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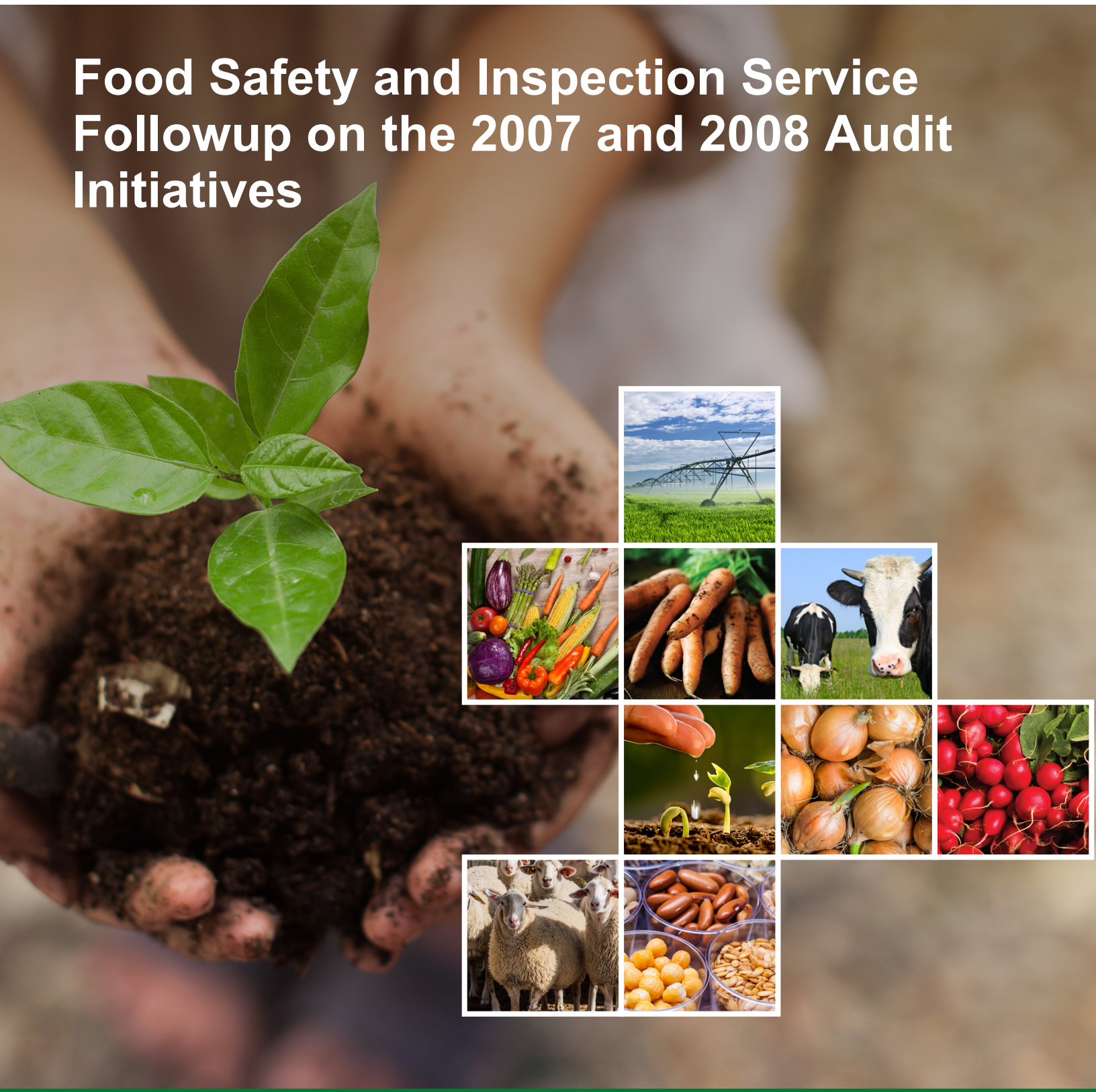
# Food Safety and Inspection Service Followup on the 2007 and 2008 Audit Initiatives



**Audit Report 24016-0001-23**

**June 2017**

OFFICE OF INSPECTOR GENERAL

# Food Safety and Inspection Service Followup on the 2007 and 2008 Audit Initiatives

## Audit Report 24016-0001-23

## OBJECTIVE

OIG's objectives were to evaluate FSIS' implementation of corrective actions resulting from two major audit initiatives in 2007 and 2008. In response to a Congressional request, we also reviewed FSIS' staffing and controls related to humane handling at slaughter establishments.

## REVIEWED

We reviewed FSIS policies and oversight at 6 of the 10 FSIS district offices nationwide. We also visited 83 of the 5,091 federally regulated slaughter and processing establishments, including 66 statistically selected and 17 non-statistically selected establishments.

## RECOMMENDS

OIG recommends that FSIS implement a process to ensure that it is completing required humane handling verification tasks at slaughter establishments and that it can support the training and the time spent to perform these tasks.

**OIG evaluated how FSIS has responded to prior audit recommendations and how the agency complies with humane handling requirements.**

## WHAT OIG FOUND

In February 2014, Senator Feinstein sent a letter to the Office of Inspector General (OIG) outlining concerns regarding two recent inhumane handling incidents at livestock slaughter establishments. The Senator requested that OIG review the Food Safety and Inspection Service's (FSIS) controls to ensure that adequately trained inspectors were properly performing humane handling activities.

OIG incorporated Senator Fienstein's concerns into a current review of how FSIS responded to 47 recommendations made in reports issued in 2007 and 2008. These recommendations involved improvements in how FSIS oversees the inspection process, how it collects critical information, and how it schedules food safety assessments.

In this review, OIG found that FSIS had procedures in place to ensure trained inspectors were completing humane handling requirements. However, based on our review of the effectiveness of the corrective actions implemented for the 47 prior recommendations, we found that for 14 of these recommendations, FSIS did not always follow corrective actions it designed to prevent reported conditions from recurring. FSIS officials were either not effectively monitoring or did not hold its staff accountable when these actions did not correct the problems identified. As a result, the deficiencies identified for these 14 recommendations continue to exist. (See Findings 1-6 for details related to these recommendations).

While we did not identify issues relating to the safety or wholesomeness of products FSIS inspects, FSIS must continue its efforts to support a comprehensive, timely, and reliable food safety inspection program.

FSIS generally agreed to take corrective actions based on our recommendations and we accepted management decision on 6 of the 18 recommendations.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: June 7, 2017

AUDIT NUMBER: 24016-0001-23

TO: Alfred V. Almanza
Acting Deputy Under Secretary, Office of Food Safety
Administrator, Food Safety and Inspection Service

ATTN: Steven Fisher
Chief Financial Officer
Office of the Chief Financial Officer

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Food Safety and Inspection Service Follow-up on the 2007 and 2008 Audit Initiatives

This report presents the results of the subject audit. Your written response to the official draft report, dated April 18, 2017, is included in its entirety, except for the enclosures, at the end of the report. Excerpts from the response and the Office of Inspector General's (OIG) position are incorporated into the relevant sections of the report. Based on your written response, we have accepted management decisions for Recommendations 4, 6, 15, 16, 17, and 18. Although the estimated completion date for Recommendation 4 extends out more than one year from the date of your audit reply, we agree to extend final action for this recommendation until December 2018. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer (OCFO).

Based on your written response, management decision has not been reached for Recommendations 1, 2, 3, 5, and 7 through 14. The information needed to reach management decision for those recommendations are described under the relevant OIG Position section following each recommendation. In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decision has not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report.

Your written response to the official draft report expressed concerns with some aspects of our report. Your concerns, along with our comments on your concerns, are listed below:

1. *FSIS stated that they made several significant changes and improvements to its processes and systems in 2015-2017, yet much of this audit work focuses on the 2012-2014 timeframe. FSIS appreciates the efforts OIG took to update the report with some of our newer processes. However, the report still uses criteria and FSIS policy and operations information from 2007-2008 for developing audit findings.*

   *OIG Comment – We disagree.* The audit team used the applicable processes and systems in place for the issues we discuss in this report. Our scope included calendar year (CY) 2012 through CY 2014 and was expanded to include some FSIS data from CY 2015. We applied the relevant directives, policies, procedures, and processes for that time. We also reviewed all the enclosures FSIS provided in their response to the official draft report and found that there were no substantial changes made to the oversight controls for the major areas we reviewed. These areas included District Veterinary Medical Specialist (DVMS) reviews, In-Plant Performance System (IPPS) reviews, completion of Specified Risk Material (SRM) tasks, and the issuance of Noncompliance records and the linking of those records for similar issues. For example, one of FSIS' enclosures included a change to the performance elements for various positions that would be assessed during the IPPS reviews. However, FSIS did not change their oversight controls in the directive for performing IPPS reviews. Supervisors are still required to perform IPPS reviews twice per year and deputy district managers are still required to review 10 percent of those IPPS reviews. Our audit report also noted when FSIS changed their processes and systems during our fieldwork, such as the new process to perform a food safety assessment at an establishment.

2. *FSIS stated that it strengthened [their] approach to noncompliance and made it more data-driven. FSIS utilizes Early Warning Alerts in the Public Health Information System (PHIS), which are based on adverse trends in Public Health [noncompliance records] and give inspection program personnel (IPP) the data to be able to determine trends and take appropriate actions. As outlined in Notice 13-16 issued in Feb. 2016, FSIS calculates Public Health Regulation (PHR) non-compliance rates for each meat, poultry, and egg products official establishment. […] When IPP and Frontline Supervisors (FLS) receive the Early Warning Alert, they are to take a number of steps as directed in Notice 13-16. We find this enhanced approach to be more robust and evidence-based than the approach we were using in 2008 following OIGs prior audits. FSIS believes our current strategies, defined by the rules of practice and paired with the Early Warning Alerts, provides our workforce with real-time enforcement capabilities.*

   *OIG Comment- We disagree.* FSIS' response did not address OIG's concerns about inspectors issuing noncompliance records on an inconsistent basis. We acknowledge that FSIS issued Notice 13-16 in February 2016 that described Early Warning Alerts and the Public Health Regulation (PHR) criterion as a tool to help FSIS identify trends in Public Health noncompliance records. However, after review of Notice 13-16, we found that the

guidance was expired (as of March 1, 2017) and it was unclear whether this process remained effective. FSIS did not provide any additional information that the notice was reissued or replaced by a directive. In addition, our review of FSIS Directive 5000.1, dated April 4, 2017, still requires inspectors to issue noncompliance records and link those records for similar issues.

3. *FSIS stated that another area of concern was our reporting of Specified Risk Material (SRM) controls. FSIS stated that the Bovine Spongiform Encephalopathy (BSE) situation in the U.S. is different than when OIG conducted work on BSE surveillance and industry SRM controls more than a decade ago. OIG completed its first BSE-related report in August 2004, and OIG issued another report February 2006. The World Organization for Animal Health (OIE) places the U.S. as a "Negligible BSE risk." In the present day, there are a number of animal diseases of concern to FSIS, yet the report seems to single out BSE and related SRM control verification tasks above others, and overlooks the change of the level of risk of BSE in the U.S.*

   *OIG Comment- We disagree.* We acknowledge in the report that the U.S. was listed as a "Negligible BSE Risk" (see footnote 6). In Findings 4, we discuss SRM verification tasks that were not completed. FSIS requires the completion of all assigned tasks, some of which include SRM verification tasks by in-plant inspectors (FSIS Directive 13000.1). We did not "…single out BSE and related SRM control verification tasks above others," but we were following up on prior recommendation 20 from Audit Report 24601-0007-KC. Since FSIS still requires SRM verification tasks to be completed, we believe that FSIS in-plant inspectors not completing or explaining why the required task was not completed is still a reportable issue.

4. *FSIS stated that they had concerns regarding our statement that "FSIS needs to ensure that district veterinary medical specialist reviews are completed on time (32 percent were not)." The report cites this figure of 32 percent in several places; however, the methodology used to calculate it is never explained and the figure is not given much context. FSIS strongly disagrees with OIG's statement that DVMS reviews were not taking place on time. This implies that FSIS is negligent in completing these reviews, which is not the case at all. For the 18-month window ending in FY 2016, 98 percent of all active slaughter plants had a current Humane Handling Verification Visit within an 18-month window. The remaining 2 percent constitute either plants that newly came on board during this period or plants that slaughter infrequently.*

   *OIG Comment- We disagree.* In the report, we describe the methodology we used in arriving at the 32 percent of DVMS reviews that were not completed timely. We compared the date of the first DVMS review to the date of the following DVMS review for the same establishment, and if more than 18 months had passed between these two reviews, we identified it as not completed timely (see footnote 40). In addition, we applied a conservative approach applying the 18 month timeframe since the criteria requires that DVMS reviews are completed every 12 to 18 months (FSIS Directive 6910.1). In response to this report, FSIS provided the results of their review which showed that 98 percent of DVMS reviews were completed within an 18 month window (ending on October 7, 2016). However, FSIS did not provide the data to show when the

previous DVMS review was completed for those establishments. As a result, we are unable to validate FSIS' claim that 98 percent of DVMS reviews were completed timely. The documentation provided with their response to this report did not show that two DVMS reviews for the same establishment were conducted within 18 months of each other.

5. *FSIS stated that OIG makes mention of positions that can and cannot enter data on humane handling activities into the system. OIG makes references to a position entitled "non-public health veterinarian." It is important to note that such a position does not exist at FSIS. OIG's citing of a position that does not exist to make its finding makes the Agency question the merit of the finding, as it is unclear what exactly OIG is referring.*

   *OIG Comment- We disagree.* We used the term Non- PHV (or non-public health veterinarian) as referring to other positions that conduct humane handling work such as Consumer Safety Inspectors or Food Inspectors (see footnote 155). FSIS also makes mention of this position in FSIS directive 6900.2, which states "PHVs and non-PHVs are to enter the hours devoted to verifying humane handling activities…" This term was also used in the discussion draft of this report without comment from FSIS during the exit conference.

6. *FSIS stated that OIG also inappropriately uses projections, stating that some of these prior recommendations "were related to FSIS oversight at 83 FSIS-inspected establishments…[OIG] reviewed…[and that OIG] estimates that 40 percent of all establishments (2,029) have weaknesses with these areas of FSIS oversight." Later in the report, OIG makes another projection stating "[OIG] estimate[s] that FSIS inspectors at 198 establishments (19 percent) may not be ensuring that humane slaughter requirements are consistently enforced." OIG uses a small amount of data, outdated, and inaccurate information to make projections like these throughout the report. These projections make generalizations that simply may not be correct or misleading. OIG also does not acknowledge the uncertainty in their estimates until the very last pages of the report.*

   *OIG Comment- We disagree.* We made our sample selection and subsequent projections based on data provided by FSIS. The projections we used were based on what the audit team found at the establishments. An external statistician verified all the sampling methodology and the sample analysis and projections. We were fully transparent about the uncertainty associated with the estimates, based on our sample size, and the level of precision. The report provides the uncertainty intervals and the confidence levels in footnotes accompanying every estimate reported and additional information is included in Exhibit G-Sampling Methodology for FSIS Follow Up on the 2007 and 2008 Audit Initiatives.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publically available information and will be posted in its entirety on our website (http://www.usda.gov/oig) in the near future.

## Table of Contents

# Background and Objectives

## Background

The Food Safety and Inspection Service (FSIS) is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. Operating under the Federal Meat Inspection Act (FMIA) and the Humane Methods of Slaughter Act (HMSA), in addition to other authorities, FSIS inspects these products at official slaughter and processing establishments, verifies that the establishments meet regulatory requirements, and enforces those requirements.[1] Additionally, FSIS ensures that establishments implement food safety systems that comply with Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) standards at both slaughter and processing establishments.[2] HACCP requires that all significant hazards identified with the product and/or production environment must be identified and controlled. In fiscal year (FY) 2016, FSIS received a budget of approximately $1.2 billion for food safety and inspection services.

FSIS oversees 10 district offices nationwide[3] that employ nearly 8,000 FSIS full-time and other inspection personnel stationed across the United States in approximately 6,200 federally inspected establishments.[4] FSIS inspectors include public health veterinarians, food inspectors, front-line supervisors, and consumer safety inspectors.

According to FSIS, food inspectors are responsible for inspecting animals prior to slaughter (ante-mortem) as well as carcasses after slaughter (post-mortem), to ensure the meat is safe for human consumption. Front-line supervisors are responsible for managing, coordinating, and supervising the inspection and enforcement activities at each assigned establishment through a subordinate supervisory structure. The supervisors' duties include, but are not limited to: overseeing and coordinating compliance reviews, including implementation and assessment of in-plant inspection programs; determining the adequacy of inspection resources; ensuring the comprehensive analysis of corrective action to resolve noncompliances; managing and implementing program changes; utilizing FSIS information systems; and overseeing establishments' compliance with HACCP and other regulatory requirements.

Consumer safety inspectors are primarily responsible for conducting regulatory oversight activities inside establishments. Both consumer safety inspectors and public health veterinarians

[1] 21 U.S.C. Ch. 12 (May 22, 2008). 7 U.S.C. Ch. 48 (October 10, 1978). The other authorities include the Poultry Products Inspection Act P.L. 85-172 as amended and the Egg Products Inspection Act P.L. 91–597.
[2] FSIS has set pathogen reduction performance standards for *Salmonella* that slaughter plants and plants that produce raw, ground meat and poultry must meet (Title 9 Code of Federal Regulations (CFR) 310.25(b)). In addition, slaughter plants are required to conduct microbial testing for generic *E. coli* to verify that their process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria. (FSIS Directive 5000.1, Verifying An Establishment's Food Safety System, issued March 4, 2014.)
[3] Alameda, California; Atlanta, Georgia; Chicago, Illinois; Dallas, Texas; Denver, Colorado; Des Moines, Iowa; Jackson, Mississippi; Philadelphia, Pennsylvania; Raleigh, North Carolina; and Springdale, Arkansas.
[4] According to FSIS' Strategic Plan for 2011-2016, there are over 6,200 federally inspected establishments nationwide. Our sample universe consisted of 5,074 of these establishments and included slaughter and processing establishments only.

observe animal handling and the slaughter process to ensure compliance with HMSA. In addition, FSIS employs enforcement, investigation, and analysis officers (EIAOs) who perform risk-based, targeted reviews of establishments' food safety systems through food safety assessments (FSA).[5]

FSIS regulations require that all livestock offered for slaughter at an official establishment be examined on the day of and before slaughter. There are three possible outcomes from the examination: the animal is either (1) passed for slaughter; (2) deemed "suspect," which requires further inspection by a public health veterinarian post-mortem; or (3) condemned. Both suspect and condemned animals must have metal identification tags placed in an ear and be properly tracked (disposition documented) in official inspection records. Post-mortem inspection is performed on carcasses in the slaughter area. Inspectors look for signs of disease or pathological conditions that would render the carcass (or parts of it) unwholesome, or otherwise unfit for human consumption.

