UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE

WASHINGTON, DC

FSIS DIRECTIVE

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NEW SWINE SLAUGHTER INSPECTION SYSTEM: ANTE-MORTEM AND POST-MORTEM INSPECTION AND VERIFICATION OF FOOD SAFETY AND READY-TO-COOK REQUIREMENTS

CHAPTER I - GENERAL

I. PURPOSE

This directive provides instructions to inspection program personnel (IPP) including consumer safety inspectors (CSIs) and Public Health Veterinarians (PHVs) on how to perform ante-mortem and post-mortem inspection in establishments operating under the New Swine Slaughter Inspection System (NSIS). It also provides instructions to CSIs and PHVs on how to verify that these establishments produce ready-to-cook (RTC) pork.

KEY POINTS:

- Provides instructions on how to perform on-line and off-line inspection procedures at market hog slaughter establishments operating under the NSIS
- Provides instructions on how to use Public Health Information System (PHIS) to document the results of NSIS verification tasks including: the Livestock Zero Tolerance Verification task, NSIS Ante-Mortem Food Safety Verification task, NSIS Post-Mortem Food Safety Verification task, and NSIS RTC Verification task
- Provides instructions on how to verify that market hog slaughter establishments operating under the NSIS meet RTC pork requirements
- Differentiates establishment and inspection activities using terms including establishment "sorting" and CSI "inspection"; establishment "remove or discard" and IPP "condemn"; and establishment "subject" pens and "U.S. Suspect" pens.

II. BACKGROUND

A. On October 1, 2019, the Food Safety Inspection Service (FSIS) published the final rule "Modernization of Swine Slaughter Inspection" (<u>84 FR 52300</u>). The final rule established an optional new inspection system for market hog slaughter establishments, called the NSIS. The rule goes into effect on December 2, 2019. Establishments that elect to implement the NSIS must start following the new NSIS regulations on the date that they convert to the NSIS.

B. Key elements of the NSIS include:

 Use of designated "subject" pens by the establishment to hold swine identified by the establishment for further sorting and "U.S. Suspect" pens (9 CFR 307.2(a), 309.2(m)-(n), and 313.1(c)) to hold only swine identified by CSIs for PHV disposition;

- 2. Requiring establishment personnel to sort and remove unfit animals before FSIS conducts antemortem inspection (9 CFR 309.19(a)-(b)) and to identify and remove or mark for removal any condemnable conditions or defects on carcasses and parts before FSIS conducts post-mortem inspection (9 CFR 310.26(b));
- 3. Requiring establishment personnel to identify animals or carcasses that they have sorted and removed for disposal before FSIS conducts antemortem or slaughter with a unique tag, tattoo, or similar device (9 CFR 309.19(c));
- 4. Requiring establishments to develop, implement, and maintain written procedures in their HACCP systems (i.e., HACCP, Sanitation SOP, prerequisite program) to ensure that animals and carcasses that have been sorted and removed for discard do not enter the human food supply and are properly disposed of according to 9 CFR part 314 (9 CFR 309.19(b));
- Requiring establishments to maintain records to document the total number of animals and carcasses that they have sorted and removed for disposal during ante-mortem (9 CFR 309.19(d)) and post-mortem sorting on each day per shift and the reasons for their removal (9 CFR 310.26(d)(2));
- Requiring establishment personnel to immediately notify IPP if they identify an animal or carcass that they suspect has a reportable or foreign animal disease (FAD)(e.g., African swine fever, classical swine fever [hog cholera], Foot-and-Mouth Disease, or Nipah virus encephalitis)(9 CFR 309.19(e));
- 7. Requiring establishments to maintain records documenting that products resulting from their slaughter operations meet the definition of a RTC pork product, which is any slaughtered pork product sufficiently free from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor which is suitable for cooking without need of further processing (9 CFR 301.2 and 310.26(d)); and
- 8. Removing maximum line speeds and authorizing establishments to determine their own line speeds based on their ability to maintain process control (9 CFR 310.26(c)).

C. The District Manager may allow NSIS market hog establishments to slaughter other classes of swine under traditional inspection subject to the current staffing under NSIS. Establishments may request a waiver of slaughter regulations in accordance with the *Salmonella* Initiative Program (SIP) (<u>76 FR 41186</u>) to slaughter classes of swine other than market hogs under the NSIS.

CHAPTER II – INITIAL IMPLEMENTATION

A. All market hog establishments have until March 30, 2020 to notify their FSIS District Office (DO) of their intent to operate under NSIS. Establishments that do not notify their DO of their intent to convert to NSIS by that date will be deemed to have chosen to continue operating under the traditional inspection system. Traditional market hog slaughter establishments that decide that they would like to convert to NSIS after March 30, 2020 may notify their DO of their intent at any time after that date.

B. After the DO receives notification of the establishment's request to convert to the NSIS, the PHV or Inspector-in-Charge (IIC) is to review the establishment's facilities, plans, and procedures and document any discussions with the establishment in a Memorandum of Interview (MOI) as described in <u>FSIS</u> <u>Directive 5000.1</u>, *Verification of the Establishment's Food Safety System*.

