFR 417 and a Sanitation Standard Operating Procedure (SOP) in accordance with 9 CFR 416.



# ADDITIONAL DEFINITIONS

- Poultry Chiller Makeup Water
- Free Available Chlorine
- Reuse Water





# Potential Contamination Points



# POTENTIAL CONTAMINATION POINTS

- Live receiving and hanging
- Stunning and Bleeding
- Scalding
- Feather removal and Picking
- Evisceration
- On-line reprocessing
- Off-line reprocessing
- Product reconditioning
- Chilling



# LIVE RECEIVING & HANGING

- Poultry arrive at the establishment in transport cages, are unloaded, and are hung on shackles before stunning and bleeding
- Potential for contamination with enteric pathogens because of the presence of these pathogens on the feathers, skin, crop, and cloaca & in the feces



# STUNNING & BLEEDING



- Point in the slaughter process where the bird is stunned, cut, & bled
- Stunning methods used typically used include electrical, mechanical, or chemical
- Bleeding ensures death by slaughter and ensures that poultry have stopped breathing before going into the scalding



# SCALDING

- Point in the slaughter process where the birds are placed in hot water in order to facilitate feather removal
- *Salmonella* and *Campylobacter* contamination consistently decrease when scalding is well controlled



# FEATHER REMOVAL & PICKING



- 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





# EVISCERATION

- Point in the process where removal of the internal organs, and of any processing defects, from the poultry carcasses occurs
- Evisceration includes multiple processes. It begins at the transfer point (i.e., re-hang) and ends when the carcass enters the chiller.



# ON-LINE REPROCESSING



- Point in the slaughter process where contaminated eviscerated carcasses are reprocessed on-line following the provisions of a waiver granted in accordance with 9 CFR 381.3(b)





# NOTE

Establishments need to have requested to participate in the *Salmonella Initiative Program (SIP)* or have a SIP letter (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.

See FSIS Directive 5020.1 for additional information regarding SIP verification



# OFF-LINE REPROCESSING

- 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)



# PRODUCT RECONDITIONING



- Point in slaughter and further processing where contaminated eviscerated carcasses & parts that have fallen on the floor, or otherwise have become contaminated off-line, are reconditioned in order to restore sanitary conditions.



# CARCASS CHILLING

- Point when eviscerated carcasses are chilled in order to inhibit microbial growth and meet the regulatory requirements of 9 CFR 381.66(b)(1)
- There are two types of chilling systems: immersion and air
- Cross-contamination may occur when sanitary conditions are not maintained in the chiller, or when carcasses entering the chiller carry high levels of pathogens





# GIBLET CHILLING

- Cross-contamination may occur when sanitary conditions are not maintained in the giblet chiller, or when parts entering the chiller carry high levels of contamination





# FSIS VERIFICATION



# PHIS SANITARY DRESSING TASK

- PHIS schedules the Poultry Sanitary Dressing verification task approximately once every 1 ½ weeks
- IPP are not limited to conducting the Poultry Sanitary Dressing task all in one day
- Can be spread out over a period of days, *if necessary*, in order to gather as much available information so that IPP can make a sound regulatory decision about the *system*



# FSIS VERIFICATION

- The verification activities addressed in the directive are to be used in conjunction with, and can be conducted simultaneously with, those addressed in the following directives:
  - FSIS PHIS Directive 5000.1, Verifying an Establishment's Food safety System
  - FSIS Directive 6100.3 Ante-mortem and Post-mortem Poultry Inspection
  - FSIS 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations
  - FSIS Directive 7000.1, Verification of Non-food Safety Consumer Protection Regulatory Requirements, Part IV, G





# FSIS VERIFICATION

- IPP need to verify, in off-line activities, that **9 CFR 416.1** and **9 CFR 381.65(a)** are met by establishment through the implementation of sanitary dressing and process control measures.
- IPP verify that preventive steps are taken and that contamination events are rare.



# FSIS VERIFICATION

- In addition, before the carcasses enter the chiller, IPP conduct zero tolerance checks to verify compliance with **9 CFR 381.65(e)** to determine that no visible fecal contamination is on the carcasses.



# FSIS VERIFICATION

- IPP that perform off-line slaughter verification duties are to perform the PHIS Poultry Sanitary Dressing task to verify that insanitary conditions are not being created.
  - 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.
  - Verify that the sanitary dressing, and process control procedures, are sufficient to prevent the contamination of carcasses during slaughter operations.



# FSIS VERIFICATION

- Conditions that could affect the sanitary dressing and process control system, include but are not limited to, the following:
  - An increased number of positive establishment or FSIS *Salmonella* or *Campylobacter* test results;
  - An increased number of establishment generic *E.coli* or indicator organism test results that exceed either the establishment's or regulatory control limits;



# FSIS VERIFICATION

- An increase in fecal zero tolerance noncompliances;
- 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).