The United States Department of Agriculture (USDA) has implemented a number of regulatory actions to reduce the likelihood that high-risk tissues would enter the human food supply. Non-ambulatory disabled or downer cattle have been banned from the food supply because these animals could be demonstrating symptoms of a central nervous system disorder, such as *bovine spongiform encephalopathy* (BSE).[6] Prior to April 17, 2009, USDA allowed the slaughter of animals that become non-ambulatory because of an acute injury after passing ante-mortem inspection, but only if the public health veterinarian re-examined the animal and determined it was acceptable for slaughter. On April 17, 2009, USDA implemented a final rule requiring that all cattle that are non-ambulatory disabled at an official establishment, including those that become non-ambulatory disabled after passing ante-mortem inspection, be condemned and disposed of properly.[7] In addition, this rule requires that establishments notify FSIS inspection personnel when cattle become non-ambulatory disabled after passing ante-mortem inspection.

In 2004, FSIS declared certain beef tissues and products to be specified risk materials (SRM) and banned these products from the human food supply. The SRM final rule[8] declares that SRMs are inedible because they present a sufficient risk of exposing humans to the BSE agent so as to render them unfit for human food. Establishments are required to control or prevent SRMs from entering the food supply. Establishments that process cattle both under and over 30 months of age must segregate the banned materials and ensure the slaughter equipment is properly cleaned after animals 30 months and older are processed. Carcasses containing SRMs can be processed

[5] FSAs are reviews conducted by EIAOs at the establishments by reviewing the food safety documents (HACCP, Sanitation Standard Operating Procedures (SSOP), etc.). These reviews assess and verify that the establishments are able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements.

[6] BSE, widely referred to as mad cow disease, is a progressive neurological disorder of cattle that results from infection by an unusual transmissible agent called a prion. If humans eat diseased tissue from infected cattle, they may develop the human form of mad cow disease that destroys the brain and spinal cord. The World Organization for Animal Health has designated the United States' status as "Negligible BSE risk."

[7] Title 9 CFR 309, "Requirements for the Disposition of Cattle that Become Non-Ambulatory Disabled Following Ante-mortem Inspection."

[8] Title 9 CFR 309, 310 and 318 "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter".

and shipped to other establishments for further processing, provided that proper controls are established to ensure that these processors remove all SRMs before they are marketed for consumption.

Under HACCP, establishments—rather than Federal inspectors—are responsible for (1) identifying food safety hazards such as contamination by fecal material that are reasonably likely to occur, and (2) establishing controls that prevent or reduce these hazards. As part of this approach, establishment officials must develop plans that identify the point (known as the critical control point) where they will take steps to prevent, eliminate, or reduce each hazard identified.

According to FSIS procedures, all establishments must also have site-specific standard operating procedures for sanitation.[9] These procedures explain the process establishments must follow to prevent direct contamination or adulteration of products. For example, an establishment may have a procedure that ensures all food contact surfaces, equipment, and utensils are cleaned daily (after production) by rinsing, soaping, and sanitizing. FSIS inspectors at the establishment routinely check records to verify an establishment's compliance with those procedures.[10] FSIS officials stated that they have developed a number of verification testing programs in which FSIS inspectors at establishments collect samples of products, and in some cases, samples of contact surfaces and the processing environment, to determine whether a pathogen, chemical residue, or other contaminant is present. Test results help FSIS inspectors verify that establishment sanitation procedures are working, and identify and assist establishments whose process controls may be underperforming. Additionally, FSIS inspection program personnel periodically perform hazard analysis verification (HAV) tasks, which are in-depth reviews of a plant's food safety system. HAV tasks are designed to identify isolated noncompliances as well as to evaluate how the system has been developed and implemented.

As part of enforcing HMSA, FSIS inspectors verify the humane treatment of livestock in slaughter establishments. HMSA states that the slaughtering and handling of livestock are to be carried out only by humane methods to prevent the unnecessary suffering of animals. The inspectors have specific duties to include ensuring that there are adequate measures in the event of inclement weather, observing truck unloading, confirming water and feed availability, observing the handling of livestock during ante-mortem inspection, observing the handling of suspect and disabled livestock, observing electric prod use, monitoring for slips and falls, checking stunning effectiveness, and checking for conscious animals on the slaughter rail.

In recent years, Congress has taken actions intended to ensure that FSIS enforces HMSA, such as providing specific funding for FSIS to enhance how it monitors slaughter practices.[11] In response, FSIS created the position of district veterinary medical specialist in each of its districts. These specialists are the primary contact in each district for humane handling and slaughter issues, and serve as the liaison between the district office and headquarters on all humane handling matters. District veterinary medical specialists are responsible for onsite coordination

[9] FSIS Directive 5000.1, "Verifying an Establishment's Food Safety System," Rev. 4, dated March 3, 2014.
[10] Inspectors are to perform two pre-operational site-specific standard operating procedure verifications per week and one operational site-specific standard operating procedure verification at each establishment in an assignment during each shift. (FSIS Directive 5000.1.)
[11] Public Law No. 107-20, 115 Stat. 155, 164 (2001) (Supplemental Appropriations Act, 2001).

of nationally prescribed humane slaughter procedures. They conduct onsite verification of humane handling activities, and they disseminate directives, notices, and other information from headquarters through the district office to veterinary medical officers in the field. FSIS implemented the Humane Handling Activities Tracking System (HATS) to document the time spent by FSIS inspection personnel in verifying that humane handling slaughter requirements are met.

FSIS has implemented regulations and directives that contain instructions to inspection personnel about how to implement and enforce the agency's legal authorities. When inspectors identify violations of the laws, FSIS regulations, or directives, they may take enforcement actions. Depending on the seriousness of the violation, inspectors have six different courses of action that range from issuing a citation to suspending the plant.[12]

In September 2007, FSIS awarded a contract to design the Public Health Information System (PHIS). PHIS was designed to replace many of FSIS' older systems and automate FSIS' paper-based business processes into one comprehensive and fully automated data-driven inspection system. PHIS is a web-based application that requires internet connection and an eAuthentication account in order to obtain system access, and it includes four inspection modules—domestic, import, export, and predictive analytics.[13]

*Prior Office of Inspector General (OIG) Audits*

Prior OIG audits have evaluated how well FSIS performed and monitored inspections in slaughter and processing establishments.

In February 2007, FSIS announced plans to implement a pilot risk-based inspection program. Congress and other stakeholders were concerned that FSIS was implementing such a program prior to correcting deficiencies reported in previous OIG audits. They believed that there were known issues with FSIS' methodology for determining risk that had not been addressed. Further, Congress was concerned that food safety may be compromised if risk-based inspection was implemented at that time. Thus, Congress prevented FSIS from using funds to implement risk-based inspection until OIG studied the program and FSIS addressed and resolved the issues identified. Accordingly, we conducted an audit to determine whether FSIS had the infrastructure and management controls in place to support a comprehensive, timely, and reliable data-driven risk-based inspection program. At its conclusion, we identified concerns that FSIS needed to correct in order to support a comprehensive, timely, and reliable data-driven risk-based inspection program. Those concerns included FSIS' assessments of establishments' food safety systems, security over information technology resources and application controls, data management infrastructure and analyses, and management control structure. We made 35 recommendations concerning these issues.[14]

[12] These six actions are (1) issuance of a noncompliance record, (2) issuance of a regulatory control action, (3) issuance of a Notice of Intended Enforcement (NOIE), (4) suspension, (5) withholding the mark of inspection, and (6) withdrawal of inspection.

[13] eAuthentication is a password-based system used by Department of Agriculture (USDA) employees that allows them access to web-based applications and services via the internet.

[14] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk Based Inspection at Meat and Poultry Establishments*, December 2007.

Independently, on January 30, 2008, a national organization released a video showing the mistreatment of non-ambulatory cattle at a California slaughterhouse. The video showed the establishment's workers administering repeated electric shocks, ramming cattle with a forklift, and shooting them with high-intensity water in an apparent attempt to force cows to their feet for slaughter. After the video's release and FSIS' investigation of these activities, the establishment voluntarily recalled approximately 143 million pounds of raw and frozen beef products. The establishment ceased operations due to the inhumane handling identified in the video. This incident caused the public, Congress, and USDA to question how these events could occur at a slaughter establishment inspected by FSIS. Accordingly, OIG conducted an audit to identify whether the events that occurred at the establishment were systemic or due to control failures by FSIS personnel located at the establishment. The audit evaluated the adequacy of FSIS' pre-slaughter and humane handling controls at 10 other slaughter establishments that also slaughtered cull cows.[15]

In our November 2008 audit report, we found that the events at the aforementioned establishment were not a systemic failure of FSIS' inspection process, but were rather due to deliberate actions committed by establishment personnel to avoid required inspections, as well as noncompliance with required inspection procedures by FSIS in-plant staff.[16] In addition, we found that the agency could strengthen management controls over the inspection process and organizational controls over personnel resources. We made 25 recommendations regarding management controls, pre-slaughter activities, and the handling of SRM.

In these two reports, we made a total of 60 recommendations. However, 15 of these recommendations dealt with the implementation of PHIS, and 13 of these 15 recommendations were evaluated in an August 2015 OIG audit.[17] Therefore, we did not, address those 13 recommendations in this audit.[18] Instead, we tested the effectiveness of 47 prior audit recommendations during this audit (see Exhibit C).[19]

In our August 2015 report, we identified weaknesses during PHIS' design and implementation. This included cost overruns during its development, inconsistent plant internet connection, and inaccurate establishment profiles.[20] We also found that inspectors were not always utilizing a function in PHIS that enabled them to record the reasons why inspection tasks were not performed. In addition, we found issues with FSIS access privileges for separated employees

[15] A cull cow is any cow that has left the herd. Cows are culled from a herd for reasons such as unsatisfactory milk production, reproductive failure, a weak condition, or old age.
[16] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, November 2008.
[17] These 13 recommendations were evaluated in Audit Report 24601-0001-23, *Public Health Information System for Domestic Inspection*, August 2015.
[18] Two prior audit recommendations—Recommendation 13 (Audit Report 24601-07-Hy) and Recommendation 20 (Audit Report 24601-07-KC) were partially covered during Audit Report 24601-0001-23, *Public Health Information System for Domestic Inspection*, since the recommendations covered both system related and non-system related actions. The non-system related actions were covered during this audit.
[19] Audit Report 24601-07-KC, Evaluation *of FSIS Management Controls over Pre-Slaughter Activities,* November 2008, and Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk Based Inspection at Meat and Poultry Establishments*, December 2007.
[20] Audit Report 24601-0001-23, *Public Health Information System for Domestic Inspection*, August 2015.

and prior PHIS-related OIG audit recommendations that were not properly implemented.[21] OIG recommended that FSIS provide a written assessment of the current status of PHIS' implementation and develop and implement internal controls that require ongoing monitoring. In addition, we recommended that FSIS develop and implement a plan to: review and correct establishment profile data; ensure inspectors are assigned a manageable number of tasks; ensure that the most important tasks are routinely performed; and effectively implement the actions agreed to from our prior audit work.[22]

*Prior Government Accountability Office (GAO) Audits*

In February 2010, a GAO audit concluded that FSIS inspectors did not take consistent enforcement actions when they witnessed humane handling violations.[23] GAO's review of violations also identified incidents in which inspectors did not suspend plant operations or take regulatory actions when they appeared warranted. GAO determined that the inconsistent enforcement actions may be due in part to the lack of clarity in current FSIS guidance and inadequate training. Specifically, the guidance did not clearly indicate when certain enforcement actions should be taken for an "egregious" act—defined as an act that was cruel to animals or a condition that was ignored and led to the harming of animals. A noted humane handling expert stated that FSIS inspectors needed clear directives to improve consistency of HMSA enforcement, coupled with adequate training.

*Hotline Complaints*

We received two hotline complaints regarding humane handling violations.[24] The first hotline complaint was received in July 2013. It alleged that FSIS was involved in the mismanagement of food safety issues and was not enforcing humane handling requirements. The second hotline complaint was received in December 2013. It alleged that FSIS violated humane slaughter regulations at swine slaughter plants.

*Congressional Concerns*

On February 20, 2014, Senator Feinstein sent a letter to OIG outlining her concerns regarding two recent inhumane handling incidents at livestock slaughter establishments. Specifically, in January 2014, an undercover video showed multiple incidents of inhumane handling at a New Jersey veal calf establishment. Further, in February 2014, a California beef establishment recalled over a year's worth of product because it was processed without the benefit of a full inspection by FSIS inspectors. Both of these incidents occurred while FSIS inspectors were onsite at the establishments. As a result of these incidents, Senator Feinstein requested a review of FSIS' human resources staffing and management decisions concerning livestock slaughter establishments. Specifically, she requested that we review FSIS controls to ensure that

[21] Audit Report 24601-0001-23, *Public Health Information System for Domestic Inspection*, August 2015, Recommendations 5 and 6.
[22] Recommendations 1, 2, 3, 6, and 7 of Audit Report 24601-0001-23, *Public Health Information System for Domestic Inspection*, August 2015.
[23] GAO-10-203, *Humane Methods of Slaughter Act: Actions Are Needed to Strengthen Enforcement,* February 2010.
[24] The USDA OIG hotline allows the public to report violations of laws and regulations relating to USDA programs.

inspectors were in place, adequately trained, and properly performing pre-slaughter and humane handling activities. See our responses to the Senator's concerns following this section.

## Objectives

Our objective was to evaluate FSIS' implementation of the corrective actions taken in response to OIG audit reports issued in 2007 and 2008, Audit Report 24601-0007-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, and Audit Report 24601-0007-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*. These corrective actions include the (1) management controls system, (2) staffing and supervision of in-plant inspectors, (3) implementation of the Humane Methods of Slaughter Act, and (4) removal of specified risk materials (e.g., brain, skull, spinal cord, distal ileum, etc.).

In response to Senator Feinstein's letter, we evaluated whether FSIS had controls in place to ensure effective human resource management, and that the right mix of human capital (i.e., food inspectors, consumer safety inspectors, public health veterinarians, and district veterinary medical specialists) was in place, adequately trained, and properly performing pre-slaughter and humane handling activities.

## Response to Senator Feinstein's Request for Information

On February 20, 2014, Senator Feinstein sent a letter to OIG outlining her concerns regarding two recent inhumane handling incidents at livestock slaughter establishments. As a result of these incidents, Senator Feinstein requested a review of FSIS' human resources staffing and management decisions concerning livestock slaughter establishments.

In response, OIG revised existing steps in this review to fully incorporate her concerns. We evaluated if FSIS had controls in place to ensure that the right mix of human capital (i.e., food inspectors, consumer safety inspectors, public health veterinarians, and district veterinary medical specialists) was in place, if inspectors were adequately trained, and if inspectors were properly performing pre-slaughter and humane handling activities. To answer these concerns, we reviewed requirements for training personnel and determined if employees received the correct type of training. We reviewed education required for these positions, and determined whether inspectors were meeting the requirements. We also evaluated the district veterinary medical specialists to see if they were completing their reviews timely. During our visits to 32 slaughter establishments, we observed 2 food inspectors performing humane handling tasks and evaluated their performance according to FSIS' criteria. Finally, we reviewed how FSIS tracks full-time equivalent hours charged to humane handling activities.

Based on these steps, we found that FSIS has procedures in place to ensure that inspectors with the required education and training were in place to complete humane handling requirements. However, we noted that FSIS could improve how it manages these employees in a number of different ways, such as requiring ongoing training.[25]

We also found the following issues relevant to the Senator's concerns. FSIS needs to ensure that district veterinary medical specialist reviews are completed on time (32 percent were not).[26] FSIS was also not completing 34 percent of the humane handling tasks at 12 of the slaughter establishments we visited (see below). We also found that FSIS could not reliably track the full-time equivalent (FTE) hours for performing humane handling activities, data which the agency must report to Congress.[27]

> In her letter, the Senator requested that we "*[c]omplete an analysis of the training, authority, and education needed for inspectors who must enforce complex food safety and animal welfare regulations including whether it is appropriate and effective to deploy Food Inspectors for these duties.*"
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> **Training**
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> To assess FSIS training requirements for inspectors who are required to enforce food safety and animal welfare regulations, we reviewed program descriptions, policies, and

[25] Finding 2 and 3.
[26] Finding 1. We considered the reviews untimely if the district veterinary medical specialist did not complete the review within 18 months.
[27] Finding 5.

directives to determine the training requirements for public health veterinarians, consumer safety inspectors, and food inspectors.

In our current audit, we found that FSIS did have policies requiring newly promoted or newly hired inspectors to receive training, but there was no requirement for ongoing or annual training as agreed to in the prior audit.[28] For example, food inspectors assigned to livestock facilities received training in areas such as ante-mortem and post-mortem inspections, humane handling, and HAACP when starting the new position. In addition, the training for newly hired or promoted consumer safety inspectors and public health veterinarians included areas such as PHIS, establishment profiles, HAV tasks, humane handling, and HAACP. However, the training records did not show additional ongoing inspection related training for these inspectors. We maintain that such ongoing training is necessary so that inspectors will remain up-to-date on all their responsibilities, including food safety and humane handling. (See Findings 2 and 3.)

In addition, In-Plant Performance System (IPPS) reviews are designed to assess inspectors' knowledge, but we found that supervisors were not always performing IPPS reviews in required timeframes. While FSIS does require front-line supervisors to evaluate inspectors' knowledge of job assignments twice a year through IPPS reviews and determine whether additional training is needed, we found that front-line supervisors were not consistently assessing inspectors on their job proficiency.[29] Specifically, we found that front-line supervisors in the six district offices we reviewed did not complete IPPS reviews timely and did not ensure that inspectors were assessed on all elements and sub-elements of these reviews. The timely and thorough completion of IPPS reviews ensures that inspectors are able to perform their tasks.

**Authority**

As required under the FMIA, in-plant personnel (i.e., public health veterinarians, consumer safety inspectors, or food inspectors) are to examine and inspect all livestock before slaughter to determine whether the animals are fit for slaughter for human food. According to FSIS Directives 6100.1 and 6900.2, in-plant personnel can perform humane handling and ante-mortem inspections if the inspectors are trained in those areas. As stated above, we determined that FSIS has trained public health veterinarians, consumer safety inspectors, and food inspectors and has given them authority to perform humane handling and ante-mortem inspections.