C. The PHV is to evaluate the establishment's proposed changes and notify the DO through the Frontline Supervisor (FLS) on the suitability of such facilities, plans, and procedures for operating under the NSIS. The PHV is to identify and notify the DO of any potential conflicts including:

- 1. Line configuration including location and space allocated for sorters and IPP at each inspection station;
- 2. Presentation of heads, viscera, and carcasses;
- 3. Adequacy of facilities including lighting, inspection area, and use of a mirror (9 CFR 310.26(a) and 9 CFR Part 307);
- 4. Means of identifying and tracking carcasses removed from slaughter, including those removed before and after FSIS ante-mortem inspection;
- 5. Means of identifying, handling, tracking, and marking of heads, carcasses, and parts intended for additional sorting off-line before post-mortem inspection, indicating the presence of specific conditions (e.g. abscess or localized TB), or disposal; and
- 6. Expected start date.

D. As directed by the FLS, the PHV is to document in a MOI notification to the establishment regarding the final details or any additional changes required per above before implementation of NSIS.

- E. Before the first day of implementation of NSIS at the official establishment, the PHV or designee is to:
 - Perform an Update Establishment Profile task to update the task list and slaughter line information before implementation of NSIS. See instructions in <u>FSIS Directive 5300.1</u>, *Managing the Establishment Profile in PHIS.* Select "NSIS" as the inspection system in the PHIS **Establishment Profile - Slaughter** page for each slaughter line operating under the new inspection system; and
 - After updates have been entered into PHIS and the system has had sufficient time to refresh, review the Establishment Profile – Inspection Tasks page to confirm that PHIS has assigned the NSIS Ante-Mortem Food Safety Verification task, NSIS Post-Mortem Food Safety Verification task, and NSIS RTC Verification tasks at the establishment.

F. IPP are to perform both on-line and off-line inspection activities when assigned to a facility using the NSIS. CSIs are to rotate between on-line and off-line positions, under the direction of the PHV. Questions about the rotation pattern are to be made through supervisory channels to the DM.

G. IPP are to ensure that animals inspected and passed at ante-mortem are fit for slaughter and carcasses and parts that pass inspection at post-mortem are safe, wholesome, and not adulterated.

- 1. On-line post-mortem inspection activities include inspecting the head, viscera, and carcass of each animal at fixed locations on the evisceration line. CSIs are to identify and retain for PHV disposition carcasses and parts that may be affected with food safety or other conditions requiring PHV disposition that establishment employees have sorted and presented to CSIs for post-mortem inspection.
- 2. Off-line inspection activities include conducting ante-mortem inspection and verifying establishment sorting and humane handling procedures. Other off-line inspection activities include verifying establishment's sanitary dressing procedures, process controls, and compliance with Sanitation Standard Operating Procedures (Sanitation SOPs), Sanitation Performance Standards (SPSs),

and HACCP regulatory requirements throughout the slaughter area, along the evisceration lines, and other areas as directed by the PHV. These off-line inspection tasks consist of review and observation, records review, or both components. See <u>FSIS Directive 6410.4</u>, Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens.

H. During the first 30 days after implementation of NSIS, the PHV is to correlate with plant management regularly, if not daily, to address issues regarding implementation and as needed thereafter. The PHV is to notify the FLS of any issues and document discussions with the establishment in an MOI.

CHAPTER III – ANTE-MORTEM INSPECTION AT NSIS ESTABLISHMENTS

I. ANTE-MORTEM INSPECTION AND VERIFICATION

A. Except where instructed otherwise in this directive, IPP including CSIs under direction of the PHV are to conduct ante-mortem inspection on swine presented for slaughter by the establishment in accordance with FSIS Directive 6100.1. Ante-Mortem Livestock Inspection.

B. IPP are to verify the establishment meets humane handling requirements following the instructions in <u>FSIS Directive 6900.2</u>, *Humane Handling and Slaughter of Livestock*.

C. As scheduled in PHIS and as directed by the PHV, IPP are to review daily sorting activities by the establishment and available slaughter records as part of a HACCP systems verification task (e.g., Slaughter HACCP). IPP are to:

- 1. Verify that Establishment sorters are implementing the establishment's ante-mortem sorting procedures (9 CFR 309.19 (a)) as written (9 CFR 309.19(b));
- Verify that the establishment follows and maintains effective written sorting procedures in its HACCP system. Effective sorting procedures ensure that abnormal and unhealthy animals are removed from healthy animals before being presented to IPP for ante-mortem inspection, and that animals removed for disposal do not enter the human food supply (ref. 9 CFR 309.13) and are properly disposed of according to 9 CFR part 314 (9 CFR 309.19 (a)-(c));
- 3. Verify that establishment sorters identify all dead animals and animals that they have sorted and removed for disposal before FSIS ante-mortem inspection with a unique tag, tattoo, or similar device (9 CFR 309.19 (c));
- Verify that establishment records document on each day and shift the total number of animals and carcasses sorted and removed for disposal before slaughter and the reasons for their removal (9 CFR 309.19(d));
- 5. Enter establishment sorting information collected on each shift at ante-mortem into PHIS or verify that the establishment has electronically entered this information into PHIS. FSIS has created <u>FSIS Form 6200-20</u>, *Establishment Sorting Record*, to collect this data. Establishments may provide the information electronically if submitted in a format approved by FSIS. To avoid over counting, IPP are to verify whether or not establishment records include animals or carcasses condemned by the PHV in PHIS and adjust the numbers accordingly before entering in PHIS; and
- 6. Issue a noncompliance record if the establishment does not meet one or more of these requirements.

D. IPP are to be aware that establishments use one or more "subject" pen(s) to hold slow or other swine until they have had time to rest and recover before final sorting. After final sorting and removal of animals with condemnable conditions, if any, the establishment identifies and presents swine in the subject pen that appear otherwise healthy and eligible for slaughter to the PHV for ante-mortem inspection. The PHV is to then:

- 1. Make the disposition on each swine identified by the establishment and presented for inspection in the "subject" pen;
- 2. Track the number of swine inspected in the "subject" pen in PHIS; and
- 3. Issue a noncompliance record using the NSIS Ante-Mortem Food Safety Verification task if the establishment presents a swine for inspection in the "subject" pen with clinical signs consistent with a dying (moribund), a central nervous system (CNS) disorder, or pyrexia. The PHV is to:
 - a. Condemn the animal;
 - b. Cite 9 CFR 309.19(b) and the appropriate regulation associated with the food safety condition (i.e., 9 CFR 309.3(c) for pyrexia; 9 CFR 309.3(d) for moribund; or 9 CFR 309.4 for CNS) identified in the noncompliance record. See <u>Table 2</u> below;
 - c. Ensure all swine condemned on ante-mortem by the PHV are identified with a U.S. Condemned (Z-tag) and documented in PHIS; and
 - d. Verify establishment corrective actions when performing the next appropriate HACCP systems verification task.

E. Following Animal and Plant Health Inspection Service (APHIS) requirements, the establishment may divert otherwise healthy swine that have localized conditions (e.g., animals with arthritis or abscesses) or that do not meet establishment specifications (e.g., boars, underweight swine, swine with hernias) to another official establishment, where they will receive FSIS inspection before slaughter.

F. If an establishment notifies IPP that they have identified an animal or carcass that they suspect has a reportable or FAD condition (e.g., African swine fever, classical swine fever [i.e., hog cholera], or Nipah virus encephalitis), the PHV is to follow instructions in <u>FSIS Directive 6000.1</u>, *Responsibilities Related to Foreign Animal Diseases and Reportable Conditions*.

- G. The PHV is to:
 - 1. Inspect and make disposition on any swine placed in the "U.S. Suspect" pen by the CSI; and
 - 2. Issue a noncompliance record for any swine condemned by the PHV for a food safety condition.

H. IPP are to add the appropriate HACCP systems verification task not already scheduled in PHIS, as needed, to document all NSIS verification activities that they perform on each shift, citing the regulations verified on each shift and results. See <u>Attachment 1</u> for a summary of the inspection tasks to use to verify NSIS requirements.

CHAPTER IV – POST-MORTEM INSPECTION

I. GENERAL, PRESENTATION, AND LINE SPEED

A. Establishments are required to trim and remove any localized contamination and carcass trim defects associated with carcass dressing. Such defects do not affect the disposition of the carcass. Such defects are to be removed in a sanitary manner before FSIS inspection (9 CFR 310.26 (b)). Examples of defects eligible for trimming before inspection include all contamination (i.e., feces, ingesta, or milk) and RTC defects (e.g., hair, dirt, scurf, and claws).

B. On-line IPP are to inspect and verify that the establishment identifies (e.g., marks with ink) parts with localized conditions or defects intended for removal and disposal. On-line IPP are to retain any carcasses requiring PHV disposition. IPP are to verify that the establishment does not remove parts with defects that may affect the disposition of the entire carcass (e.g., tumor, injection sites) before inspection by the PHV.

C. The PHV is to review, correlate, and clarify which defects are eligible for trimming before inspection and those defects or conditions that are subject to inspection before trimming and disposal with establishment management as needed and with CSIs. PHVs may also include discussion of APHIS issuances covering reportable and FADs.