# FSIS VERIFICATION

- IPP are to gather information using the questions in the directive to determine whether an establishment's slaughter operation meets the requirements of **9 CFR 416.1 through 416.5** or is creating insanitary conditions that may result in product contamination.
- The questions provided at each point in the directive 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 the directive are **not** to be considered to be a checklist and are **not** all-inclusive but are to be considered when gathering information about the establishment's food safety system.



# FSIS VERIFICATION

- A negative response to one of the questions in the directive is **not** an automatic indication of regulatory noncompliance or of a system failure.
- 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.





# FSIS VERIFICATION

- The consideration of information could include, but is not limited to, considering the following information:
  - Information regarding sanitary dressing and process control procedures, and decontamination and antimicrobial intervention treatments;
  - Feedback from further processing operations to the slaughter operation
  - Observations of the plant employees performance of their assigned duties at particular points in the process.



# NOTE

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.



# Establishment Interventions



# ESTABLISHMENT INTERVENTIONS

- Interventions typically are able to reduce bacteria at a given rate (e.g., a 2 log reduction)
- For example: If the bacteria is present at a 5 log level, and the intervention is capable of a 2.0 log reduction, the intervention won't be able to address all the bacteria (i.e. the intervention is *overwhelmed*)



# OVERWHELM AN INTERVENTION

There is so much contamination on the carcass, that the establishment's intervention(s) aren't capable of working as designed and therefore not able to achieve a desired level of pathogen reduction

The establishment may no longer be able to reduce *Salmonella* and *Campylobacter* to the levels expected by the HACCP plan



# ESTABLISHMENT INTERVENTIONS

- Measures need to be taken from the beginning of slaughter process, including at receiving, to prevent contamination so that the interventions will work appropriately
- Without effective sanitary dressing and process control procedures, carcasses could become excessively contaminated, and therefore affect the capabilities of interventions.





# INCIDENTAL CONTAMINATION



# INCIDENTAL 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 (*i.e. between receiving and when carcasses fall into the chiller*), the establishment still has the opportunity to implement measures that will address the contamination *before* the carcasses enter the chiller



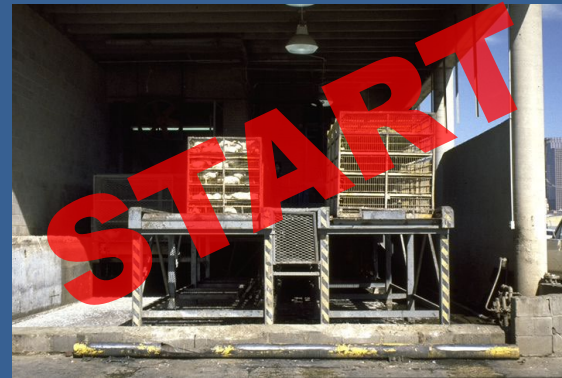


# INCIDENTAL CONTAMINATION

- 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 an insanitary condition has been created, it will be documented as SPS noncompliance.



9 CFR 416.1  
Sanitation Performance  
Standard (SPS)



**Establishment has the opportunity to implement measures throughout the slaughter process to prevent the creation of insanitary conditions until the point in the process where the carcasses fall into the chiller**



# Determining Compliance





# What do FSIS Personnel Need to Do to Determine Sanitary Dressing Non-Compliance ?

# GAD

- Gather Information
- Assess the Information
- Determine Compliance or noncompliance

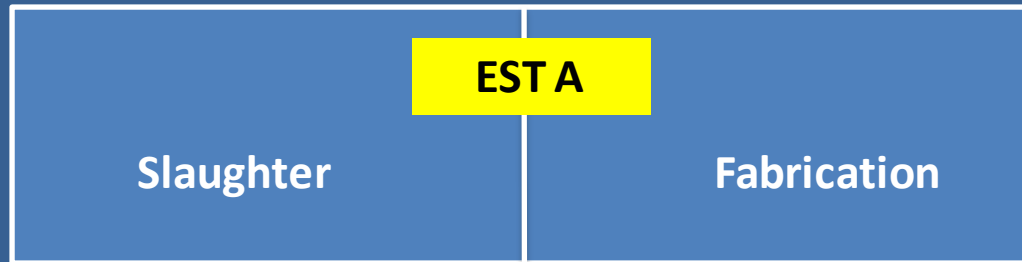


# GATHER

- Gather as much information as possible
  - In-plant Observations
    - Your own
    - On-line IPP
    - PHV/SPHV
  - Historical information
    - NRs
    - MOIs
  - Test Results
    - Establishment Results
    - FSIS Results
  - Communication with other inspectors



# COMMUNICATION



There have been problems with sanitary dressing and several zero tolerance noncompliances

Thanks...That might explain the recent positive test result of ground poultry



# ASSESS

- Sanitation is the foundation of a food safety system
- Sanitary Dressing and Process control is a part of that sanitation foundation
- Decisions made by the establishment to control enteric pathogens such as *Salmonella* and *Campylobacter* will be affected by what the establishment does in regard to sanitary dressing and process control