**Education**

We reviewed FSIS directives and recent job announcements for public health veterinarians, consumer safety inspectors, and food inspectors, and determined that FSIS has set forth specific educational requirements for each position.[30] For example, one of the job requirements for a consumer safety inspector is successful completion of a full

[28] Audit Report 24601-07-KC, *Evaluation of Management Controls over Pre-Slaughter Activities*, November 2008.
[29] See Finding 1.
[30] FSIS Directive 6100.1, Ante-mortem Livestock Inspection, July 24, 2014.

4 year course of study leading to a bachelor's degree with major study, or at least 24 semester hours/credits, in any combination of coursework in the areas of agricultural, biological, or physical sciences, food technology, epidemiology, home economics, pharmacy, engineering, or nutrition.[31] FSIS is, we believe, best positioned to determine which educational skills are necessary for these positions, and we generally find its requirements are reasonable.

The Senator requested that we "*[e]valuate how many Food Inspectors are performing these duties instead of more appropriate use of Consumer Safety Inspectors and Public Health Veterinarians, and to what extent this impacts inspection effectiveness.*"

Our audit did not disclose the widespread use of FSIS food inspectors to perform the duties of consumer safety inspectors and public health veterinarians. At the 32 slaughter establishments in our sample, we observed only 2 food inspectors performing humane handling and ante-mortem inspections. However, FSIS' records showed that these two food inspectors were provided with adequate training in these areas. All food inspectors assigned to the slaughter establishments selected for review were provided with specialized training that covered critical livestock inspection functions such as ante-mortem and post-mortem inspections when assigned to these positions. As stated earlier, while inspectors (including food inspectors) receive the necessary inspection related training when they begin their new positions, we believe FSIS needs to provide additional training and guidance to its inspectors on a continuous basis.

Although we encountered only two food inspectors performing the duties of consumer safety inspectors and public health veterinarians, we noted that FSIS does not track the data that would be necessary to determine how many food inspectors are performing humane handling responsibilities. Not all non-public health veterinarians can record humane handling inspection time in HATS. For example, during our visits to establishments, we determined that food inspectors, who were trained in humane handling inspection, sometimes performed such inspections. However, they did not directly record their time in HATS because food inspectors do not have access to the system, while all other non-public health veterinarians performing the humane handling inspections do have access. Inspectors stated that consumer safety inspectors or public health veterinarians input the food inspectors' time into HATS; however, FSIS does not have a formal process in place requiring them to enter this information. We also found that there were no controls to verify the accuracy of this time entered into the system or to ensure that the time was actually entered. Only by visiting establishments could we determine if a food inspector was performing tasks usually assigned to consumer safety inspectors and public health veterinarians. We believe that FSIS should be able to better account for food inspectors performing these additional tasks. (See Finding 5.)

The Senator requested that we "[e]*valuate if the agency performs inspection at a frequency and with appropriate staff resources to ensure effective pre-slaughter and humane handling oversight at livestock facilities for the following positions: Consumer*

[31] In addition to qualifying based on education only, the applicant can qualify based on specialized experience or a combination of experience and education.

*Safety Inspectors, Public Health Veterinarians and District Veterinary Medical Specialists.*"

Our observations at 32 FSIS-regulated slaughter establishments did not disclose issues with the frequency of inspections or staff resources for the consumer safety inspector and public health veterinarian positions during our site visits. At the 32 establishments, FSIS used 23 public health veterinarians and 17 consumer safety inspectors for humane handling inspections. However, our analysis of humane handling verification inspection tasks found that consumer safety inspectors did not always complete the assigned tasks. For example, our review of PHIS data found that, between February 2012 and January 2016, these inspectors did not complete 34 percent of the humane handling tasks assigned for the 12 statistically selected livestock slaughter establishments in our sample.[32]

District veterinary medical specialists provide more of an oversight role and do not perform inspection duties. During our current audit, we determined that the district veterinary medical specialists are required to perform routine assessments of humane handling enforcement at slaughter establishments every 12 to 18 months. However, our audit found that district veterinary medical specialists were not performing humane handling verification visits as required for the six FSIS districts we reviewed.[33] FSIS national officials stated that they did not have a sufficient number of district veterinary medical specialists to perform these reviews and have trained additional staff to assist. As of May 2016, there were 18 district veterinary medical specialists responsible oversight of humane handling activities at approximately 1,025 slaughter establishments nationwide.

The Senator requested that we "[e]*valuate if the agency collects and tracks data on humane handling inspections sufficient to assess their humane handling staff needs.*"

Our work found that FSIS collects and tracks data on humane handling inspections, but we question the reliability of that data and whether the agency can adequately determine its humane handling staffing needs.[34] We found that FSIS' quarterly reports on the inspectors' time spent on humane handling tasks continued to change in subsequent reports because the system allowed that data to be updated retroactively. As a result, we were unable to confirm the total number of FTEs devoted to humane handling tasks that FSIS reports to Congress annually.

[32] We took exception to a humane handling task if the task was not completed and the inspector did not justify the reason.
[33] See Finding 1.
[34] See Finding 5.

# Finding 1: FSIS Needs to Improve Its Controls to Ensure Corrective Actions Implemented Are Effective and Prevent Reported Conditions from Recurring

Based on our review of the effectiveness of the corrective actions implemented for the 47 prior recommendations,[35, 36] we found that for 14 of these recommendations FSIS did not follow up to ensure that its staff complied with the new requirements. The agency also did not assess the effectiveness of the corrective actions put in place. This occurred because FSIS officials relied on their staff, and did not take effective steps to monitor or hold staff accountable for complying with the established corrective actions. As a result, the deficiencies identified for these 14 recommendations continue to exist. Two of these 14 recommendations were related to FSIS oversight at 83 FSIS-inspected establishments we reviewed. We estimate that 40 percent of all establishments (2,029) have weaknesses with these areas of FSIS oversight.[37]

In September 2014, GAO revised its Standards for Internal Control in the Federal Government.[38] In that document, GAO identified that implementing an effective internal control system is a key factor in improving accountability in achieving an establishment's mission. Once an internal control system is in place, agency management should establish and operate monitoring activities over their internal control system, evaluate the results, and take remedial actions. According to FSIS' Office of Investigation, Enforcement, and Audit (OIEA) conducts audits, assessments, and reviews of Agency operations, programs, and activities to protect against waste, fraud, and mismanagement.[39] However, our review found that OIEA assessments had not conducted any reviews of District office operations since FY2012.

Although our prior reviews did not identify any issues relating to the safety or wholesomeness of products FSIS inspects, we did find that the agency's oversight of staff, information technology (IT) systems, and FSIS-inspected establishments needs improvement to ensure that its mission is accomplished. Based on our review of the corrective actions FSIS has taken to address the two prior reports, we have found an ongoing issue with how the agency monitors corrective action, as we identified continuing issues related the following areas:

[35] Audit Report 24601-07-KC, *Evaluation of Management Controls over Pre-Slaughter Activities,* November 2008, and Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk Based Inspection at Meat and Poultry Establishments,* December 2007.
[36] The remaining 13 recommendations were evaluated in Audit Report 24601-0001-23, *Public Health Information System for Domestic Inspection*, August 2015.
[37] We estimate that 2,029 establishments (40 percent) had at least one issue. We are 90 percent confident that the number of establishments with at least one issue is between 1,408 (28 percent) and 2,649 (52 percent). These issues relate to completion of HAV tasks; and issuance and/or linkage of noncompliance records. (See Findings 2, 3, and 4.)
[38] GAO-14-704G, GAO, Standards for Internal Controls in the Federal Government, September 2014.
[39] Departmental Regulation Number 1720-001, Audit Follow-up and Management Decision, November 2, 2011.

| Topic | Prior recommendations | Discussed in … |
|---|---|---|
| oversight of staff | 4 prior audit recommendations | Finding 1 |
| oversight of IT systems | 3 prior audit recommendations | Finding 1 |
| oversight of FSIS-inspected establishments | 2 prior audit recommendations | Finding 1 |
| enforcement of humane handling requirements | 1 prior audit recommendation | Finding 2 |
| issuance of noncompliance records | 1 prior audit recommendation | Finding 3 |
| Front-line supervisors' oversight of inspectors | 2 prior audit recommendations | Finding 4 |
| controls over humane handling verification data | 1 prior audit recommendation | Finding 5 |
| | **14 TOTAL RECOMMENDATIONS (9 discussed in Finding 1)** | |

We detail each of these recommendations in Exhibit C. In the remainder of this finding, we discuss, along with nine recommendations, the need to implement additional corrective action to improve how FSIS monitors its districts.

- *Recommendation 1 (Audit Report 24601-0007-KC)*—Require that district veterinary medical specialist reviews evaluate the effectiveness of in-plant FSIS personnel in overseeing slaughter establishments' humane handling activities.

In response to this recommendation, FSIS issued Directive 6910.1, District Veterinary Medical Specialist–Work Methods dated April 2009, requiring district veterinary medical specialist reviews to be completed every 12 to 18 months to evaluate the effectiveness of slaughter establishments' humane handling practices as well as providing guidance to FSIS in-plant inspectors on related noncompliance issues. During this audit, we found that all six districts we reviewed did not perform district veterinary medical specialist reviews at all slaughter establishments in a timely manner.[40] We found that, on average, 32 percent of reviews were not performed timely.

Although FSIS developed procedures requiring the performance of these reviews, it did not develop the necessary controls to ensure these reviews were completed within the required timeframes. District officials stated that they did not have a sufficient number of specialists to perform the district veterinary medical specialist reviews. However, the district veterinary medical specialist position was created and funded by Congress to provide strong oversight of humane handling and animal health issues. As a result, FSIS

[40] We considered the reviews untimely if the district veterinary medical specialist did not complete the review within 18 months.

has reduced assurance that establishments are fully complying with humane handling requirements. FSIS national officials indicated that the timeliness of district veterinary medical specialist reviews has improved.

- *Recommendation 8 (Audit Report 24601-0007-KC)*—Strengthen management controls to ensure that district management teams are performing onsite evaluations of IPPS reviews at the minimum frequency required by AssuranceNet. In addition, evaluate whether the frequency of these reviews should be increased.

FSIS supervisors are required to perform two onsite IPPS reviews per inspector per year,[41] and the district management team is required to review 10 percent of those reviews with 1 percent (of the 10 percent) being conducted onsite.

FSIS enhanced AssuranceNet to include reports to better monitor the percentage of IPPS reviews performed, but we found that the information in AssuranceNet was not always accurate. For example, the performance measure reports (generated from AssuranceNet) for the Dallas District Office for FYs 2013 and 2014 showed that all 757 IPP personnel had received the required number of IPPS reviews. However, Dallas District officials could only support that 499 IPP had the correct number of IPPS reviews. As a result, 258 of the 757 IPP (34 percent) did not receive the required number of IPPS reviews.

Although the performance measure reports were intended to improve the district's ability to monitor the completion of IPPS reviews, inaccurate data in AssuranceNet resulted in the reports being unreliable. In our discussions with district officials, they stated that they were aware of the possible errors in the AssuranceNet data; however, they did not develop an alternative method for ensuring that the required IPPS reviews were completed.

- *Recommendation 13 (Audit Report 24601-0007-KC)*—Develop procedures to require public health veterinarian to verify, at least on a periodic basis, that non-veterinary inspectors perform ante-mortem inspections in accordance with FSIS directives. Also, ensure that such observations are documented.

FSIS officials stated that they improved accountability for conducting ante-mortem and other inspection activities using IPPS reviews. FSIS' corrective action included issuing new guidelines that contain explicit instructions for conducting IPPS reviews to test (by observation) the knowledge of IPP on the policies and procedures for which they are responsible, and to document their observations on the IPPS report in AssuranceNet. While FSIS implemented the new guidelines for its IPPS reviews, our current audit found that the agency did not implement the controls to ensure district officials performed all IPPS reviews.

[41] These supervisors include front-line supervisor, supervisory public health veterinarians, and supervisory consumer safety inspector. They all are required to perform two onsite IPPS reviews.

- *Recommendation 26 (Audit Report 24601-0007-Hy)*—Provide guidance to officials, particularly at the district level, to use AssuranceNet to view performance data down to the establishment level, as well as the circuits and districts.

We found that FSIS did issue new instructions to district officials requiring them to use AssuranceNet reports to monitor completion of IPPS reviews (as discussed earlier, see Recommendation 8 above), but district officials were not always aware that their supervisors were not completing all the required IPPS reviews. For example, for the Denver District, for FY 2013, FSIS completed a total 973 IPPS reviews, but AssuranceNet listed just 120 reviews as being completed. In addition, for FY 2014, FSIS completed a total 858 IPPS reviews, but AssuranceNet indicated only 114 IPPS reviews were completed. Due to these discrepancies we concluded that the data in AssuranceNet could not be relied upon.

FSIS national officials stated that they realized the IPPS reviews were a problem and issued a revised directive on January 6, 2016, that introduced a revised IPPS review form, and new guidance on conducting IPPS reviews.[42] However, we found that the revised directive did not contain specific controls to ensure that all IPPS performance elements would be assessed each FY and that each inspector would be assessed twice a year. In addition, it did not contain additional controls to ensure district management adequately reviewed the completed IPPS reviews according to the 10 percent and 1 percent requirements.

- *Recommendation 27 (Audit Report 24601-0007-Hy)*—Modify AssuranceNet to monitor the completion and results of all required elements and sub-elements assessed during IPPS reviews.

In response, agency officials agreed to amend the AssuranceNet user guide that would instruct supervisors to focus on ensuring all applicable elements and sub-elements in an IPPS review are covered over the course of the year. We found that FSIS did not require supervisors to verify and certify that all IPPS review elements and sub-elements were completed. In addition, FSIS did not implement the additional controls necessary to ensure district officials adequately monitored their supervisors' completion of all elements in an IPPS review.

During this audit, we found that the six district offices we visited did not ensure that all elements and sub-elements of the IPPS reviews were assessed. Of the 62 inspectors we sampled in the Dallas District Office, we determined that 44 (70 percent) did not have all of the required elements and sub-elements assessed. FSIS officials did not explain why these inspectors were not assessed on all elements, but they did state that they were changing their IPPS process. FSIS' revised directive instructs supervisors to select a sufficient number of elements (and applicable sub-elements) to cover during the IPPS review to ensure all applicable elements are covered for the positions before the end of

[42] FSIS Directive 4430.3 Revision 4, In-Plant Performance System (IPPS), January 6, 2016.

the annual rating period.[43] However, this same directive does not require supervisors to verify or certify that all elements were evaluated for each inspector. FSIS officials indicated that they were working on the IPPS process and did not know why the supervisors were not verifying or certifying that all elements were evaluated for the inspectors. In addition, the directive does not require district officials to monitor the IPPS reviews and ensure each supervisor covers all elements and sub-elements.

- *Recommendation 28 (Audit Report 24601-0007-Hy)*—Implement features within AssuranceNet that will allow the system to (1) identify employees who have not worked in an IPPS-rated position for an entire rating period (e.g., retired or new employees), and (2) identify, for corrective action, instances in which employees have not received the required IPPS reviews.

In response, FSIS agreed to implement a feature in AssuranceNet that would allow users to generate reports displaying a list of employees who have not received the required number of IPPS reviews for the current rating period. We found that AssuranceNet does not have an option that allows FSIS to display employees in their position for less than 1 year. According to district officials, in order to make this determination, a report would have to be run according to each supervisor's area and a manual verification would be needed. In addition, district officials stated that they had concerns that, although AssuranceNet reports list some inspectors who have not received the required number of IPPS reviews, the report is currently inaccurate due to an inaccurate list of employees currently in AssuranceNet.

FSIS national officials stated that they were working on controls to improve the IPPS process and that they intended to issue a revised directive on how IPPS reviews are to be completed. While FSIS did issue a revised directive in January 2016, as stated earlier, this directive does not require supervisors to verify or certify that all IPPS reviews were completed. FSIS officials stated that they have not updated the AssuranceNet user guide to include a control to ensure districts can identify all employees that have not received an IPPS review.[44] Without this feature, FSIS lacks a control to ensure that all employees receive a complete review of their job performance.

- *Recommendation 20 (Audit Report 24601-0007-KC)*—Add specific fields to both AssuranceNet and IPPS for SRM-related activities and develop processes to ensure that these are adequately monitored both at the district and Headquarters levels.

FSIS implemented features in PHIS that would require in-plant inspectors to record which specific regulatory requirements (i.e., SRM removal) are verified each time they performed a task.[45] FSIS also updated PHIS policy and guidelines and required managers to monitor the completion of SRM verification tasks.

[43] FSIS Directive 4430.3 Revision 4, In-Plant Performance System (IPPS), January 6, 2016.
[44] FSIS Directive 4430.3 Revision 4, In-Plant Performance System (IPPS), January 6, 2016.
[45] In FSIS' official response, the agency stated that "[t]he Public Health Information System (PHIS) will have features that require inspection personnel to record which specific regulatory requirements are verified each time

However, we found that FSIS managers at five of the six districts we reviewed did not monitor in-plant inspectors' completion of SRM verification tasks.[46] We found that over 2,000 SRM-related tasks at beef slaughter and processing establishments were not performed in those five districts from November 2013 through January 2015. This occurred because FSIS did not develop sufficient oversight controls to ensure its supervisors adequately monitored the completion of SRM-related tasks (see Finding 4). As a result, FSIS managers were not aware that critical SRM-related tasks were not being performed and did not implement appropriate corrective actions.

- *Recommendation 12 (Audit Report 24601-0007-Hy)*—Develop and implement criteria for prioritizing the scheduling of food safety assessments.

- *Recommendation 13 (Audit Report 24601-0007-Hy)*—Develop and implement criteria for conducting periodic re-evaluations of an establishment's food safety system to assess its progress after an initial food safety assessment.

Both recommendations were designed to improve the effectiveness of the FSA scheduling system. FSIS agreed that public health would be better served by a transparent FSA scheduling system that considers establishment food safety risk.[47] FSIS determined it prudent to conduct recurring FSAs in all establishments on a pre-determined cycle, and stated that its intention was to conduct a FSA in every establishment at least once every 4 years.

We found that at three of the six districts we reviewed, FSIS did not maintain documentation showing whether an FSA was performed at every establishment.[48] Some officials explained that, when district offices merged the FSA information in AssuranceNet, they lost the date of the last FSA. Other officials stated that it would be an extremely time-consuming process for them to identify when the last FSA was performed for each establishment.

At the other three districts, we found that FSIS officials could provide documentation to support the completion of FSAs, but at the Jackson, Mississippi District Office, officials did not review all of its establishments within the 4-year cycle. Our analysis disclosed

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they are performed, even if noncompliance is not found. This data will be available to Office of Field Operations (OFO) supervisory personnel for them to track and ensure that inspectors are performing such verifications at the specified frequencies. PHIS policy and training will include guidelines for monitoring SRM verification frequencies and for responding to variations in frequency. As PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track the performance of tasks and to assure that the appropriate regulatory requirements are verified as required. These features will apply to all regulatory requirements, not just SRMs." OIG accepted FSIS' management decision for this recommendation.