D. CSIs are to notify the PHV or designee when the on-line CSI cannot adequately perform a carcass-bycarcass inspection within the time available because of:

- 1. Deficiencies in the preparation and presentation of the carcass for inspection (9 CFR 310.26(c));
- 2. The presence of persistent, unattended non-food safety defects (see Chapter III, Section II for information on persistent unattended defects); or
- 3. Repetitive observation of contaminated carcasses and parts by visible feces, ingesta, or milk (9 CFR 310.18(a-c)) at the point of final carcass inspection as per <u>FSIS Directive 6420.2</u>, *Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations.*

G. When evaluating the establishment's response to an apparent failure to prevent contamination from feces, ingesta, or milk (9 CFR 310.26(c)) or maintain process control during post-mortem inspection (e.g., after notification by the CSI), the PHV is to evaluate sorting and process control using the following parameters:

- 1. Persistent and unattended trim or processing defects that interfere with inspection or create insanitary conditions;
- 2. Deficiencies in presentation (e.g., multiple unsorted, missing, or contaminated organs);
- 3. Health conditions of a particular herd;
- 4. Repetitive presentation of contaminated heads, viscera, or carcasses for inspection; or
- 5. Any other condition that affects the on-line CSIs ability to adequately perform carcass-by-carcass inspection or creates insanitary conditions.

H. When a carcass-by-carcass inspection cannot be adequately performed due to the establishment's loss of process control and the failure to restore process control, the PHV is authorized to direct the establishment to operate at a reduced line speed per 9 CFR 310.26(c). If the PHV slows the line speed,

the PHV is to issue a noncompliance record using a separate directed HACCP systems verification task (e.g., Slaughter HACCP) and cite noncompliance with:

- 1. 9 CFR 310.18(a)) for failure to control fecal contamination of carcasses or parts; or
- 2. 9 CFR 310.26(d)(1), 310.26(c) and 301.2 for persistent and unattended defects that are interfering with the on-line inspector's ability to perform proper post-mortem procedures.

I. IPP are to refer to <u>Attachment 1</u> for a summary of the inspection tasks to use to verify NSIS requirements.

II. ON-LINE INSPECTION

A. On-line IPP are to perform inspection of the sorted head, viscera, and carcass presented for inspection using the <u>visual inspection procedures</u> described in <u>FSIS Directive 6100.2</u>, *Post-Mortem Livestock Inspection*.

- B. Under NSIS, IPP performing on-line head inspection are to:
 - Visually inspect heads and mandibular lymph nodes incised by establishment employees presented for inspection as part of the establishment's head sorting procedures in 9 CFR 310.26(b);
 - Inspect and pass heads that appear wholesome and unadulterated as defined in 9 CFR 301.2. Inspect heads identified by establishment sorters for removal or discard (e.g., abscessed or contaminated) before disposal. Retain heads and carcasses with conditions that require disposition by the PHV. See examples in <u>Table 3</u> below;
 - 3. Inspect and condemn contaminated heads (e.g., ingesta, abscess) and other condemnable defects not identified by establishment sorters for discard;
 - 4. Retain head and associated carcass not identified for removal by the establishment with any condition requiring PHV disposition; and
 - 5. Notify the off-line CSI or PHV when the establishment appears to have lost control of its sorting process.
- C. IPP performing on-line viscera inspection are to:
 - 1. Visually inspect all viscera and observe the associated carcass;
 - 2. Pass sorted viscera and associated carcasses that appear wholesome and unadulterated. Inspect parts of viscera with localized conditions identified by the establishment sorters for discard (e.g., adhesions; abscessed, contaminated) before disposal;
 - Condemn parts with localized condemnable defects (e.g., fecal contamination or open abscess). See examples in <u>Table 3</u> below;
 - Retain for PHV disposition any unsorted viscera and associated carcass and parts (e.g., head) not identified for removal and discard with any condition requiring PHV disposition. See <u>FSIS Directive</u> <u>6100.2</u>; and

5. Notify the off-line CSI or PHV when the establishment appears to have lost control of its sorting process.

NOTE: Inspection standards allow IPP to pass white offal (e.g., stomachs, intestines, bungs) with small isolated amounts of contamination (e.g. spec or fleck) requiring further processing before becoming eligible for the mark of inspection. The PHV is to correlate and provide guidance to CSIs on inspection standards as needed.

- D. IPP performing on-line carcass inspection are to:
 - 1. Visually inspect and pass carcasses that are free of feces, ingesta, milk, and any condemnable condition warranting disposition by the PHV;
 - Stop the slaughter line to allow for trimming of the carcass for feces, ingesta, or milk by establishment personnel and reinspection of the carcass by the on-line inspector, unless the establishment has provided an out rail or loop to allow off-line trimming and on-line reinspection of carcasses per instructions in <u>FSIS Directive 6420.2</u>;
 - 3. Retain any carcass and associated parts not identified by the establishment for discard or disposal requiring a PHV disposition; and
 - Notify the PHV or designee when carcasses and parts are presented with deficiencies in presentation or recurring contamination suggesting that there is a loss of process control or interfering with post-mortem inspection. See instructions below and in <u>FSIS Directive 6420.2</u>.