# REGULATORY BASIS

- Establishments are expected to slaughter and process poultry in a manner designed to prevent contamination of carcasses
  - **9 CFR 416.1** requires that establishments be operated such that they do not create insanitary conditions or contaminate product
  - **9 CFR 381.65(a)** requires prevention of carcass contamination
  - **9 CFR 381.65(e)** requires prevention of carcasses contaminated with feces from entering the chiller





# REGULATORY BASIS

- Other regulations can be integral to sanitary dressing and process control if procedures related to those regulations have been included in the SSOP, HACCP plan or a prerequisite program
  - **9 CFR 416.11 through 9 CFR 416.16**
  - **9 CFR 417**





# DETERMINING COMPLIANCE



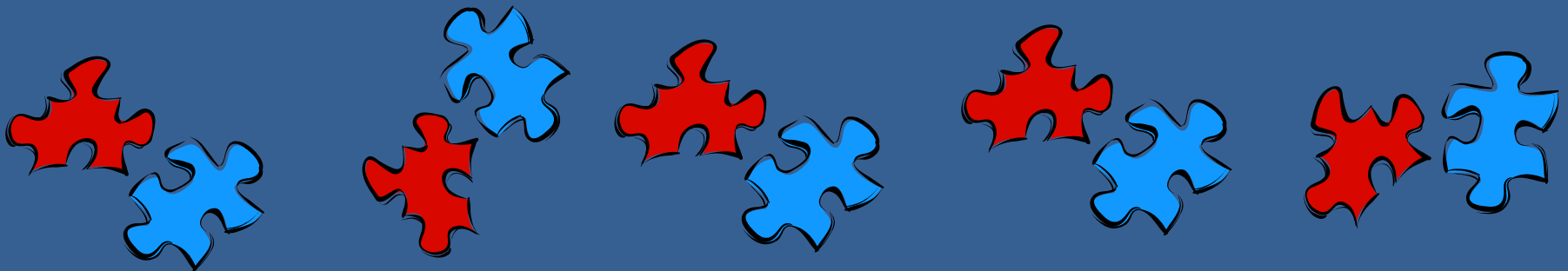
# DETERMINE

Any determination of noncompliance must be based on all the pieces of information that have been gathered regarding the system



# DETERMINING COMPLIANCE

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



# DETERMINING COMPLIANCE

- The thought process for determining compliance of the sanitary dressing and process control procedures is different because it is about considering what is happening within the system
- One specific incident will not normally be documented as a failure of the sanitary dressing or process control procedures because it does not typically represent a failure of the system.



# REMINDER

If IPP find that  
insanitary conditions exist as a result of  
incidental contamination,  
they are to document their findings using the  
PHIS SPS Verification task citing  
9 CFR 381.65(a) and the appropriate SPS  
regulations related to the incident

For additional information on this subject;

- See FSIS Directive 6410.3, Page 21
  - IKE 10-02; and
- askFSIS Q & A titled “Rail Dust



# DOCUMENTING SANITARY DRESSING NONCOMPLIANCE

- When IPP determine that the cumulative information regarding the poultry slaughter operation demonstrates the failure of the sanitary dressing/process control procedures to prevent the creation of the insanitary condition, they are to document noncompliance using the Poultry Sanitary Dressing task on a Noncompliance Record (NR).



# DOCUMENTING SANITARY DRESSING NONCOMPLIANCE

- Cite 9 CFR 381.65(a) to address the contamination of carcasses
- Cite 9 CFR 416.1 and the appropriate SPS regulations to address the creation of the insanitary condition.
  - Example: cite 9 CFR 416.5(a) if improper employee hygiene practices have resulted in the creation of an insanitary condition (i.e., contamination of carcasses)





# DOCUMENTING SANITARY DRESSING NONCOMPLIANCE

- Review available NRs to determine if a trend is developing. NRs can be associated as necessary in accordance with the instructions in FSIS PHIS Directive 5000.1, Chapter 5, to document that a trend of noncompliance is occurring





# SUMMARY



# Summary

- The slaughter process is a system
- Regulations require the prevention of the creation of insanitary conditions (i.e., contamination of carcasses and parts)
- Reducing *Salmonella* and *Campylobacter* is a regulatory requirement & is essential to ensuring food safety



# Summary

## (Continued)

- 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
- Sanitary dressing and process control procedures are key to preventing the creation of insanitary conditions and carcass contamination and to reducing the presence of pathogens



# Summary

(Continued)

- **Incidental contamination** that IPP determine has created an insanitary condition is documented as SPS noncompliance



# Summary

(Continued)

Sanitary dressing noncompliances are determined based on cumulative information reflecting the food safety system

Sanitary Dressing noncompliance is not likely to involve only one point in the process.

Sanitary Dressing noncompliance is not typically documented in regard to one contamination incident.



# Questions