[46] We did not perform this analysis during our survey work in the Philadelphia District Office because OIG did not request SRM task data for establishments not visited during survey work.

[47] The FSA scheduling system is a part of the Public Health Risk Evaluation (PHRE). The PHRE is a new decision-making process that is used by EIAOs to determine whether the district office needs to schedule an FSA. The Office of Data Integration and Food Protection provides the district office a prioritized list of establishments for scheduling FSAs. The list is based on public health risk triggers, including whether an establishment has produced adulterated product, or whether an establishment has produced product associated with an outbreak.

[48] The three districts were Dallas, Texas; Denver, Colorado; and Philadelphia, Pennsylvania.

that between 2009 and 2015, 141 of the 324 (44 percent) establishments in the Jackson, Mississippi District went more than 4 years without an FSA.[49] District officials stated that the FSIS national office informed them that the 4-year requirement for FSAs had ended in August 2013. While we found that FSIS did issue a revised directive that removed the 4-year requirement for completing FSAs, it was not effective until June 2015, and FSIS still expected the districts to continue to schedule FSAs in accordance with the original directive until the new one became effective.

Effective June 2015, FSIS no longer required districts to perform FSAs on a pre-determined cycle, but instead decided to require districts to perform Public Health Risk Evaluations (PHRE) for the establishments on the prioritized list they receive from the Office of Data Integration and Food Protection (ODIFP).[50] The PHRE is FSIS' new decision-making process used by EIAOs to determine whether an establishment needs an FSA. While OIG determined that FSIS did fully implement the prior audit recommendations,[51] FSIS stated that it decided to use this new FSA selection process beginning in 2015, because it is a risk-based method of scheduling FSAs.

Based on our review of FSIS' new process, in Directive 5100.4, some establishments would not be included in FSIS' determination of whether a PHRE (the next step in the process to determine establishment's food safety risk) should be performed. In addition, the directive did not include a timeframe as to when an FSA needs to be completed after a PHRE identifies an establishment as high-risk. While we recognize the need to prioritize FSAs, we maintain that FSIS must ensure that every establishment is considered during the selection process for a PHRE risk assessment.

When we spoke to FSIS officials about why the corrective action agreed upon for these recommendations was not adequate to correct the problems identified, they explained that it is FSIS national offices' role to issue directives and guidance and it is the district offices' role to ensure those requirements are implemented. While we agree with those roles, FSIS' OIEA needed to take an additional step to monitor the implementation and effectiveness of those controls. In addition, FSIS needed to ensure that district officials had the controls in place to ensure that supervisors and inspectors at the establishments followed the new directives and guidance.

Overall, we concluded that FSIS officials need to improve how they monitor the implementation of corrective action for audit recommendations. In addition, the agency needs to ensure that staff complies with corrective action and that the deficiencies identified by prior reviews have been resolved.

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[49] OIG reviewed the two most recent FSAs performed. These dates ranged from 2006 to 2015.

[50] The Office of Data Integration and Food Protection provides the district office a prioritized list of establishments for scheduling FSAs. This list is based on public health risk triggers, including whether an establishment has produced adulterated product, or whether an establishment has produced product associated with an outbreak. The remaining establishments included on the prioritized list are based on when an FSA was last performed at that establishment. (FSIS Directive 5100.4, Revision 1, EIAO PHRE Methodology, dated May 22, 2015).

[51] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk Based Inspection at Meat and Poultry Establishments*, December 2007.

## Recommendation 1

Require the Office of Investigation, Enforcement, and Audit (OIEA) to augment their current process to include periodic reviews on the effectiveness of the Districts' implementation of corrective actions from prior audit recommendations in the 2007 and 2008 audit initiatives.

## Agency Response

In its April 18, 2017, response, FSIS officials stated that as part of the agency's comprehensive management controls program, FSIS will assess and verify the effectiveness of corrective actions within 12 months of implementation.

## OIG Position

We do not accept management decision for this recommendation. While FSIS agreed to assess and verify the effectiveness of corrective actions within 12 months of implementation, it did not include periodic reviews. In order to reach management decision, FSIS needs to provide a response that describes how it will augment their current process to include periodic (i.e., frequency) reviews on the effectiveness of corrective actions implemented in response to OIG recommendations in the 2007 and 2008 audit initiatives.

## Recommendation 2

Require district offices to enhance their controls to ensure that district veterinary medical specialist reviews are completed within the required timeframe.

## Agency Response

In its April 18, 2017, response, FSIS stated that for the 18-month window ending in FY 2016, 98 percent of all active slaughter plants had a current humane handling verification visit within an 18-month window (Attachment 2).[52] The remaining 2 percent constitute either plants that newly came on board during this period or plants that slaughter infrequently. Additionally, district veterinarian specialists are held responsible for these visits as well as a timeframe to complete them in FSIS Directive 6910.1. These district veterinarian specialists' humane handing verification visits were also measured annually as part of a corporate measure in FSIS's Annual Plans between FY 2012 and FY 2016, targets for which were exceeded every year (see Enclosure 6).[53] Finally, the requirement to complete the humane handling verification visits are included in

[52] While FSIS did not provide an Attachment 2, FSIS inidcated on May 18, 2017 that the agency was referring to Enclosure 3 - Last Humane Handling visit as of October 7, 2016.
[53] Enclosure 6 - FSIS Performance Measure 2.2.1 percentage of slaughter plants identified during district veterinarian specialist humane handling verification visits as having an effective systematic approach to humane handling.

the FY 2017 performance plans for district veterinarian medical specialists (see Enclosure 7).[54] Agency officials also stated that FSIS has fully addressed the intent of this recommendation.

## OIG Position

We do not accept management decision for this recommendation. While FSIS' response included documentation to show district veterinarian medical specialist reviews were completed between April 1, 2015 and September 30, 2016, it did not identify if the reviews were completed within 18 months of the previous review. In FSIS' current Directive 6910.1, dated December 7, 2009, it requires that district veterinarian medical specialists are to routinely conduct a humane handling verification [review] at each livestock slaughter establishment with a Federal grant of inspection approximately every 12-18 months. In order to reach management decision, FSIS needs to describe the additional controls they plan to implement to ensure that district veterinarian medical specialists reviews are completed within the required timeframe.

## Recommendation 3

Develop and implement a process to monitor and track the completion of all of the required elements and sub-elements of employees' In-Plant Performance System (IPPS) reviews. This process should include procedures for FSIS management to verify that all the required elements and sub elements for an IPPS review are completed.

## Agency Response

In its April 18, 2017, response, FSIS stated that the IPPS reviews were reengineered and implemented in January 2016. The IPPS is aligned with performance elements (e.g. Mission Results, Communication). The new IPPS focuses on assessing whether IPP understand and can execute inspection methodology, providing supervisors with more direction on what to assess. FSIS also stated that under this new IPPS, supervisors are required to review and document all critical performance elements during the rating cycle per the revised Directive 4430.3. Field supervisors are held accountable to supervisory responsibilities, including performance of the IPPS per Agency policy, in their FY 2017 performance plans under the Supervision element (see Enclosure 5).[55] In addition, FSIS stated that along with the IPPS, they are required as supervisors to also conduct performance evaluations, which they are to document in the Performance Rating Tool. Their performance of each of these supervisory functions is dictated by FSIS policy. Furthermore, the ability to track that supervisors have completed IPPS assessment of all required performance elements during the rating cycle is part of requirements for the ongoing enhancement being made to AssuranceNet (see Enclosure 8)[56], the system that houses the IPPS. Agency officials also stated that FSIS has fully addressed the intent of this recommendation.

[54] Enclosure 7 - FSIS Performance Plan, Progress Review and Appraisal Worksheet for Non-Supervisory Positions – Veterinary Medical Officer District Veterinary Medical Specialist.
[55] Enclosure 5 - FY 2017 Performance Plans Supervisory In Plant Supervision element.
[56] Enclosure 8 - AssuanceNet Project Requirements as of March 29, 2017.

## OIG Position

We do not accept management decision for this recommendation. While FSIS' response included proposed enhancements to AssuranceNet and changes to the supervisors' performance plans, it did not include the type of controls they planned to implement to ensure that supervisors monitor and track the completion of IPPS elements and sub-elements for each employee. In order to reach management decision, FSIS needs to provide documentation that describes how the supervisors will use the proposed AssuranceNet improvements to monitor and track the completion of IPPS reviews, including all elements and sub-elements for each employee, and how FSIS management will verify that the supervisors completed their reviews.

## Recommendation 4

Make improvements to the AssuranceNet system, as necessary, to ensure data reliability.

## Agency Response

In its April 18, 2017, response, FSIS officials stated that they received feedback from its field supervisory personnel that AssuranceNet was not performing at the optimal level. FSIS also stated that to make AssuranceNet a better and more reliable tool for our employees, FSIS brought on a contractor to enhance the system. Business requirements for this project are attached (see Enclosure 8).[57] Among the enhancements are improving the speed of the system, fixing the database to accommodate for district consolidation that occurred in 2010, improving its reporting feature and programming the new IPPS form. FSIS further stated that the contractor is currently working on programing for the enhancements. Although this project will take more than a year to complete, FSIS anticipates a number of the IPPS enhancements to be delivered toward the end of 2017. On May 18, 2017 FSIS clarified that full implementation of the changes is expected to occur by December 2018.

## OIG Position

We accept FSIS' management decision for this recommendation.

## Recommendation 5

Require district offices to improve their controls to ensure supervisors adequately monitor completion of SRM tasks and implement appropriate corrective actions when those tasks are not completed.

## Agency Response

[57] Enclosure 8 - AssuanceNet Project Requirements as of March 29, 2017.

In its April 18, 2017, response, FSIS stated that per FSIS Directive 6100.4, plants slaughtering cattle or receiving carcasses with SRMs, must have a written program describing how they will remove them. This can be either in their HACCP plan, their SSOPs, or other prerequisite program. FSIS also stated that supervisors ensure completion of the SRM-related tasks, as well as other tasks in PHIS as part of their preparation for an IPPS assessment, as stated in Directive 4430.3. FSIS further stated that SRM verification is assessed under the SSOP, HACCP, or especially for Food Inspectors, under the Ante-Mortem/Post-Mortem categories of the IPPS. Furthermore, District management personnel are held accountable to perform this function in their FY 2017 performance plans under the Mission Results element (see Enclosure 9).[58] Agency officials also stated that FSIS has fully addressed the intent of this recommendation.

## OIG Position

We do not accept management decision for this recommendation. While FSIS' response included a new performance plan for district managers, it did not include what additional procedures would be implemented to ensure the completion of SRM tasks assigned by PHIS. In order to reach management decision, FSIS needs to provide documentation on how it will improve the controls to ensure supervisors adequately monitor the completion of SRM-related tasks and implement appropriate corrective actions when tasks are not completed.

## Recommendation 6

Assess whether the new FSA review process, in Directive 5100.4, requires that (1) all establishments are considered for the selection process for a PHRE risk assessment, and (2) a timeframe is included for completing a food safety assessment after an establishment is determined to be at high-risk.

## Agency Response

In its April 18, 2017, response, FSIS stated it will perform an assessment of its FSA review process. As FSIS has mentioned previously, all establishments are considered for the selection process for a PHRE. All establishments are considered by ODIFP to determine the PHRE schedule sent to Districts. In addition, Directive 5100.1 rev 4 explicitly sets a timeframe (5-7 production days) for completing each FSA, as explained in the very first significant change at the start of the directive. FSIS expects to complete the assessment by December 2017.

## OIG Position

We accept FSIS' management decision for this recommendation.

[58] Enclosure 9 – District Manager and Deputy District Manager FY 2017 performance plans (Mission Result section).

## Finding 2: FSIS Inspectors Need to Improve Enforcement of Humane Handling Requirements

In a prior audit,[59] we recommended that FSIS take steps to ensure that its inspectors were fully knowledgeable of humane handling requirements.[60] However, OIG found that FSIS inspectors at 3 of the 15 statistically selected slaughter establishments did not take appropriate regulatory or enforcement actions when animals were inhumanely treated during inspections. This occurred because FSIS front-line supervisors did not ensure their inspectors received ongoing training and guidelines on agency directives associated with the humane handling and slaughter of livestock. They also did not assess the inspectors' on-the-job performance twice a year, through IPPS reviews, as required.[61] As a result, FSIS lacks assurance that inspectors working at slaughter establishments[62] are ensuring that animals are humanely treated. Based on our sample, we estimate that FSIS inspectors at 198 establishments (19 percent) may not be ensuring that humane slaughter requirements are consistently enforced.[63]

FSIS has issued directives to enforce the Humane Methods of Slaughter Act (HMSA). FSIS Directive 6900.2 provides instructions to inspection program personnel for conducting, handling, monitoring, and enforcing humane handling activities at slaughter establishments.[64] Specifically, the directive states that an "egregious situation" is "any act or condition that results in severe harm to animals," such as multiple attempts to stun and render an animal unconscious before slaughter, using excessive force such as prodding or dragging to move ambulatory or non-ambulatory animals,[65] and withholding water from livestock while in holding pens. When inspectors observe these violations, they are required to notify plant management and document, with a noncompliance record, the violation and the actions taken by the plant to correct it. Inspectors can document more than one violation and different types of violations in a single noncompliance record.

In our prior audit, we recommended that FSIS strengthen human capital management by establishing a structured training and development program, with strong organizational controls, to demonstrate the competency of the inspection workforce in fulfilling its mission.[66] FSIS officials stated that they would establish policies and procedures to ensure that all inspection personnel would receive formal, entry-level, on-the-job, or classroom training based on their job description, performance standards, and agency policies and procedures within 1 year or less of starting their positions. Further, FSIS would require that inspection program personnel recertify

[59] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, November 2008.
[60] Handling and slaughter practices that cause a minimum of excitement, pain, injury, or discomfort to livestock.
[61] FSIS Directive 4430.3 Revision 4, In-Plant Performance System (IPPS), dated January 6, 2016.
[62] There were 1,025 slaughter establishments in our universe.
[63] We are 90 percent confident that the number of establishments with this issue is between 88 (9 percent) and 308 (30 percent).
[64] FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, August 15, 2011.
[65] Non-ambulatory animals are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.
[66] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, dated November 2008. (See Recommendation 7.)

this training annually. Although FSIS officials developed directives to establish policies and procedures related to this training, they did not require the recertification of that training annually.[67]

Despite this agreement to better train inspectors, we found that FSIS inspectors did not take regulatory action, such as issuing a noncompliance record, when egregious violations occurred. At one establishment, we observed plant personnel sitting on, holding, and pulling the tail of a non-ambulatory cow in an attempt to get the animal to its feet for slaughter. When the animal did not rise, OIG questioned the FSIS inspector onsite about the next steps for dealing with a non-ambulatory animal. The inspector was not familiar with the procedure for dealing with non-ambulatory animals and contacted the district veterinary medical specialist for guidance. The specialist informed the inspector that a non-ambulatory animal could be slaughtered as custom exempt.[68]

However, this guidance was contrary to the FSIS directive, which states that non-ambulatory animals must be condemned.[69] The regulation further states that condemned animals should be killed in the pen or outside and disposed of, not taken into the official establishment to be slaughtered.[70] In addition, once an establishment offers an animal for ante-mortem inspection, the establishment cannot change the animal's status to "intended for custom exemption."[71]

After OIG questioned the observation, FSIS corrected the situation, condemned the carcass, and prevented it from entering the food supply. However, if we had not been present, the inspector could have allowed a condemned animal to be slaughtered and processed for human consumption because the inspector was not familiar with the directive.

We discussed this issue with the inspector and district manager. The district manager informed us that the district veterinary medical specialist interpreted the regulation incorrectly when responding to the inspector, but the district veterinary medical specialist later realized the mistake and provided the correct interpretation. However, the inspector did not issue a noncompliance record, which is required for this kind of action. FSIS did not provide a reason why the noncompliance record was not issued. The FSIS district manager agreed that the establishment should not have attempted to move the non-ambulatory animal, but did not agree that someone was sitting on it. FSIS officials also stated that, although the initial decision to allow the cow to be slaughtered under custom exempt was inappropriate, the agency took immediate corrective action and thus a noncompliance record did not need to be issued.

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[67] FSIS Directive 6100.1, Revision 2, Ante-Mortem Livestock Inspection, July 24, 2014; FSIS Directive 5930.1, Revision 4, Custom Exempt Review Process, July 15, 2009; FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, August 15, 2011.

[68] An animal categorized as custom exempt does not require FSIS inspection because the processed animal cannot be sold and can only be consumed by the owner of the animal, members of the owner's household, or nonpaying guests.

[69] FSIS Directive 6100.1, Revision 2, Ante-Mortem Livestock Inspection, July 24, 2014, provides instructions on ante-mortem inspections and how to handle non-ambulatory disabled cattle.

[70] 9 CFR 309.13 (a).

[71] FSIS Directive 5930.1, Revision 4, Custom Exempt Review Process, dated July 15, 2009, provides instructions for conducting custom exempt facilities reviews.

OIG maintains that a noncompliance record should have been written based on the actions that occurred at the establishment. In addition, while the daily disposition form showed that the animal was disposed of on the day our visit,[72] we did not witness the disposition and the disposition form was not signed by the public health veterinarian until October 2, 2015.[73]

In another instance, we found that FSIS inspectors did not issue the required enforcement action such as a Notice Of Intended Enforcement (NOIE) following a repeated ineffective stunning practice.[74, 75] In December 2014, an establishment was suspended because it unsuccessfully attempted to render an animal unconscious with one stun, as the directive required.[76] The establishment agreed, in its corrective action plan, to have a second stun gun available as a back-up in case the original stun gun was ineffective. Two months later, in February 2015, the establishment received a noncompliance record for ineffective stunning. Both the suspension and noncompliance record were issued by district veterinary medical specialists who were conducting site visits.

During our site visit to this establishment on November 17, 2015, we observed one animal regain consciousness after it was stunned. The establishment did not assess whether the animal was unconscious prior to shackling, and the animal began to vocalize once hoisted.[77] After this occurred, the establishment personnel retrieved the original stun gun used on the animal and applied a second stun that rendered it unconscious. Though the prior corrective action required a back-up stun gun in the event the original stun gun did not work, a back-up stun gun was not available.