III. VERIFICATION OF THE POST-MORTEM HACCP SYSTEM

A. Off-line IPP are to verify using the appropriate HACCP systems verification task (See <u>Attachment 1</u>) that the establishment has developed, implemented, and maintains written procedures, controls, corrective actions, and records for post-mortem sorting within its HACCP system. IPP are to verify that establishment procedures address at a minimum:

1. Sorting and removal or identifying for removal before the FSIS on-line viscera inspection of carcasses and parts with conditions that otherwise would require PHV disposition (e.g. septicemia, toxemia, pyemia, cysticercosis, and other condemnable conditions per 9 CFR 310.26(b);

NOTE: The disposition of carcasses with septicemia, pyemia, toxemia or cysticercosis is dependent on the examination of the entire carcass and viscera together. FSIS verification of establishment sorting to remove these food safety conditions is performed after establishment sorting of the viscera with the carcass. Noncompliance is based on PHV disposition of the entire carcass and its parts not identified for disposal by the establishment after sorting at the viscera station and retained by IPP.

- 2. Removal or marking of feces, ingesta, and milk before the FSIS inspection of the head, viscera, and carcass (9 CFR 310.18(a)). See <u>FSIS Directive 6420.2</u>; and
- 3. Documenting the results of those sorting procedures on each shift.

B. As directed by the PHV, off-line CSIs are to observe carcasses requiring further sorting off-line and review establishment records documenting reasons for discarding entire carcasses at post-mortem daily. Off-line CSIs are authorized to retain any sorted carcass or parts including those not identified for discard, as needed and as directed by the PHV, for correlation or PHV disposition. IPP are to complete the

appropriate HACCP systems verification task to document compliance or non-compliance with the regulations that were verified.

C. IPP are to enter establishment sorting information collected on each shift at post-mortem into PHIS or verify that the establishment has electronically entered this information into PHIS. FSIS has created <u>FSIS</u> Form 6200-20, *Establishment Sorting Record*, to collect this data. Establishments may provide the information electronically if submitted in a format approved by FSIS. To avoid over counting, IPP are to verify whether or not establishment records include animals or carcasses condemned by the PHV in PHIS and adjust the numbers accordingly before entering in PHIS.

IV. VERIFICATION USING THE LIVESTOCK ZERO TOLERANCE TASK

A. Off-line IPP in official establishments operating under NSIS are to:

 Except as described below, perform the Livestock Zero Tolerance Verification task referenced in <u>FSIS Directive 6420.2</u> twice per shift on each slaughter line or more often as directed by the PHV. CSIs are to schedule the routine and as many directed Livestock Zero Tolerance Verification tasks as needed to document their verification activities and verify the establishment is meeting regulatory requirements;

Table 1 – Number of Carcasses Examined by the Off-line CSIs when Performing the LivestockZero Tolerance Verification Task - Minimum (2X) per Shift.

Livestock Carcass Sample Size			
Number of Animals Slaughtered per Shift	Number of Carcasses* to be Sampled per Task	Number of Sides to be Sampled per Task	
100 or fewer	2	4	
101 to 250	4	8	
251 to 500	8	16	
More than 500	12	24	

*In NSIS establishments, CSIs observe heads and viscera before examining carcasses.

- Examine each carcass selected for examination at the point of carcass inspection before the final wash and identify any fecal, milk, or ingesta contamination using the same criteria for swine in <u>FSIS Directive 6420.2</u>, Attachment 2;
- Issue a noncompliance record when carcass contamination with feces, ingesta, or milk is found. See instructions in <u>FSIS Directive 6420.2</u>, Attachment 2, for identifying feces, ingesta, and milk and verify remaining corrective actions by performing the Slaughter HACCP task. See instructions in <u>FSIS Directive 5000.1</u>;
- 4. Examine head, cheek, and weasand meat, if saved, at the point of packing or packaging for feces, ingesta, and milk as specified in <u>FSIS Directive 6420.2</u>, at least once per shift, and as per instructions in this directive. Retain head, cheek, and weasand meat when feces or ingesta contamination is found. Notify the PHV and establishment of the noncompliance, document the positive finding, and verify corrective actions as per Section III above; and
- 5. Perform additional Livestock Zero Tolerance Verification tasks on carcasses or head, cheek, and weasand meat as directed by the PHV.

V. DOCUMENTING VERIFICATION RESULTS AND ENFORCEMENT

A. Unless specified otherwise in this directive or directed by the PHV, IPP are to perform tasks scheduled in PHIS as instructed in the applicable directive and document the results in PHIS.

- B. Off-line IPP performing the Livestock Zero Tolerance Verification task are to:
 - 1. Document compliance with 9 CFR 310.18(a) and 9 CFR 310.26(b) and any other regulations verified in PHIS. IPP are to mark the task as "Inspection Completed" each time carcasses and head, cheek, and weasand meat are examined and no feces, ingesta, or milk contamination is found:
 - 2. Issue a noncompliance record and cite 9 CFR 310.18(a) when carcasses, head, cheek, or weasand meat selected for verification are observed by the CSI to be contaminated with feces, ingesta or milk;
 - 3. Verify removal of all contamination on carcasses or parts when feces, ingesta or milk are found while performing the Livestock Zero Tolerance Verification or HACCP systems verification task: and
 - 4. Verify required corrective actions when performing the next appropriate Slaughter HACCP tasks per instructions in per FSIS Directive 6420.2 and FSIS Directive 5000.1.