The inspector issued a noncompliance record for this violation. However, according to FSIS Directive 6900.2, if an animal regains consciousness after stunning, it is considered an egregious violation. The directive states that if an egregious violation occurs and the establishment has a robust system in place, inspectors should issue an NOIE, which provides FSIS enforcement actions above what a noncompliance record allows.[78, 79] Specifically, the directive states, "If the establishment continues to have noncompliances or does not adequately correct the noncompliances of the aforementioned nature, the Inspector in Charge is to communicate this to

[72] The day of our visit was September 18, 2015.
[73] The daily disposition form is completed by the public health veterinarian to document the decision made to condemn an animal.
[74] An NOIE provides notification to an establishment that there is a basis for FSIS to withhold the mark of inspection or to suspend inspection. NOIE provides the establishment an opportunity to present immediate corrective action and further planned preventive action. NOIE also notifies the establishment that it has three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved.
[75] FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, August 15, 2011.
[76] FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, August 15, 2011.
[77] "Hoisted" is the process whereby an animal after it is shackled, is raised, usually from a lying position, and suspended by a leg or legs.
[78] A robust system includes written procedures and records detailing how humane handling practices are implemented and maintained at the establishment in order to comply with regulations. In addition, these written procedures and records are made available to FSIS.
[79] An NOIE can be given in lieu of a suspension at establishments with a robust system in place. This enforcement action gives the establishment three days to respond instead of an immediate suspension of operations.

the front-line supervisor and district veterinary medical specialist to determine whether a NOIE should be issued for multiple noncompliances."

Since an egregious violation occurred, and it was a repeat violation, FSIS should have issued an NOIE, according to its own regulations. However, FSIS national officials stated that an NOIE was not issued because the establishment took immediate action and rendered the animal unconscious. They also stated that they took appropriate action by issuing a noncompliance record. OIG maintains that, given the egregious nature of the offense and the fact that it was a repeated offense, FSIS should have at a minimum issued an NOIE.

Last, we found that FSIS inspectors did not follow procedures for issuing noncompliance records when an establishment did not have water available for animals awaiting slaughter. Based on FSIS directives, the establishment is responsible for ensuring all animals have access to water.[80] However, during our site visit to an establishment, we observed that goats awaiting slaughter in a holding pen did not have access to water.

We brought this issue to the attention of the inspector and he instructed the establishment to fill the water in the pen. The establishment personnel informed us that the person normally responsible for providing water to the animals was not available to fill the water on the day of our visit. The inspector issued a memorandum of interview for this incident. However, based on the FSIS directive, the inspector should have issued a noncompliance record.[81]

Rather than ensure the inspector's knowledge and practical application of the directive requirement was correct, the front-line supervisor stated that a noncompliance record was not necessary. The front-line supervisor explained that it is up to the inspection staff to determine whether to issue a noncompliance or memorandum of interview. In addition, the supervisor stated that the records at this establishment did not show that a lack of water was part of an ongoing noncompliance trend, so a noncompliance record would not be necessary. However, the FSIS directive does not indicate that an establishment must have a history of noncompliance in an area before an FSIS inspector can issue a noncompliance record.[82]

The inspector later indicated that the issuance of a memorandum of interview was incorrect and that he should have issued a noncompliance record. Both FSIS district and national officials agreed that a noncompliance record should have been issued; however, the district officials stated that they would not issue a noncompliance record because a memorandum of interview had already been prepared and provided to the establishment.

In each incident described above, inspectors did not issue the appropriate regulatory or enforcement action as required by FSIS directives. FSIS relied on its inspectors to interpret the directives and issue the appropriate enforcement; however, the inspectors were not fully knowledgeable of the requirements and the necessary regulatory or enforcement actions. Additionally, we found that FSIS did not implement procedures to require recertification of

[80] FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, August 15, 2011.
[81] Ibid.
[82] Ibid.

training annually as agreed upon in a prior recommendation.[83] Unless FSIS officials provide sufficient ongoing training and continually assess their inspectors' on-the-job performance, inspection personnel may continue to allow inhumane handling incidents to occur and not prescribe the appropriate enforcement action.

## Recommendation 7

Implement a process that requires FSIS inspectors to receive annual recertification on humane handling requirements. This process should require specific ongoing training to all staff including front line supervisors on current and new program requirements and the applicable directives, including examples of how to apply those requirements at the district and establishment levels. This recertification training should also include guidance on issuing the various disciplinary tools (e.g., noncompliance records and notice of intended enforcement (NOIE)).

## Agency Response

In its April 18, 2017, response, FSIS stated the agency holds itself accountable by adding humane handling training metrics to the FY 2017 Annual Plan. In the FY 2017 Annual Plan specifically, FSIS has committed to deliver humane handling refresher training to 40 percent of public health veterinarians in livestock slaughter establishment by September 30, 2017. Further, the agency will be adding humane handling content to the IPP Help Button, a real-time reference resource, to refresh IPP knowledge on humane handling requirements whenever needed. FSIS also stated that the IPP Help Button has proven to be a useful tool for FSIS employees, receiving an average of 25,680 hits per month (see Enclosure 10).[84] FSIS also stated that humane handling-related requirements for establishments do not change frequently enough to require an annual recertification process. As seen above, FSIS has a process in place to train inspectors on humane handling requirements and to provide refresher training. Agency officials also stated that FSIS has fully addressed the intent of this recommendation.

## OIG Position

While we agree with FSIS' planned corrective actions, we do not accept management decision for this recommendation. In order to reach management decision, FSIS needs to provide ongoing refresher training to all staff—including front line supervisors—on current and new program requirements and the applicable directives. In addition, FSIS needs to include guidance on issuing the various disciplinary tools such as noncompliance records and NOIE.

## Recommendation 8

[83] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, November 2008. (See Recommendation 7.)
[84] Enclosure 10 - IPP Help Button Hits-February 2016 through February 2017.

Require district offices to enhance their controls to ensure front-line supervisors routinely assess each employee's knowledge and practical application of program requirements during the performance of their duties as it relates to humane handling. These controls should provide for the retraining of those employees who do not demonstrate minimal knowledge, skills, and abilities.

## Agency Response

In its April 18, 2017, response, FSIS stated the reengineered IPPS process implemented in January 2016 fulfills this function, as it is a tool by which front-line supervisors and other in-plant supervisors routinely assess each employee's knowledge and execution of inspection methodology, including humane handling requirements. District management personnel are also required per FSIS Directive 4430.3 to perform oversight of the IPPS completed by the front-line supervisors. In addition, FSIS stated that the District management personnel are held accountable to perform this function in their FY 2017 performance plans under the Mission Results element (see Enclosure 9).[85] Agency officials also stated that FSIS has fully addressed the intent of this recommendation.

## OIG Position

We do not accept management decision for this recommendation. While FSIS included the revised performance elements for the District Manager and Deputy District Manager, FSIS' response did not include a description of the additional controls it will implement to ensure the front-line supervisors routinely assess each employee's knowledge and practical application of program requirements related to humane handling. In order to reach management decision, FSIS needs to provide a response that describes what enhanced controls it will implement to ensure front-line supervisors assess the employees' humane handling knowledge on an ongoing basis and then provide for retraining, if necessary.

[85] Enclosure 9–District Manager and Deputy District Manager FY 2017 performance plans (Mission Result section).

## Finding 3: FSIS Needs to Issue and Link Noncompliance Records

When FSIS inspectors find noncompliances with program requirements, they issue a noncompliance record that establishments must address. When inspectors note a systemic series of noncompliances, they are to link noncompliance records—[86]this should result in progressive enforcement action.

A prior OIG audit recommended that FSIS provide specific criteria for inspectors to use when issuing noncompliances so that they do so consistently.[87] However, of the 83 selected establishments we visited, inspectors at 22 establishments did not link noncompliance records during our period of review (i.e., calendar years (CY) 2012 through 2014) and/or did not issue noncompliance records during our site visits performed in CYs 2014–2015. This occurred because FSIS inspectors had differing opinions on when a noncompliance record should be issued or linked (see Exhibit D). In addition, while FSIS revised its directive on issuing and linking noncompliance records[88] (based on a previous audit recommendation),[89] the agency did not provide supplemental training with instructions and examples to ensure the revised directive was followed. As a result, FSIS is not always timely identifying issues that could affect an establishment's food safety system. Based on our sample, we estimate that 547 establishments (11 percent) had noncompliance records that were not linked[90] and 820 establishments (16 percent) had issues with noncompliance records that should have been written, but were not.[91]

During a prior audit, we found FSIS inspection personnel did not always link noncompliance records identifying recurring sanitary deficiencies.[92] Additionally, if noncompliance records were linked, inspection personnel did not have sufficient guidance on when to take further enforcement actions. We recommended that FSIS expedite the development of specific criteria that provide a basis for establishing when corrective actions are inadequate, and appropriate enforcement actions should be initiated for repetitive deficiencies. Those criteria should also define when progressive enforcement actions should be taken.

In response to this previous audit, FSIS revised Directive 5000.1 to include additional instructions concerning linking noncompliance records and initiating enforcement actions if a noncompliance is not corrected, persists, or recurs.[93] Previously, the directive did not include

[86] FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, Rev. 4, Mar. 4, 2014.
[87] 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007. (See Recommendation 33.)
[88] FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, Rev. 4, March 4, 2014.
[89] Recommendation 33, from Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007.
[90] We are 90 percent confident that the number of establishments with this issue is between 206 (4 percent) and 887 (17 percent).
[91] We are 90 percent confident that the number of establishments with this issue is between 496 (10 percent) and 1,144 (22 percent).
[92] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007.
[93] Noncompliance records serve as FSIS' official notification and documentation of an establishment not meeting one or more regulatory requirements.

these additional instructions. FSIS' updated directive states that after inspectors document a noncompliance record, they are to consider whether the noncompliance record is associated with previous noncompliances at that establishment.[94] For each noncompliance record, FSIS inspectors are to use the reporting tools in PHIS to identify previous records that might be associated with the current one. Inspectors are to associate two or more records when they indicate an ongoing trend of related noncompliances or systemic problems with the establishment's food safety system.

FSIS issued the revised directive, but district officials did not ensure their inspectors consistently issued or linked noncompliance records when they became aware of potential issues with an establishment's food safety system.

*Inspectors Did Not Issue Noncompliance Records for Program Violations*

At 16 of the 22 establishments,[95] we observed that FSIS inspectors did not issue noncompliance records when they should have, even though FSIS updated its instructions to inspectors on when to issue them. This occurred because FSIS inspectors had differing opinions on when a noncompliance record should be issued and FSIS left it up to the discretion of the IPP. FSIS needs to revise its policy and provide the training to ensure consistency when issuing noncompliances.

During pre-operational inspections[96] at 73 establishments,[97] we found that 45 had program violations regarding establishment sanitation. Of those 45 establishments, 30 were issued noncompliance records for violations and 15 were not. At the 15 establishments that were not issued a noncompliance record, FSIS inspection personnel usually allowed the establishments to immediately correct the sanitation issues. Correcting the immediate problem is important, but issuing noncompliance records would have better enabled FSIS to identify trends over time and take progressive enforcement action when needed. (Exhibit D shows instances in which inspectors did not issue or link noncompliance records in accordance with FSIS regulation and directives.)

During operational hours, FSIS inspection personnel at one establishment did not issue a noncompliance record when a contaminant was present. We observed, during our visit, that hair was left on a carcass after slaughter, and we informed the inspector of this observation. The inspector stated that a noncompliance record could not be issued

[94] FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, Apr. 11, 2011, updated Mar. 4, 2014. Prior FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, dated June 1, 2006.
[95] This includes two establishments discussed in Finding 2, where OIG determined that the FSIS inspectors should have issued noncompliance records but did not.
[96] Prior to operations, FSIS inspectors conduct pre-operational inspections to verify that the establishment implements the pre-operational procedures in the sanitation standard operating procedure effectively to prevent contamination of food contact surfaces or adulteration of products.
[97] We did not observe pre-operational inspection at 10 of the 83 establishments visited because the inspectors conducted the review before the auditors arrived.

because hair is not considered a contaminant.[98] However, FSIS regulations specifically state that "carcasses, organs, and other parts shall be handled in a satisfactory manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector."[99] FSIS directives also state that, if a contaminant is present, a noncompliance record should be issued.[100]

At another establishment, we observed that an inspector classified hair as a contaminant and issued the establishment a noncompliance record. However, the inspector at the first establishment was not aware of this classification and did not issue a noncompliance. We concluded that the inspector's lack of familiarity with the directive could lead to repeat violations and the potential to process a contaminated carcass. FSIS national office officials agreed that the hair was a contaminant, but stated that this was not a food safety issue because hair is not necessarily a systematic issue that warrants a noncompliance record.

During operational hours at another establishment, we observed foreign material, a small piece of blue plastic in a large tub of raw chicken scheduled to be ground into patties, but a noncompliance record was not issued. We informed the inspector of the plastic, but the inspector disagreed that foreign material was in the product. He stated that it was a chicken vein. After discussion, the inspector directed the establishment staff to remove the blue fragment in question and found that it was a small piece of plastic. The inspector stated that a noncompliance record would not be issued since the foreign material was not in the final product. However, FSIS regulations state that "product must be protected from adulteration during processing"[101] and "if contamination occurs, it shall be promptly removed."[102] Since the meat had plastic in it, it was not in compliance with safety regulations and a noncompliance should have been issued. The inspector was not able to differentiate between animal parts and plastic and did not know when to remove the material in question until OIG pressed the issue.

Last, we found that noncompliance records were not issued in the event of unsanitary conditions during an operational inspection at another establishment. We observed a piece of garbage—the inner seal of a bleach container—in a bin containing sanitized table tops. After we informed the inspector of this contaminant, the inspector directed the establishment staff to remove the seal. However, the inspector did not take any further action such as issuing a noncompliance record.

We later discussed this situation with the inspector's supervisor and were told the inspector required the establishment to clean and sanitize the table tops again, which they

[98] The hair was not removed from the carcass during our visit. FSIS officials stated that the hair was a contaminant, but it was not a food safety issue because hair is not necessarily a systematic issue that warrants a noncompliance record.
[99] 9 CFR 310.18(a).
[100] FSIS PHIS Directive 6420.2, Verification of Procedures for Controlling Fecal Material, Ingesta, And Milk in Slaughter Operations, Apr. 11, 2011.
[101] 9 CFR 416.4(d).
[102] 9 CFR 310.18(a).

did to the inspector's satisfaction. Thus, the inspector did not feel the issue required a noncompliance record. However, FSIS' directive states that "insanitary conditions may be isolated and only affect a limited area of an establishment and not affect the sanitary condition of other product or equipment. In such cases, inspectors are to document the noncompliance, take the appropriate enforcement action, and verify that the situation is addressed to bring the establishment back into compliance."[103] The inspector, instead of issuing a noncompliance record, used his own discretion and remedied the situation immediately. A record of noncompliance would have documented the problem and ensured a record of the sanitary issues at the establishment.

*Inspectors Did Not Link Noncompliance Records for Similar Food Safety Issues*

At 11 of the 22 establishments, we found that while some inspectors issued noncompliance records, they did not link similar noncompliances (i.e., sanitation) that could allow FSIS to take more progressive enforcement actions to correct an establishment's food safety system (see Exhibit D). FSIS' process to issue noncompliance records and link them is a critical aspect in its overall controls to identify weakness in an establishment's food safety system. If this process fails, FSIS cannot adequately address issues that affect food safety. Based on our sample, we estimate that inspectors at 547 establishments nationwide are not properly linking noncompliance records.[104]

FSIS links noncompliance records that can support more progressive enforcement action, such as slowing assembly line speeds, and in extreme cases, shutting down operations until a problem is corrected. By not linking noncompliance records, FSIS runs the risk of not taking proper progressive enforcement actions on establishments. The FSIS directive states that inspectors are to associate (or link) two or more noncompliance records when they indicate an ongoing trend of related noncompliances or systemic problems with the establishment's food safety system.[105] The directive also states that the following characteristics may help inspectors determine when to link a noncompliance record, but these factors, in themselves, do not justify associating them: (1) two or more noncompliance records have the same regulatory citation, (2) two or more noncompliance records resulted from the same type of inspection procedure, or (3) two or more noncompliance records occurred within a reasonably close period of time. The inspector makes a final decision concerning when a noncompliance record should be linked; however, FSIS provides guidance that will help ensure consistency between the inspection staff.

We found that FSIS updated its directives to include instructions to inspectors on linking noncompliance records as well as informing supervisors of repeated noncompliance records; however, much of the enforcement process is subject to the judgment of IPP.

[103] FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, Rev. 4, Mar. 4, 2014.
[104] We are 90 percent confident that the number of establishments with this issue is between 206 (4 percent) and 887 (17 percent).
[105] FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, Rev. 4, Mar. 4, 2014.

The available guidance is not adequate to assist inspection staff in making these decisions and ensuring that the decisions are consistent among the staff.

For example, during CYs 2012 through 2014, we found that inspectors at one establishment issued over 80 noncompliance records and that 7 of those related to peeling or flaking paint in food processing areas. However, because the flaking paint was on different equipment or in different rooms within the same establishment, the inspectors determined that these issues were not linkable because the flaking paint in the first room was caused by something different than the flaking paint in the second room. Variations in the directive give inspectors the authority not to document issues such as this one, potentially resulting in inspectors failing to identify trends that could affect an establishment's food safety system. If FSIS had linked such issues, then the agency would have more information on possible trends that could require establishments to fix sanitation issues before they have the potential to become a food safety problem.

FSIS national officials stated that their inspectors need the flexibility the directive offers since the inspectors work closely with the establishments on a daily basis. However, FSIS officials further stated that they would consider reviewing the directive again to ensure it provides the guidance needed for their inspectors to timely identify trends.

OIG maintains that FSIS should take a more conservative approach to issuing and linking noncompliance records since these noncompliances relate to the establishments' food safety system. Unless the agency issues noncompliance records consistently and timely for new problems, and unless it consistently links noncompliance records to similar records issued previously, FSIS is not adequately overseeing establishments' controls over food safety and processing. We concluded that FSIS needs to revise its policy and provide the training and direction necessary to ensure consistency among its inspectors nationwide.

## Recommendation 9

Issue immediate appropriate communication to FSIS personnel to emphasize the importance of and requirements for issuing noncompliance records and linking those noncompliance records, if applicable, when regulatory violations occur. In addition, develop and implement specific policy that provides examples detailing when noncompliance records should be written for noncompliance with food safety requirements.

## Agency Response

In its April 18, 2017, response, FSIS stated it has numerous directives and notices that outline how IPP are to determine whether establishments are meeting regulatory requirements (e.g., FSIS Directives 5000.1, 5100.1, 5000.4, 5000.6, 5030.1, 5100.1, and others). Similarly, the directives and notices state that when noncompliance is found, IPP are to issue a noncompliance record to the establishment. The directives or notices typically state which regulation to cite on the noncompliance record. Therefore, FSIS disagrees that an additional Notice or Directive on this is necessary. Additionally, it should be mentioned that FSIS has strengthened its approach

to noncompliance and made it more data-driven. FSIS utilizes Early Warning Alerts, an additional tool for employees, which is based on adverse trends in Public Health noncompliance records and gives IPPs the data to be able to determine trends and take appropriate actions. As outlined in Notice 13-16 issued in February 2016, (see Enclosure 2).[106] FSIS calculates Public Health Regulation (PHR) non-compliance rate for each meat and poultry (including processed eggs) official establishment. Every year, FSIS establishes cut points at 2 levels: Tier 1 and Tier 2. Tier 2 is the lower threshold at which IPP will be notified with an Early Warning Alert that an establishment has a non-compliance rate that is elevated and is at or exceeds the Tier 2 cut point. Tier 1 is the higher threshold at which FSIS will consider the establishment for a PHRE. Early Warning Alerts provide our workforce with real-time enforcement capabilities.

However, the report notes concerns about noncompliance records for foreign contaminants and sanitation. FSIS implemented provisions of the Food, Conservation, and Energy Act of 2008 by amending the Federal meat and poultry products inspection regulations to require official establishments to promptly notify the appropriate District Office that an adulterated or misbranded meat or poultry product has entered commerce. Under 9 CFR 418.2, establishments are required to report to FSIS when they have shipped or received adulterated or misbranded product, including product that is adulterated because it contains foreign contaminants. FSIS intends to issue instructions to inspectors to clarify how to enforce this requirement. FSIS also intends to issue guidance to industry or work with industry to provide comments on industry guidance on how to address foreign contaminants.

## OIG Position

We do not accept management decision. We acknowledge FSIS' numerous directives and notices relating to the issuing and linking of noncompliance records. However, during our fieldwork we found that FSIS staff was inconsistent in the application of those directives and notices. In addition, FSIS referenced its Notice 13-16, but that notice expired on March 1, 2017. In order to reach management decision, FSIS needs to provide documentation of the communication it sent to employees emphasizing the importance of issuing and linking noncompliance records when regulatory violations occur, the agency's plan to provide specific policies that provide examples detailing when noncompliance records should be written for food safety noncompliances, and when those noncompliance records should be linked.

## Recommendation 10

Issue guidance to clarify that FSIS inspectors are to remove contaminated product in accordance with the principles of HACCP for product that is allowed to pass the critical control point, or the inspector observes adulteration and the establishment has failed to observe it or act on it.

[106] Enclosure 2 - FSIS Notice 13-16 dated February 11, 2016.

## Agency Response

In its April 18, 2017, response, FSIS stated that its regulations on HACCP and SSOP define these responsibilities for regulated establishments and IPP. IPP complete thorough regulatory training, including HACCP principles, during their inspection methods course. IPP knowledge and execution of inspection methodology is verified through IPPS assessments twice a year. Additionally, the IPP Help Button provides information on HACCP in real-time (see Enclosure 11),[107] and has proven to be an effective tool getting an average of 25,680 hits per month (see Enclosure 10).[108] In addition, as noted in response to recommendation 9, FSIS intends to issue instructions to inspectors to clarify how to enforce requirements that establishments notify FSIS when they have shipped or received adulterated or misbranded product, as required under 9 CFR 418.2.

## OIG Position

We do not accept management decision for this recommendation. While we agree that FSIS' Help Button could be a valuable tool for food inspectors, it does not provide the guidance needed to ensure contaminated product is appropriately handled. In order to reach management decision, FSIS needs to provide guidance to clarify that during inspections at establishments, FSIS inspectors are to remove contaminated product when observed.

## Recommendation 11

Provide training to all FSIS district and establishment personnel on issuing noncompliance records and linking noncompliance records if appropriate. This training should include a module that specifically addresses concerns that warrant a noncompliance record and when it is appropriate to link two or more noncompliance records.

## Agency Response

In its April 18, 2017, response, FSIS stated it has already fulfilled the intent of this recommendation through the launch of the IPP Help Button. It is available on all FSIS computers including those that are used in the field and contains helpful interactive tools to guide employees in their understanding of FSIS policy. The Help Button contains an array of information on noncompliance records (see Enclosure 12).[109] The Help Button has proven to be a useful tool for our employees, getting an average of 25,680 hits per month (see Enclosure 10).[110] Additionally, it should be mentioned that FSIS has strengthened its approach to noncompliance and made it more data-driven. FSIS utilizes Early Warning Alerts, an additional tool for employees, which is based on adverse trends in Public Health noncompliance records and gives IPPs the data to be able to determine trends and take appropriate actions. As outlined

[107] Enclosure 11 - IPP Help Button menu – HACCP.
[108] Enclosure 10 - IPP Help Button Hits-February 2016 through February 2017.
[109] Enclosure 12 - Noncompliance Records Information Help Button.
[110] Enclosure 10 - IPP Help Button Hits-February 2016 through February 2017.

in Notice 13-16 issued in Feb. 2016, (see Enclosure 2),[111] FSIS calculates PHR non-compliance rate for each meat and poultry official establishment. Every year FSIS establishes cut points at 2 levels, Tier 1 and Tier 2. Tier 2 is the lower threshold at which iIPP will be notified with an Early Warning Alert that an establishment has a non-compliance rate that is elevated and is at or exceeds the Tier 2 cut point. Tier 1 is the higher threshold at which FSIS will consider the establishment for a PHRE. Early Warning Alerts provide our workforce with real-time enforcement capabilities. Agency officials also stated that FSIS has addressed this recommendation.

## OIG Position

We do not accept management decision for this recommendation. We acknowledge that FSIS implemented Early Warning Alerts for noncompliance record trends and a Help Button with an array of information on noncompliance records. However, we observed inconsistent application of noncompliance records by establishment personnel and more needs to be done to improve continuity of issuing noncompliance records and linking noncompliance records for similar issues. In order to reach management decision, FSIS needs to provide a plan for training all FSIS district and establishment personnel on issuing noncompliance records and linking noncompliance records, if applicable.

[111] Enclosure 2 - FSIS Notice 13-16.

## Finding 4: FSIS Front-Line Supervisors Need to Improve their Oversight of Inspectors at Establishments

While FSIS inspectors serve as the first line of defense against contaminated products entering the food supply, the agency's front-line supervisors are responsible for overseeing the activities of the inspectors at all establishments in their circuit and for ensuring inspectors perform daily inspection verification activities.[112, 113] A prior audit report recommended that FSIS include data fields in its systems so that supervisors could record the completion of important inspection tasks.[114] We found that 44 of 59 front-line supervisors did not fully perform their oversight responsibilities at 55 of the 83 establishments we visited (see Exhibit E).[115] This occurred because FSIS did not develop sufficient oversight controls to ensure its supervisors adequately monitored the completion of tasks relating to inspection verification activities. As a result, there is reduced assurance that inspectors are identifying potential food safety risks.

PHIS generates inspection tasks that inspectors perform daily or periodically to monitor the establishments' activities. FSIS relies on these inspection tasks to ensure establishments are adequately following sanitation, HACCP, humane handling, and labeling requirements. According to FSIS Directive 13,000.1, routine tasks are inspection verification activities conducted on a routine, ongoing, or planned basis when the establishments are in operation.[116] PHIS generates these tasks based on information in the establishment profile.[117] These profiles include information such as products produced, HACCP systems, and other general information about the establishment. In addition, directed tasks are verification activities performed on an as-needed basis in response to inspection findings, sample results, or other available information.[118]

In Recommendation 20 of our November 2008 report, we recommended that FSIS add specific fields to both AssuranceNet and IPPS for SRM-related activities and develop processes to ensure these are adequately monitored both at the district and headquarters levels.[119]

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[112] FSIS Directive 4430.3, IPPS, Sept. 11, 2012, states that supervisors are to ensure that IPP are reporting inspection results in accordance with agency regulatory requirements, policies, and procedures. The directive was updated on Jan. 6, 2016, but this requirement remained the same. In addition, FSIS Directive 1010.2, Circuit Maintenance Guidelines, Sept. 22, 2008, defines a circuit as an organizational structure of plants and positions designed to deliver program services and provide supervision in an efficient and effective manner to IPP.

[113] Front-line supervisors are responsible for overseeing and coordinating the review, implementation, and ongoing assessment of the domestic meat, poultry, and egg products inspection program in their assigned area.

[114] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, November 2008.

[115] Sixty-six establishments were statistically selected and 17 were non-statistically selected.

[116] FSIS Directive 13,000.1, Scheduling In-PHIS , Rev.1, Aug. 31, 2012.

[117] FSIS Directive 5300.1, Managing the Establishment Profile in the PHIS , Apr. 11, 2011, states that FSIS uses the establishment profile information to assign routine inspection tasks, to create tailored inspection tasks, to generate FSIS sample requests, and to manage inspection assignments.

[118] According to FSIS Directive 13,000.1, Scheduling In-Plant Inspection Tasks in the PHIS , Aug. 31, 2012, IPP issuing a noncompliance record will allow the computer system PHIS to generate a directed task for the same area that resulted in a noncompliance record.

[119] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, November 2008.

In response to this audit recommendation, FSIS added a feature to PHIS for recording all inspection tasks performed including those related to SRMs. In addition, it issued FSIS Directive 1300.1 that required inspectors to record which specific regulatory requirements are verified when performing a task and recording completion of that task within PHIS. This guidance stated that supervisors are responsible for ensuring that inspectors are correctly applying the procedures, verifying applicable regulatory requirements, making informed decisions, properly responding to updated information and directed tasks, and completing the work as expected.

Based on our current review, however, we found that front-line supervisors did not ensure that inspectors: (1) completed assigned tasks related to SRMs[120] and HAV;[121] (2) maintained accurate or updated establishment profiles at assigned establishments; and (3) documented the results of their review of the establishment's in-plant testing in a memorandum of interview.[122]

*FSIS Supervisors Need to Ensure that Inspectors Complete SRM Control Verification Tasks*

SRMs are tissues in cattle considered to be of high risk for prion contamination.[123] Prions are thought to be the cause of a group of brain-related diseases called transmissible spongiform encephalopathies.[124] The removal of SRM from all cattle presented for slaughter is the most important safeguard against BSE, more commonly known as mad cow disease.[125] PHIS assigns SRM control verification tasks to inspectors to verify that establishments properly remove all SRM in cattle before processing.

[120] SRM tasks are designed to verify the implementation of establishments' SRM control programs through review of records and direct observation to ensure establishments effectively remove, segregate, and dispose of SRM. IPP are required to conduct the SRM verification control task once every two weeks per shift at establishments.
[121] FSIS Directive 5000.6, Performance of the Hazard Analysis Verification Task, Mar. 4, 2014, states that effective Apr. 1, 2014, IPP are required to conduct the HAV task once every quarter per establishment. HAV tasks are reviews of a plant's food safety system. HAV is designed to identify isolated noncompliances as well as to evaluate how the system has been developed and implemented.
[122] FSIS Directive 5000.2, revision 2, Review of Establishment Testing Data by Inspection Program Personnel, Dec. 4, 2008, requires inspection program personnel to conduct and document weekly meetings with plant management to discuss food safety issues and in-plant testing results.
[123] Specified Risk Material (SRM) Control, dated July 21, 2016, states that establishments that slaughter cattle or process carcasses or parts of cattle must identify, remove, and segregate SRMs from edible materials, and dispose of them according to regulations created to help ensure food safety. SRMs are inedible and cannot be used for human food.
[124] Prion diseases or transmissible spongiform encephalopathies are a family of rare progressive neurodegenerative disorders that affect both humans and animals. They are distinguished by long incubation periods, characteristic spongiform changes associated with neuronal loss, and a failure to induce inflammatory response. The causative agents of transmissible spongiform encephalopathies are believed to be prions. The term "prions" refers to abnormal, pathogenic agents that are transmissible and are able to induce abnormal folding of specific normal cellular proteins called prion proteins that are found most abundantly in the brain. The functions of these normal prion proteins are still not completely understood. The abnormal folding of the prion proteins leads to brain damage and the characteristic signs and symptoms of the disease. Prion diseases are usually rapidly progressive and always fatal.
[125] 9 CFR 310.22 (a) defines SRMs as: (1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, and dorsal root ganglia of cattle 30 months of age or older, and (2) the tonsils and distal ileum of all cattle.

At the 66 statistically selected establishments we visited, 28 establishments either slaughtered cattle, or processed carcasses or parts of cattle. Inspectors at these establishments thus should have completed tasks requiring that they verify the establishment staff identifies, removes, segregates, and disposes of SRM.[126]

We reviewed the SRM control verification task reports for November 2013 through January 1, 2016 for the 28 establishments and found that 2,844 routine SRM verification control tasks were assigned to the inspectors, but 2,052 of these tasks (74 percent) were not performed, nor was the non-performance of these tasks justified. For example, four front-line supervisors stated that they did not monitor SRM task completion. Of these four front-line supervisors, one stated he was unaware that these tasks were not completed and that other priorities prevented him from ensuring that the required tasks were completed by the assigned inspectors. This supervisor also stated that the inspectors should have provided a justification for not completing the task. A second front-line supervisor stated that it was not his responsibility to ensure these tasks were being completed.

We discussed this problem with FSIS national officials, and they stated that the establishment profiles may have inaccurately shown these establishments as slaughter facilities instead of processing facilities. PHIS uses the establishment profile information to create tailored inspection tasks based on the type of slaughter or processing facility. Therefore, it is critical that the profile accurately reflects the type of establishment and the products produced. FSIS national officials stated that SRM control verification tasks only apply to cattle slaughter facilities; however, this statement is not supported by FSIS guidance.[127] The guidance instructed IPP assigned to cattle slaughter or beef processing establishments to perform the SRM control verification task.[128]

Despite these problems with FSIS inspectors' not completing tasks, we did not observe any instances where SRMs were not removed during our site visits. However, FSIS has reduced assurance that inspectors are adequately identifying establishments that are not properly removing SRM from cattle.

FSIS implemented specific controls over the removal of SRM and issued FSIS Notice 70-13 requiring inspectors assigned to cattle slaughter or beef processing establishments to perform the SRM control verification task. That task should verify the implementation of an establishment's SRM control program through review of records and direct observation of the SRM removal.[129] In addition, this directive states that establishments must develop, implement, and maintain written procedures for segregating, removing, and disposing of SRM. FSIS needs to ensure inspectors properly complete SRM verification tasks and front-line supervisors properly monitor the

[126] FSIS provided this information for only 62 of the 66 statistically selected establishments. This information was not obtained for 4 of the 66 statistically selected establishments and the non-statistically selected establishments due to time constraints.
[127] FSIS Notice 70-13, Specified Risk Material Control Verification Task, Oct. 30, 2013.
[128] Processing establishments may receive carcasses or parts that contain vertebral columns from cattle 30 months of age or older from another federally inspected establishment for further processing.
[129] This task is required to be performed once every 2 weeks on each shift.

inspectors to ensure that the tasks are completed, or that reasons for noncompletion are adequately justified.

*FSIS Front-Line Supervisors Need to Ensure that Inspectors Complete HAV Tasks*

HAV tasks are reviews of a plant's food safety system and are designed to identify isolated noncompliances and evaluate how the system has been developed and implemented. We found that 21 of the 59 front-line supervisors did not ensure HAV tasks were completed at 21 of the 83 establishments (25 percent) visited.[130, 131] Based on our sample, we estimate that 1,081 establishments (21 percent) had at least one incomplete HAV task for CY 2014.[132, 133] The front-line supervisors stated that other daily tasks, such as filling in on the inspection lines, prevented them from performing these oversight activities.

For the sampled establishments, we obtained a task list from the district officials showing HAV tasks completed for CY 2014 from district officials. Based on our review of the list, we determined that HAV tasks were not always performed. Much like their supervisors, inspectors indicated that, due to staffing shortages and other daily tasks that needed to be completed, they did not have enough time to complete the HAV task.

We discussed this issue with FSIS national officials, and they stated that the completion of these tasks had improved in 2015. However, FSIS officials provided us with a task list for CY 2015 for these establishments that did not support this claim. Instead, this report showed that the agency still did not complete 39 percent of the HAV tasks scheduled for CY 2015.

*FSIS Front-Line Supervisors Did Not Ensure Inspectors Updated and Corrected Establishment Profiles*

Establishment profiles include information about the products produced and product volume at that establishment. This information is critical because FSIS uses it to assign routine inspection tasks, create directed inspection tasks, generate FSIS sample requests, and manage inspection assignments.[134]

We reviewed the establishment profiles for 83 sampled establishments and verified the establishments' location and contact information, the types of products produced, and the production volume. For 3 of the 83 establishments we visited, the establishment profile contained inaccurate information regarding product volume, plant size, or inspection personnel. For example, the establishment profile for one processing establishment showed the total product volume for "fully-cooked, not shelf stable" was greater than

[130] Many FSIS front-line supervisors are required to oversee multiple establishments within a circuit.
[131] Of these 21 establishments, 16 were statistically selected, and 5 were non-statistically selected.
[132] We are 90 percent confident that the number of establishments with this issue is between 410 (8 percent) and 1,752 (34 percent).
[133] HAV tasks were not implemented by FSIS until Apr. 1, 2014.
[134] FSIS Directive 5300.1, Managing the Establishment Profile in the Public Health Information System, Apr. 11, 2011.

600,000 pounds a day.[135] However, during our site visit, the inspector stated the volume was incorrect and should be shown as "120,000 pounds of beef trim received and only 20,000 pounds produced."[136] The inspector stated that this correction was made earlier, but PHIS did not save the changes and the inspector did not report the problem. The other two inspectors agreed that they had not reviewed and updated the establishment profiles as required. In addition, the two front-line supervisors assigned to these three establishments were not monitoring these activities, and one supervisor was unaware that the establishment profiles were not updated.

FSIS Directive 5300.1 requires inspectors to ensure the establishment profile is updated every month and contains accurate and current data about the establishment's operations.[137] Also, inspectors are required to resolve any issues or discrepancies regarding profile information before showing the task as complete in PHIS. In addition, in January 2016, FSIS revised FSIS Directive 4430.3; the front-line supervisors are now responsible for monitoring to ensure inspectors are keeping the establishment profile current.[138]

In a prior audit, we also found inspectors did not update establishment profiles.[139] During that audit, FSIS stated that by July 31, 2016, it would develop and begin the implementation of a plan that would continually maintain updated establishment profiles and would develop a process for periodic supervisory reviews of the establishment profile data for completeness and accuracy. During this audit, we requested the plan; however, FSIS national officials stated that they were still developing it. FSIS also stated that it would include additional instructions in FSIS Directive 4430.3 requiring front-line

[135] This process category applies to establishments that further process products by using primarily a full lethality heat process step (e.g., cooking) to achieve food safety. The finished products that establishments produce under this process category are not shelf stable. FSIS requires these products to be frozen or refrigerated for food safety purposes. These products also meet the definition of ready-to-eat, which is a meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. Ready-to-eat product is not required to bear safe-handling instruction (as required for non-ready-to-eat products by 9 CFR 317.2(1) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety and can include frozen meat or poultry products (9 CFR 430.1).