C. The PHV is to issue a noncompliance record using the appropriate NSIS Ante-mortem Food Safety Verification task or NSIS Post-mortem verification task when the establishment fails to identify and remove for disposal (i.e. PHV condemns) animals or carcasses with food safety conditions specified in 9 CFR 309.19(b) or 9 CFR 310.26(b). The PHV is to cite the appropriate sorting regulation(s) (e.g. 9 CFR 310.19(b)) verified and the regulation associated with the food safety condition. See Table 2 below.

Table 2 – Verifiable Regulations Associated with Food Safety Condition Noncompliance under NSIS		
	Ante-Mortem Sorting Regulation (9 CFR 309.19(b))	Post-Mortem Sorting Regulation (9 CFR 310.26(b))
Food Safety Conditions	Pyrexia (9 CFR 309.3(c)); Moribund (9 CFR 309.3(d)); or CNS (9 CFR 309.4)	Septicemia, pyemia, toxemia (9 CFR 311.16); or Cysticercosis (9 CFR 311.24));

D. The PHV is to document the results of all verification tasks and regulations verified by the PHV in PHIS. The PHV is to issue a noncompliance record after determining food safety conditions exist in animals or carcasses not identified for discard by the establishment requiring PHV disposition. See Attachment 1.

E. If the PHV determines that the establishment did not properly sort for and notify FSIS of a notifiable animal disease (including any FAD), the PHV is to document noncompliance using the appropriate HACCP system task or Other Inspection Requirements task. Notifiable animal diseases are designated by World Animal Health Organization (CFR 309.19(e)).

VI. PHV ROLES AND RESPONSIBILITIES AT POST-MORTEM

A. The PHV is to:

- 1. Verify that the establishment removes defects eligible for trimming (i.e., not affecting inspection or required for disposition of the carcass by the PHV). See examples in <u>Table 3</u> below;
- Verify that the defects or conditions on carcasses or parts not eligible for trimming before inspection and identified by the establishment for removal or discard receive inspection before disposal (e.g., head abscess);
- 3. Observe daily off-line sorting of carcasses and their associated parts and verify that establishment records accurately document the reasons why carcasses and associated parts are discarded;
- 4. When needed or requested, meet with establishment management and discuss sorting decisions on establishment sorted carcasses and parts. The PHV should not issue a noncompliance record when the establishment requests a correlation;

Examples of Localized Carcass Trim Defects Removable before Inspection, Chilling per RTC Standards, and	Examples of Localized Carcass Trim Defects Requiring Removal before Inspection	Examples of Localized Carcass Defects Requiring Inspection before Removal	Examples of Conditions Requiring Inspection and Subject to PHV Disposition
Shipping in Commerce*			
Bile, dirt, foreign material (e.g., grease); individual attached hairs, toe nails, scabs, minor bruises, skin lesions, bile	Fecal, ingesta, and milk contamination	Localized Abscess; localized healed adhesions of the heart and lung	Tumors; active, inflamed, or generalized disease conditions involving carcasses and parts

Food Safety Consumer Protection Regulatory Requirements.

- 5. Make dispositions on carcasses and associated parts retained for PHV disposition. See instruction in <u>FSIS Directive 6100.6</u>, *Post-Mortem Dispositions for Public Health Veterinarians*;
- 6. Document all PHV dispositions made in PHIS using FSIS Form 6502-2 (MPD tags) or ("B-series") FSIS Form 6502-1 ("B-series") tag numbers in PHIS. See instructions in <u>FSIS Directive 6100.2</u>;
- 7. Issue a noncompliance record citing 9 CFR 310.26(b) and the appropriate regulation associated with the food safety condition for failure to sort septicemia, toxemia, pyemia, or cysticercosis before viscera inspection using the NSIS Post-Mortem Food Safety Verification task; See <u>Attachment 1</u>;
- Issue a noncompliance record using the Slaughter HACCP or appropriate HACCP systems verification task citing 310.26(b) when the PHV observes repeated failures by the establishment to sort and discard entire carcasses and associated parts with other condemnable non-food safety conditions (e.g., lymphoma) using the appropriate HACCP systems verification task;

NOTE: Condemnation of a single carcass by the PHV for other condemnable non-food safety conditions, (e.g., lymphoma) may not indicate a loss of establishment process control.

- Collect and submit, or designate the collection and submission of all directed and inspector generated residue samples as instructed in <u>FSIS Directive 10,800.1</u>, Residue Sampling, Testing, and Other Verification Procedures under the National Residue Program for Meat and Poultry Products; and
- 10. Perform or direct the performance of additional HACCP systems verification tasks (e.g., Livestock Zero Tolerance Verification task (<u>FSIS Directive 6420.2</u>); Slaughter HACCP Verification (<u>FSIS Directive 5000.1</u>); Performance of the Hazard Analysis Verification (HAV) task (<u>FSIS Directive 5000.6</u>)) by off-line CSIs when one or more of the following are observed:
 - a. One or more failures to sort, identify, or dispose of animal, carcasses, or parts with food safety or other condemnable conditions;
 - b. Major changes to the establishment methods, procedures, or facilities;
 - c. Documentation of repetitive or frequent food safety noncompliance;
 - d. Evidence of inadequate corrective actions involving food safety;
 - e. Abnormal or unexpected trends in the numbers and reasons for retained (i.e., unsorted) carcasses, zero tolerance failures, or animals or carcasses identified for removal (i.e., discarded); or
 - f. HACCP system noncompliance.

CHAPTER V – VERIFICATION OF READY-TO-COOK (RTC) PORK

I. GENERAL

A. NSIS establishments are required by 9 CFR 310.26(d)(1) to maintain records of procedures and results documenting that the products resulting from their slaughter operations meet the definition of RTC pork (9 CFR 301.2).

B. Definition in 9 CFR 301.2:

RTC pork is...any slaughtered pork product <u>sufficiently free</u> from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, icterus, foreign material, and odor which is suitable for cooking without need of further processing.

C. CSIs are to verify that NSIS establishments have adopted any of the following acceptable or equivalent criteria to determine whether they are producing RTC pork that meets:

- 1. Other Consumer Protection (OCP) standards developed for the <u>Hazard Analysis of Critical Control</u> <u>Points-Based Inspection Models Project (HIMP) pilot</u> (p. 8);
- 2. Alternative standards used under an approved SIP waiver; or
- 3. Other OCP performance standards or defect criteria as defined in a published study or a scientifically or statistically based study that the establishment conducted itself to support and document that they are meeting the RTC definition.

II. RTC PROCESS CONTROL DURING ON-LINE INSPECTION

A. When on-line CSIs believe that the presentation of persistent and unattended trim or RTC processing defects (i.e., not meeting the definition of RTC in 9 CFR 301.2 per 9 CFR 310.26(d)(1)) demonstrates a lack of process control, the on-line CSI is to notify off-line personnel.

B. IPP are to use the following definitions for persistent and unattended RTC defects:

- 1. The phrase "persistent trim and processing defects" means the defect(s) on carcasses continue to occur repetitively. Trim and processing defects that are persistent include numerous carcasses, either in a row or in clusters that have obvious, severe, or numerous problems that could affect the usability of the product.
- 2. The phrase "unattended defects" means the establishment has had the opportunity to respond to persistent defects and has not effectively corrected the problem.

NOTE: Examples of non-food safety trim and processing defects include RTC dressing defects such as toenails, hair, bruises, fractures, skin lesions, scars, bile stains and localized conditions (e.g., minor bruises, post-mortem fractures) not warranting PHV disposition.

C. When notified of persistent and unattended trim or RTC processing defects by on-line or off-line CSIs indicating a loss of process control or when the establishment failed to restore compliance with the RTC standard, the PHV is to direct the off-line inspector to conduct a directed NSIS RTC Verification task.

D. On-line CSIs are not to routinely direct establishment trimming of RTC defects or use a zero-tolerance standard for RTC defects.

E. If the PHV determines that the presentation of persistent unattended trim or processing defects indicates a loss of process control that affects the on-line inspectors' ability to conduct a carcass-by-carcass inspection, the PHV is to direct the establishment to reduce its line speed. The PHV is then to issue a noncompliance record citing 9 CFR 310.26(d) (1) and 9 CFR 310.26(c). See Directed RTC Verification below.

III. ROUTINE RTC VERIFICATION

A. Off-line IPP are to schedule a routine NSIS RTC Verification task when available in the PHIS task list (e.g., monthly) and review establishment records documenting that the establishment is producing product meeting RTC standards as required by 9 CFR 310.26(d)(1). The routine RTC task only has a recordkeeping component (i.e., no review and observation component).

B. When conducting the monthly routine NSIS RTC Verification task, off-line CSIs are to verify that the establishment maintains records to document that the products resulting from its slaughter operations meet the definition of RTC pork in 9 CFR 301.2 per 9 CFR 310.26(d)(1). Such records demonstrating the establishment is producing RTC pork may include:

- 1. The definitions of the non-food safety or RTC non-conformances, processing, and trim defects for which the establishment is monitoring;
- 2. Statistical process control charts, HACCP records, or other documentation;
- 3. Monitoring procedure, the number of carcasses examined to determine whether they meet the RTC definition at the end of the slaughter process and before carcasses and parts enter the cooler;

- 4. The frequency of monitoring and records results of these monitoring activities;
- 5. Criteria that the establishment uses to determine whether the products resulting from its slaughter operation meet the RTC definition; and
- 6. Establishment action levels (e.g., OCP performance standards) and corrective actions for RTC processing and trim defects when the establishment exceeds its defect criteria.