[136] During our prior Audit Report 24601-0001-23, *Implementation of the Public Health Information System for Domestic Inspection*, August 2015, we found that establishments profile contained inaccurate product volumes. As a result, we determined that FSIS had reduced assurance that important inspection tasks and vital microbiological testing are performed to ensure products entering the food supply are safe for human consumption.

[137] FSIS Directive 5300.1, Managing the Establishment Profile in the Public Health Information System, Apr. 11, 2011.

[138] FSIS Directive 4430.3, In-Plant Performance System, Jan. 6, 2016, states that supervisors are to review data sources to determine whether inspectors responsible for maintaining the PHIS system at the plant level are keeping the establishment profile current, completing routine inspection tasks, properly entering data concerning scheduled procedures performed or not performed, and entering unscheduled procedures performed. This data review will give the supervisor insight into the decisions the inspector makes regarding which procedures to perform and at what frequency.

[139] Audit Report 24601-0001-23, *Implementation of the Public Health Information System for Domestic Inspection*, August 2015.

supervisors to monitor the completion of routine inspection tasks during IPPS assessments.[140] As stated above, this revised directive was issued in January 2016.

As part of our current review of this topic, we requested a list from FSIS showing all planned and performed tasks for the 66 statistically selected establishments.[141, 142] We found that, between February 2012 and January 2016, 1,740 of 4,045 (43 percent) "update establishment profile" planned tasks were not performed at 62 establishments. Inspectors who did not perform these tasks justified their decision for only 121 of the tasks, citing staffing issues or other high-priority work. Inspectors provided no justifications for the remaining tasks.

Since PHIS uses the establishment profile information to allocate inspection tasks, inspectors must review the establishment profile and update as needed. Since FSIS has stated that it is developing a plan that would ensure inspectors continually update the establishment profiles, we are not making any recommendations in this area.

*FSIS Front-Line Supervisors Did Not Review and Document In-Plant Testing Results*

In response to a prior audit recommendation,[143] FSIS developed FSIS Directive 5000.2 requiring inspection program personnel to conduct and document weekly meetings with plant management to discuss food safety issues and in-plant testing results.[144] For establishments that have micro-organism testing,[145] such as *Escherichia coli* biotype 1 (generic *E. coli*), as part of their HACCP plans,[146] inspectors are required to review the test results at least once a week. Inspectors must document their review of the results of these in-plant tests in a memorandum of interview and discuss these reviews with plant management during weekly meetings. This memorandum is required to include the testing results reviewed, the time period covered by these tests, and any concerns. In addition, front-line supervisors are required to periodically review the memoranda and raise any concerns to a higher level (i.e., the district office).

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[140] FSIS Directive 4430.3, In-Plant Performance System, Jan. 6, 2016.

[141] FSIS provided the "update establishment profile" task data for the original listing of 66 statistically selected establishments only; however, 4 of those establishments were replaced by other establishments during the course of our site visits for various reasons, such as the establishment was suspended. The "update establishment profile" task data were not requested for the replacements or the non-statistically selected establishments because of time constraints.

[142] This includes sampling testing for the following; *Listeria* spp.; *Salmonella* spp., *E. coli* O157:H7, or *Campylobacter*.

[143] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk Based Inspection at Meat and Poultry Establishments*, December 2007 Recommendations 31 and 32.

[144] FSIS Directive 5000.2, revision 2, Review of Establishment Testing Data by Inspection Program Personnel, Dec. 4, 2008.

[145] Microbiological methods are presented for sample preparation, isolation and identification of the major foodborne pathogenic microorganisms and their toxins, meat tissue species identification, and the detection of antimicrobial residues.

[146] Generic, or biotype 1, *E. coli* is found in the feces and intestinal tract of all meat and poultry animals. Finding this bacterium on a slaughtered and dressed carcass indicates that fecal contamination has occurred. USDA requires processors to do carcass testing for generic *E. coli* in order to evaluate the hygiene of the plant's slaughter and dressing procedures. If high levels of generic *E. coli* are detected, then the processor is to adjust the slaughter/dressing process so that it is more sanitary.

During our site visits to the 83 selected establishments, we reviewed establishment records showing the in-plant testing results for the most recent 2-month period. We then compared establishment records to the FSIS memoranda for the same period and found that establishment record test results were documented by the establishment, but the memoranda did not document that these test results were discussed with the management at the establishment. The review showed that in-plant testing, such as for *E. coli* in raw beef products, had been conducted at the establishments, but the inspectors at 28 of the 83 establishments did not document their reviews of these results, nor did they note any concerns with the testing results in the memorandum provided to officials during the weekly meetings.[147]

The inspectors stated this was not a high priority for the inspector and; therefore, they did not document their reviews in the memorandum. Inspectors also stated that, while the discussions were not documented, they did discuss the test results with management at the establishments. The front-line supervisors stated that other priorities—such as acting on behalf of other inspectors in establishments because they were short staffed—prevented them from ensuring the test results were reviewed, properly documented, and the issues resolved. They stated that they do not document the review of this task.

Overall, we found that FSIS did not have specific procedures in place instructing the front-line supervisors on properly supervising and monitoring the inspection verification activities conducted by their assigned staff. Specifically, there were no procedures requiring front-line supervisors to review and evaluate the duties of assigned staff, document identified deficiencies, and requiring the staff to implement appropriate corrective actions to ensure that inspection tasks were completed.

In addition, while the FSIS ODIFP generated and provided monthly reports to the district offices showing information such as tasks not performed and establishments not visited, the district managers and supervisors still indicated that they were unaware that inspection tasks were not performed.[148] FSIS needs to strengthen its overall management controls and oversight to ensure that both district managers and front-line supervisors are routinely monitoring and properly identifying issues with establishments and in-plant personnel in their circuits. These additional controls should include the development of specific guidance and training that addresses adequate monitoring and supervision.

## Recommendation 12

Develop and implement procedures for district officials to follow and document when performing oversight and monitoring of front-line supervisors' activities.

[147] Twenty-one front-line supervisors were responsible for overseeing the activities at these 28 establishments.
[148] The ODIFP is also responsible for coordinating all the agency's data collection, analysis, and integration activities across program areas. In this role, it provides the district offices with monthly reports that can be used to monitor the completion of activities (i.e., tasks assigned to the inspectors) within the district. This office closely collaborates with other offices within FSIS to ensure adherence to emergency management policies, food defense directives, and the consistency and quality of data analyses.

## Agency Position

In its April 18, 2017, response, FSIS stated that District management officials are held accountable to supervisory responsibilities in their FY 2017 performance plans (see Enclosure 13).[149] They are required as supervisors to conduct performance evaluations of subordinate employees, including front-line supervisors, and to document these evaluations in the Performance Rating Tool. Additionally, district management officials are required to review 10 percent of IPPS assessments conducted field supervisors, including those performed by front-line supervisors. FSIS has the procedures in place, between its performance management system and IPPS, for district management personnel to verify front-line supervisors are completing their supervisory responsibilities. Agency officials also stated that FSIS believes it has fully addressed the intent of this recommendation.

## OIG Position

We do not accept management decision for this recommendation. While FSIS's response included updated performance plan requirements for district managers, it did not describe what updated procedures would be implemented to ensure managers perform and document their oversight of front-line supervisors' activities. In order to reach management decision, FSIS needs to provide its plan to develop and implement procedures for district officials to follow when performing oversight and monitoring of front-line supervisors' activities.

## Recommendation 13

Develop and implement a policy that requires front-line supervisors to document their monitoring and oversight activities (separate from the twice per year IPPS review requirement) at assigned establishments on a periodic basis.

## Agency Response

In its April 18, 2017, response, FSIS stated what OIG is recommending is largely fulfilled by the IPPS, which field supervisors are required to document per Directive 4430.3, which was issued in January 2016 and fully addresses this recommendation. In addition, front-line supervisors are held accountable to these supervisory responsibilities in their FY 2017 performance plans (see Enclosure 14).[150] They are required as supervisors to also conduct performance evaluations on top of the IPPS, which they are to document in the Performance Rating Tool. Their performance of each of these supervisory functions is dictated by FSIS policy. Front-line supervisors have been effective in carrying out these supervisory responsibilities, as evidenced by performance rate of PHIS tasks. For example, the HAV task performance rate in CY 2016 was over 90 percent, well above FSIS's management control (See Enclosure 15).[151] FSIS must note that

[149] Enclosure 13–District Manager and Deputy District Manager FY17 Performance Plan Supervisory element.
[150] Enclosure 14–Front-Line Supervisor FY17 Performance Plan Supervisory Element.
[151] Enclosure 15–FSIS HAV Task Performance analysis for CY16.

OIG's statement in Finding 4 related to this recommendation that "FSIS did not develop sufficient oversight controls to ensure its supervisors adequately monitored the completion of tasks…" is not supported by evidence, but rather is OIG's opinion. As stated above, the fact is FSIS holds FLSs responsible for monitoring and oversight activities not only through the IPPS Directive 4430.3, but also through our performance management system. Agency officials also stated that FSIS has fully addressed the intent of this recommendation.

## OIG Position

We do not accept management decision for this recommendation. FSIS' response included documentation showing that they updated IPPS, but the basic controls requiring the front-line supervisors to document their monitoring and oversight activities were not addressed. In addition, FSIS provided documentation to show that the performance of HAV tasks has improved, but did not address why front-line supervisors did not ensure all in-plant testing and SRM tasks were completed. In order to reach management decision, FSIS needs to include a plan to develop and implement a policy that would require front-line supervisors to document their monitoring and oversight activities. This policy should also include additional controls to document the deficiencies identified and the corrective actions implemented to ensure assigned PHIS tasks are completed.

## Recommendation 14

Provide the front-line supervisors with training on managing their circuits and using system-generated reports to monitor and oversee inspection activities at assigned establishments. This training should include guidance on preparing adequate documentation of these activities.

## Agency Response

In its April 18, 2017, response, FSIS stated PHIS contains 100+ standard reports (see Enclosure 16)[152] as well as an alerting function that provides FSIS's front-line supervisors with information to manage and oversee the inspection activities in their circuits. PHIS has a complete directory of all of the reports available, with details of what is contained in each report. ODIFP field analysts are available to help field personnel with PHIS. In addition, ODIFP has provided presentations to front-line supervisors at national meetings and district meetings highlighting what reports are available and how to access the reports. Additionally, FSIS is in the process of developing a Supervisory Help Button, similar to the IPP Help Button. FSIS anticipates it will be available to field supervisors by September 30, 2017. Agency officials also stated that FSIS has fully addressed the intent of this recommendation.

## OIG Position

We do not accept management decision for this recommendation, although we accept FSIS' initial corrective actions. However, in order to reach management decision, FSIS needs to

[152] Enclosure 16 - PHIS Report Directory.

provide its guidance to front-line supervisors on preparing adequate documentation of inspection activities.

# Finding 5: FSIS Needs to Strengthen Controls to Ensure Humane Handling Verification Data Accuracy

FSIS is required to devote 148 FTE positions toward enforcing requirements concerning the humane handling of animals at the establishments. In a prior audit, we recommended that FSIS improve how it compiles the data documenting establishments' compliance with these requirements, and the agency agreed.[153] However, we found that FSIS still lacks assurance that it is fulfilling those requirements because the agency cannot ensure that the time recorded in its system of record accurately represents time spent on humane handling inspection activities. More specifically, we found a number of inconsistencies with FSIS' process for recording data in the HATS. The system only allows inspectors to record time in 15 minute increments and not by actual time spent performing activities. Not all non-public health veterinarians' time spent performing humane handling inspection activities is recorded in the system.[154] Additionally, inspectors can change HATS data at any time after a reporting period has ended. These issues occurred because FSIS did not design the system to accept actual time spent on humane handling verification activities. In addition, FSIS' Office of Field Operations did not implement policies and procedures to identify and follow up on report anomalies (such as the number of total FTEs changing with each humane handling report as it was issued). As a result, FSIS may be over- or under-reporting time spent conducting humane handling activities including when it reports that information to Congress.

Public Law 113-76 states, "that no fewer than 148 FTE positions shall be employed during a FY for purposes dedicated solely to inspections and enforcement related to the Humane Methods of Slaughter Act." Additionally, the Office of Management and Budget Circular A-123 states that "application controls should be designed to ensure transactions are properly authorized and processed accurately and the data is valid and complete.[155] Controls should be established at an application's interfaces to verify inputs and outputs, such as edit checks."[156]

In a prior audit, we reported that FSIS did not have adequate criteria for making the most effective use of its inspection resources based on HATS data.[157] In response to the audit's recommendation, FSIS developed quarterly humane handling reports that management can use to identify anomalies or variances in slaughter establishment noncompliance or inspector performance that could require additional follow-up by district management. The report uses data collected from HATS, which records the time inspectors spend performing humane handling verification activities. FSIS also uses data from HATS to account for the 148 FTEs required to be devoted to humane handling activities and reported to Congress.

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[153] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, November 2008.
[154] Non-public health veterinarians are in-plant personnel other than public health veterinarians, such as food inspectors and consumer safety inspectors.
[155] Office of Management and Budget, Circular A-123, Management's Responsibility for Internal Control, December 21, 2004.
[156] Edit checks are an application control to ensure data are accurate and complete.
[157] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls over Pre-Slaughter Activities*, November 2008.

We obtained and reviewed the quarterly humane handling reports for January 2012 to December 2014 and analyzed the humane handling time recorded in HATS. According to those reports, FSIS reportedly met and exceeded the Congressional mandate of 148 FTEs. The total time spent on humane handling tasks (verification and enforcement of humane handling requirements in federally inspected establishments), as reported by the inspectors in HATS, equaled 156 FTEs for FY 2012, 177 FTEs for FY 2013, and 171 FTEs for FY 2014.

However, we were not able to verify these FTEs or the total time spent on humane handling activities because of errors we found in the HATS reports.[158] For example, our analysis of the quarterly reports found inconsistences with the data reported from quarter to quarter, in that the time recorded for the second quarter could change when the report was generated for the third quarter.[159] Therefore, we could not use these data to determine if FSIS was meeting the Congressional mandate of 148 FTEs. In addition, we found that while FSIS did generate these reports, it did not issue any guidance on how management should use the information in the report (i.e., how to analyze the data for trends and anomalies).

During fieldwork, we visited six district offices and discussed humane handling verification with the district veterinary medical specialist and how inspectors record time spent on humane handling activities in HATS.[160] According to FSIS Directive 6900.2, inspectors are required to report time spent verifying humane handling activities in quarter hour increments rounding up to the next quarter hour. For example, if inspectors spend 20 minutes verifying HATS humane handling, they would record 2 quarter hour increments (i.e., 30 minutes) with a minimum of one quarter hour recorded for the ante-mortem inspection HATS category during each slaughter shift.[161] Inspectors are only required to record in HATS a minimum of a quarter hour of humane handling activities per day in any category.[162]

District veterinary medical specialists at multiple locations expressed concerns with the accuracy of the time reported in HATS, particularly at very small and small establishments.[163] One specialist explained that at some of the smaller establishments, where slaughter shifts can last an hour from start to finish, an inspector could constantly observe all nine HATS categories at one

[158] Humane handling activities refer to the actions taken by an establishment to ensure compliance with the Humane Methods of Slaughter Act, i.e., ante-mortem checks and ensuring food and water for animals.
[159] In the reports, for example, data for the first quarter of FY 2012 showed a total of 72,350 hours of humane handling time. When we reviewed the data for the second quarter of FY 2012, the first quarter data showed 72,470 hours of humane handling time.
[160] The district veterinary medical specialist reviews and analyzes inspection information in HATS. The specialist determines if the number of IPP who routinely perform HATS activities in the establishment is sufficient, and whether all HATS categories are evaluated regularly.
[161] At very small establishments, where only a few animals are slaughtered each day, inspectors do not have to follow the rule that one quarter hour be recorded in the ante-mortem category per slaughter shift. Instead, when more than one HATS activity may be completed in one quarter hour, inspectors should rotate through the appropriate HATS categories throughout the week.
[162] There are nine HATS categories: (1) inclement weather; (2) truck unloading; (3) water and feed availability; (4) ante-mortem inspection; (5) suspect and disabled; (6) electric prod/alternative object use; (7) slips and falls; (8) stunning effectiveness; and (9) conscious animals on the rail.
[163] FSIS has three establishment size categorizes: very small, which indicates fewer than 10 employees or annual sales of less than $2.5 million; small, which indicates 10-499 employees; and large, which indicates 500 or more employees.

time; however, that inspector cannot record time for humane handling that exceeds the duration of the slaughter shift. Another district veterinary medical specialist stated that some tasks at the smaller establishments may only take 1 minute, but that because of the way HATS was developed, the inspector must record the task as taking 15 minutes, which leads to inaccurate totals. Additionally, because FSIS does not require inspectors to immediately record time spent on tasks in the system, inspectors working the second shift may not actually enter their time until after midnight, thus causing the time to be documented on the next day's total and not on the actual date of slaughter.

We also found that not all non-public health veterinarians can record humane handling inspection time in HATS. For example, during our visits to establishments, we determined that food inspectors trained in humane handling inspection sometimes performed such inspections. However, they do not directly record their time in HATS because food inspectors do not have access to the system. Inspectors stated that the consumer safety inspector or public health veterinarians input the food inspectors' time into HATS; however, they do not have a formal process for entering this information. We also found that there were no controls to verify the accuracy of this time entered into the system or to ensure that the time was actually entered.

Finally, we found that, while most district veterinary medical specialists review HATS data for trends or anomalies, the results of these reviews are not documented. Generally, the specialists or front-line supervisors are responsible for reviewing HATS data. They perform this task during or prior to their site visits, and they ensure that the data are recorded correctly; that they are consistent with the historical data for a particular establishment; and that the districts are on track with meeting the congressional FTE requirement.

We discussed HATS with FSIS national officials and asked why the time was recorded in 15 minute increments. They explained that the time was recorded in HATS in 15 minute increments because the agency's general time management system only accepts time in 15 minute increments.

An FSIS official informed us that FSIS does not verify the accuracy of the data collected; it only collects and produces reports. The official also stated that HATS' recorded time may be changed if the need arose. OIG believes that FSIS needs a process in place that verifies the accuracy of the information reported and requires justification for major changes in the HATS time already recorded.