NOTE: Establishments are required to have documentation that their products meet RTC standards. Such documentation may include written procedures not incorporated within the HACCP system.

- C. When conducting a routine NSIS RTC Verification task, the off-line CSI is to notify the PHV when:
 - 1. The establishment does not have records to document that the products resulting from its slaughter operation meet the definition for RTC pork; or
 - 2. Establishment records do not include the minimum information required in 9 CFR 310.26(d)(1) and 9 CFR 301.2 to support that shipped product met RTC standards.

D. CSIs are to notify the PHV of results; CSIs are not to issue noncompliance records when performing the *routine* NSIS RTC Verification task unless directed by the PHV.

IV. DIRECTED RTC VERIFICATION

- A. When directed by the PHV to perform the directed NSIS RTC Verification task, the off-line CSI is to:
 - 1. Verify products meet the RTC definition by observing product at the end of the slaughter process and before carcasses and parts leave the slaughter floor and enter the cooler;
 - 2. Perform both review and observation and recordkeeping and select "both" under the activity tab in PHIS;
 - 3. Use the same sampling methodology and criteria set by the establishment's RTC program when examining product;
 - 4. Review findings with the PHV; and
 - 5. Issue a noncompliance record citing 9 CFR 310.26(d)(1) when:
 - a. The level of defects on the slaughter floor exceed the criteria set by the establishment;
 - b. The establishment did not take the necessary corrective actions to restore process control when the evaluation criteria were exceeded;
 - c. The PHV determines that the presentation of persistent and unattended trim or processing defects indicates a loss of process control that affects the on-line inspectors' ability to adequately conduct a carcass-by-carcass inspection; or
 - d. The establishment does not have sufficient records to document that the products resulting from its slaughter operation meet the definition for RTC pork.

V. PHV RESPONSIBILITIES FOR RTC VERIFICATION

The PHV is to:

- 1. Correlate with on-line and off-line CSIs and the establishment regarding the nature and level of persistent and unattended RTC defects at the end of the slaughter process before entering the cooler that interfere with inspection; and
- 2. Perform or assign performance of a directed RTC verification task and follow up or verify that the off-line CSIs follow the instructions for performing a directed RTC task.

CHAPTER VI. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through <u>askFSIS</u> or by telephone at 1-800-233-3935, if needed, after correlation with your supervisor. When submitting a question, use the **Submit a Question** tab, and enter the information indicated below in the designated fields.

Subject Field:	Enter Directive 6600.1.
Question Field:	Enter your question with as much detail as possible.
Product Field:	Select General Inspection Policy from the drop-down menu.
Category Field:	Select Slaughter - Livestock from the drop-down menu.
Policy Arena:	Select Domestic (U.S.) only from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question.**

NOTE: Refer to <u>FSIS Directive 5620.1</u>, *Using askFSIS*, for additional information on submitting questions.

Jerri Nintemann

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Table 4 – NSIS Verifica	tion Tasks and F	Regulations in FSIS Dire	ctive 6,600.1
		Ante-Mortem	Post-Mortem
NSIS Verification Tasks:	Estimated Frequency		
NSIS Ante-Mortem Food Safety Verification Task	As needed by PHV when food safety disposition is made on US Suspect or other unsorted animal.	(9 CFR 309.19(b)) Condemnation of animal with food safety conditions not sorted by the establishment is a noncompliance.	
NSIS Post-Mortem Food Safety Verification task	As needed by PHV when PHV condemns a retained or other unsorted carcass with a food safety condition.		(9 CFR 310.26(b)) Condemnation of a retained or other unsorted carcass with a food safety condition by the PHV is a noncompliance.
Livestock Zero Tolerance Verification task	2X per shift (1X per shift for head, cheek, and weasand meat)		(9 CFR 310.18(a)))
HACCP systems verification tasks involving HACCP, SSOP, and PR programs. E.g., Slaughter HACCP Verification Task (9 CFR Part 417); Operational Sanitation Verification Task – (9 CFR Part 416)	Daily by PHV and CSIs	IPP verify ante-morte recor- Includes verifying sortin and at post-mortem he inspection and off-lin Includes CSIs verifying records and retaining viscera or carcass off-lin as nee PHV verifies ante-mort sorting records; reviews decisions, and make neces (E.g., Verify implem procedures (impleme verification, recordkee actior	rds. Ig before ante-mortem ead, viscera, and rail ie sorting locations; establishment sorting sorted carcasses at he sorting or inspection eded; tem and post-mortem e stablishment sorting es dispositions, as sary. mentation of written entation, monitoring, eping, and corrective
NSIS RTC Verification task	Monthly per this directive.		Routine (monthly) and as directed by the PHV

Update Establishment	At	See FSIS Directive 5,300.1, Managing the
Profile task	implementation	Establishment Profile in PHIS.
	and monthly	