Although the information from the quarterly humane handling reports makes it appear that FSIS is adhering to the 148 FTE requirement established by Congress, FSIS' current method for entering time into the system compromises the accuracy of what is reported. OIG believes that FSIS needs to assess its current use and reporting of HATS data and ensure that the data entered into HATS are accurate enough to assist the agency in assessing its humane handling staffing needs.

## Recommendation 15

Complete an assessment of the process used for recording HATS verification activities (rounding methodology and minimum reporting requirements) and evaluate whether the current process provides the most accurate representation of the agency's time devoted to monitoring humane handling activities. This assessment should document the analysis performed to reach the conclusions. If the assessment shows that a different process is needed, establish timeframes for implementing the new process and also establish a process to verify that the actions are completed within the established timeframes.

## Agency Response

In its April 18, 2017, response, FSIS stated the agency uses the same method as that used at the Department-level and records time in 15-minute increments. This is also a standard practice in many industries. FSIS is on target to meet the annual 148 FTEs/year in Humane Handling oversight and has exceeded the required number of hours since the Congressional mandate was implemented.

That being said, FSIS will perform an assessment of the process used for recording HATS verification activities and evaluate whether the current process provides the most accurate representation of the agency's time devoted to humane handling activities. The assessment will identify ways for district officials to help ensure the accuracy of the time reported in HATS and ways to identify anomalies and trends in the data. The assessment will also evaluate when edits can be made to HATS data and the necessary approvals. FSIS estimates it will complete its actions for this recommendation by May 2018.

## OIG Position

We accept FSIS' management decision for this recommendation.

## Recommendation 16

Develop and implement guidance for district management to help ensure the accuracy of the time reported in HATS and to identify anomalies and trends in the data.

## Agency Response

In its April 18, 2017, response, FSIS stated as outlined in response to recommendation 15, FSIS will perform an assessment of the process used for recording HATS verification activities and evaluate whether the current process provides the most accurate representation of the agency's time devoted to humane handling activities. The assessment will identify ways for district officials to help ensure the accuracy of the time reported in HATS and ways to identify anomalies and trends in the data. The assessment will also evaluate when edits can be made to HATS data and the necessary approvals. If the agency determines, based on the results of the assessment, that additional oversight by district management is needed, FSIS will develop the

necessary guidance to the field. FSIS estimates it will complete its actions for this recommendation by May 2018.

## OIG Position

We accept FSIS' management decision for this recommendation.

## Recommendation 17

Develop and implement policies and procedures that detail when edits can be made to HATS data and indicate that these edits can only be made by certain officials with justifications approved by headquarters.

## Agency Response

In its April 18, 2017, response, FSIS stated it has controls in place in PHIS to ensure the integrity of the HATS data. When personnel need to make a change to this data, they must provide a justification and only then will the system allow them to make the change. The system maintains a history of justifications, date the edit was made, and who made it, all of which is accessible to the personnel's chain of command. Additionally, FSIS re-extracted the FY13 and FY14 HATS data in February 2017, recalculated the FTE times, and compared today's results to what was provided to OIG. The data are within 1 FTE of the originally reported values. Out of a total of more than 170 FTEs reported to Congress for FY13 and FY14, this represents less than a 1 percent change (approximately 0.6 percent). FSIS believes the ability to compute the same staff year total to within 1 FTE several years after the reporting period indicates that 1) the reported data are reasonably consistent and 2) the data was accurately reported as exceeding the Congressional mandate. Agency officials also stated that FSIS believes it has the measures in place already that address this recommendation.

As outlined for recommendations 15, and 16, FSIS will perform an assessment of the process used for recording HATS verification activities and evaluate whether the current process provides the most accurate representation of the agency's time devoted to humane handling activities. The assessment will identify ways for district officials to help ensure the accuracy of the time reported in HATS and ways to identify anomalies and trends in the data. The assessment will also evaluate when edits can be made to HATS data and the necessary approvals. FSIS estimates it will complete its actions for this recommendation by May 2018.

## OIG Position

We accept FSIS' management decision for this recommendation.

## Finding 6: FSIS Still Needs to Improve Access to PHIS for Inspectors in the Field

In an audit published in August 2015, we reported that FSIS had not ensured that its inspectors could reliably use PHIS because connectivity problems prevented timely completion of inspection tasks and recording of results.[164] During this current audit, we found that, although FSIS had implemented several improvements to assist inspectors with connection to PHIS, inspectors at 36 of 75 establishments (48 percent) stated that they still could not always connect to PHIS while at the establishment.[165] This problem occurred because FSIS applied limited solutions (such as the disconnected user application (DCU)[166] and mobile WiFi (MiFi) devices[167]) instead of developing a nationwide strategy to ensure all inspectors can connect to PHIS while they are at establishments performing their tasks. While our audit did not identify contaminated or uninspected product released into commerce as a result of this weakness, we believe that time spent dealing with connectivity issues interferes with inspectors' primary function, performing inspection activities that ensure safety for the nation's food supply.

PHIS replaced legacy systems such as the Performance-Based Inspection System and the Electronic Animal Disposition Reporting System. These systems were used to record and manage HACCP-related activities at FSIS-inspected meat and poultry establishments, and the disposition of livestock and poultry presented for slaughter. We agree with FSIS officials that integrating the functions of these legacy systems into PHIS saved time and effort because food safety information would be contained in one location.

During our previous audit of FSIS' implementation of PHIS, we found that inspectors could not consistently access PHIS and therefore could not timely review their scheduled tasks and record task completion. We previously reported that inspectors had limited access to PHIS because they lacked reliable internet connections or because the DCU application that FSIS implemented to address poor connection issues was either not functioning properly on the inspectors' computers, or it was not operational.

In January 2015, FSIS stated that field connectivity had improved due to upgrades that included introducing MiFi devices in the field. FSIS also explained that DCU now comes pre-installed on all laptops. They also stated that agency officials tested the newest DCU version on these new laptops and concluded that performance has improved over the prior version. Therefore, we agreed not to make recommendations in the August 2015 audit report regarding the PHIS connectivity problem. We chose to evaluate FSIS' progress on this issue in this audit.

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[164] Audit Report 24601-0001-23, *Implementation of the Public Health Information System for Domestic Inspection*, August 2015.

[165] We did not review connectivity issues at the eight establishments we visited during the survey portion of our audit.

[166] DCU allows inspection personnel to work in an offline capacity when connection is not available. This application allows inspection personnel to view PHIS establishment profile information and record information like inspection task results on their computer without connecting to the internet.

[167] MiFi is a brand name used to describe a wireless router that acts as a mobile Wi-Fi hotspot. FSIS stated that MiFi is a generic reference to wireless hotspots that do not connect directly to a personal computer and require no software installation.

From June 2015 through December 2015, we performed site visits at 75 establishments and interviewed inspectors regarding their experience connecting to PHIS and their use of the DCU application.[168] Inspectors at 36 establishments stated that they still had issues connecting with PHIS:

- We observed connectivity issues at 12 of the 36 establishments while we conducted our site visits. At the 12 establishments, 10 inspectors either used the Evolution Data Optimized (EVDO)[169] or a MiFi device when attempting to connect to PHIS, and 2 inspectors used Digital Subscriber Line (DSL). Of these 12 inspectors, 5 also used DCU when connectivity was not available.

- Inspectors at the other 24 establishments stated they had issues with connectivity for reasons ranging from "no access to the internet" to "the system being down."

- Inspectors at 15 of those 24 establishments did not use DCU, but instead used other methods to work around the connectivity issue. For example, inspectors at eight establishments waited until they visited an alternate site with good connectivity to enter tasks completed at the previous establishment (see Exhibit F).[170]

These problems interfere with inspectors' ability to perform their duties. Since PHIS is the system that assigns tasks and records the results of task completion, inspectors must have real time and reliable access to ensure accurate and efficient work.

In response to the August 2015 audit report, FSIS acknowledged there were instances of limited connectivity to PHIS in certain geographically remote areas, but FSIS officials stated that at no time was food safety jeopardized because of that problem. They maintained that PHIS is a tool inspectors use to assist them in managing and documenting their work, and those inspectors are empowered to use their judgement in prioritizing and performing tasks to ensure the wholesomeness of the food supply. We agree that connectivity issues at some of the establishments can be attributed to geographically remote locations. However, FSIS should have accounted for this in the agency's implementation of PHIS since FSIS is not able to control the location of an establishment that needs inspection services.

The agency's prior actions from our previous audit of FSIS' implementation of PHIS are a positive step towards improving access to PHIS, but those actions did not fully resolve connectivity issues.[171] FSIS needs to develop a nationwide strategy to ensure all inspectors can connect to PHIS at the establishment where they perform their tasks. This step will help ensure

[168] We visited 75 establishments from June to December 2015, which includes 66 statistically selected and 9 non-statistically selected establishments. During the audit survey, we also visited another eight non-statistically selected establishments from November 2014 through May 2015. We did not review connectivity issues at the eight establishments we visited during the survey portion of our audit.
[169] EVDO is a 3G digital service provided by cellular carriers.
[170] The FSIS directive for using DCU does not require the inspector to enter the information into the system the day of the inspection.
[171] Audit Report 24601-0001-23, *Implementation of the Public Health Information System for Domestic Inspection*, August 2015.

the timely recording of inspection tasks and provide FSIS with real-time access to inspection results.

## Recommendation 18

Develop and implement an action plan to resolve the connectivity issues preventing inspectors from using PHIS at every establishment. This plan should include a nationwide assessment that identifies establishments with connectivity issues and provides specific dates for resolving the connectivity issues.

## Agency Response

In its April 18, 2017, response, FSIS officials stated that it has been working on solving connectivity issues for its field employees for a number of years now, and has made great strides. Connectivity is vastly better today, as FSIS has upgraded all 3G devices to 4G, installed hundreds of T1 connections, and has distributed thousands of MiFi devices in the field. FSIS is aware of 60 federally-inspected establishments remaining nationwide (see Enclosure 17)[172] that do not have connectivity. The Agency worked with each district to identify these locations, and has been deploying innovative connectivity solutions to each site, such as Cradlepoint, Cisco 819, and portable satellite. FSIS official also stated that it anticipates having connectivity addressed at these locations by May 31, 2017. Once this occurs, the Agency will sunset the Disconnected State Application in PHIS, as it will no longer be needed by its employees.

## OIG Position

We accept FSIS' management decision for this recommendation.

[172] Enclosure 17–Listing of FSIS establishments with no connectivity.

## Scope and Methodology

To accomplish our audit objectives, we evaluated FSIS' implementation of 47 of 60 audit recommendations[173] from two prior OIG audits.[174] These 47 recommendations covered areas such as the lack of oversight controls for (1) district veterinary medical specialist reviews, (2) IPPS assessments, (3) food safety assessments, (4) oversight of specified risk material tasks, (5) pathogen testing documentation, (6) information technology support systems, and (7) training and development of inspection personnel. We performed our audit at FSIS Headquarters in Washington, D.C.; 6 of 10 FSIS district offices; and 83 of 5,092 federally inspected slaughter and processing establishments (see Exhibit A). Our audit scope was CY 2012 through CY 2014, but we expanded this scope to include data from CY 2015 as needed to meet our audit objectives.[175] Our audit field work was conducted from June 2014 through May 2016**.**

In June 2014, we initiated a survey to obtain and evaluate FSIS' current policies and procedures related to the audit objective. To conduct our survey, we non-statistically selected two FSIS district offices[176] and eight slaughter establishments for review. The two FSIS district offices were selected based on hotline complaints received related to humane handling violations and because each district was responsible for overseeing slaughter and processing activities at a large number of establishments.[177] Within the two FSIS districts, we non-statistically selected eight establishments (four from each district) for review based on factors including whether the establishments were visited during one of the prior audits,[178] hotline complaints, the type of establishment (e.g., slaughter, processing, or both), and establishments' size.

During the audit phase, we statistically selected 5 FSIS district offices[179] and 66 federally inspected establishments for review (see Exhibit G for sample design). However, since so few cull cow slaughter establishments were selected in that sample, we also non-statistically selected 9 cull cow slaughter establishments because one aspect of our objectives was to ensure implementation of the corrective actions related to the removal of SRM.

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[173] The other 13 prior recommendations dealt with the implementation of the PHIS, and they were reviewed during a prior OIG audit, Audit Report 24601-0001-23, *Public Health Information System for Domestic Inspection*, August 2015. There was a total of 16 recommendations reviewed during that audit, and 3 of those recommendations were also reviewed during this audit.

[174] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007, and Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, November 2008.

[175] For the IPPS review analysis, we limited our scope to FY 2013-2014 for four out of the six districts (Dallas, Texas; Denver, Colorado; Jackson, Mississippi; and Philadelphia, Pennsylvania) and FY 2014 for the other two districts—Des Moines, Iowa, and Raleigh, North Carolina. This decision was due to the volume of documentation needed to review this area and concerns from FSIS headquarters about the overall volume of the data requested for this audit.

[176] These two district offices were located in Philadelphia, Pennsylvania, and Raleigh, North Carolina.

[177] These districts were responsible for 569 and 869 establishments, respectively.

[178] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007, and Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, November 2008.

[179] One of the five selected districts was located in Raleigh, North Carolina, which was also the location we non-statistically selected for our survey work. The other districts were located in Dallas, Texas; Denver, Colorado; Des Moines, Iowa; and Jackson, Mississippi.

Of these nine additional establishments, four were also visited during one of the previous OIG audits.[180] In total, we visited 83 federally-inspected establishments, including 66 statistically selected establishments and 17 non-statistically selected establishments.[181] We interviewed at least 151 FSIS inspectors assigned to the 83 establishments we visited. We also interviewed 53 front-line supervisors, 8 district veterinary medical specialists, and 6 district managers.

FSIS uses several information technology systems to streamline and monitor its oversight of establishment food safety systems. We performed data validation tests from the data FSIS provided us from the following systems: PHIS, AsssuranceNet, and HATS. We did not perform any additional testing to evaluate those information technology systems and make no representation as to the adequacy of FSIS' information technology systems or reports. While we did not detect any errors in the universe listing of establishments FSIS extracted from PHIS, during our audit fieldwork we found several data errors in AssuranceNet and HATS reports.[182]

To accomplish our audit objectives, we:

- Reviewed FSIS' management decisions and final actions for the 47 prior audit recommendations.[183]
- Interviewed FSIS officials regarding the implementation of prior audit recommendations related to pre-slaughter activities and risk-based inspections.
- Reviewed Federal laws and FSIS regulations related to the slaughter, inspection, processing, and testing of meat and poultry products.
- Reviewed and analyzed FSIS policies, procedures, guidance, and directives related to the slaughter, inspection, processing, and testing of meat and poultry products. Specifically, we reviewed the procedures related to humane handling during pre-slaughter, post-mortem inspection, and removal of SRMs.
- Analyzed the quarterly humane handling reports to determine the number of hours performed by FSIS inspection program personnel on human handling activities at livestock facilities.
- Analyzed system task reports that FSIS extracted from PHIS, AssuranceNet, and HATS.
- Interviewed FSIS district officials and assessed their oversight of front-line supervisors and establishment personnel.
- Interviewed district veterinary medical specialists and assessed the adequacy of their monitoring and supervision of pre-slaughter and humane handling activities.
- Evaluated district officials' monitoring of positive test results from product samples to identify trends and to ensure appropriate corrective actions were taken.
- Interviewed FSIS inspectors and public health veterinarians as well as their front-line supervisors on the process for monitoring an establishment's food safety system.

[180] Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, November 2008.
[181] For these 17 non-statistically selected establishments, 8 were selected during the survey coverage and 9 were cull cow establishments selected during the audit coverage.
[182] HATS data are housed within PHIS.
[183] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007, and Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, November 2008.

- At food processing establishments, we observed FSIS inspectors perform duties such as pre-operational inspections to ensure food contact surfaces are clean and sanitized.
- At slaughter establishments, we observed FSIS inspectors perform pre-slaughter activities designed to ensure establishment personnel followed humane handling requirements. In addition, we observed stunning and ante-mortem inspection processes including the removal, segregation, and disposition of SRMs.
- At each establishment in our sample we analyzed, as applicable, the (1) HACCP and humane handling plans, (2) in-plant testing procedures and results, and (3) noncompliance records issued and linked.
- During the audit phase, we evaluated the staff's ability to connect to PHIS. This analysis was conducted at both the district offices and the establishments.

We conducted this audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

# Abbreviations

BSE .....*bovine spongiform encephalopathy*
CFR.....Code of Federal Regulations
CY .....calendar year
DCU .....Disconnected User Application
DSL.....Digital Subscriber Line
EIAO .....enforcement, investigations, and analysis officer
EVDO .....evolution data optimized
FMIA.....Federal Meat Inspection Act
FSA .....Food Safety Assessment
FSIS.....Food Safety and Inspection Service
FTE .....full-time equivalent
FY .....fiscal year
GAO.....Government Accountability Office
HACCP .....Hazard Analysis and Critical Control Point
HATS .....Humane Handling Activities Tracking System
HAV.....Hazard Analysis Verification
HMSA .....Humane Methods of Slaughter Act
IPP.....in-plant personnel
IPPS.....In-Plant Performance System
IT.....information technology
MiFi.....mobile Wi-Fi
NOIE .....notice of intended enforcement
ODIFP .....Office of Data Integration and Fraud Protection
OFDER .....Office of Food Defense and Emergency Response
OFO.....Office of Field Operations
OIEA .....Office of Investigation, Enforcement, and Audit
OIG .....Office of Inspector General
PHIS .....Public Health Information System
PHR.....Public Health Regulation
PHRE .....public health risk evaluation
SRM .....specified risk material
SSOP .....sanitation standard operating procedure
T1 .....T-carrier
USDA.....United States Department of Agriculture

# Exhibit A: FSIS District Offices, States, and Number of Establishments Visited

The table identifies the FSIS districts we visited and includes the district name and location, States covered, and the number of establishments visited during the audit.

| District Name and Location | States Covered | States Visited | Number of Establishments Visited |
|---|---|---|---|
| Philadelphia, PA | Connecticut ▪ Massachusetts ▪ Maine New Hampshire ▪ New York ▪ Pennsylvania Rhode Island ▪ Vermont | 3 | 4 |
| Raleigh, NC | Delaware ▪ District of Columbia ▪ Maryland North Carolina ▪ New Jersey ▪ Virginia West Virginia | 5 | 23 |
| Jackson, MS | Alabama ▪ Kentucky ▪ Mississippi ▪ Tennessee | 4 | 10 |
| Des Moines, IA | Iowa ▪ Minnesota ▪ North Dakota South Dakota ▪ Wisconsin | 4 | 14 |
| Denver, CO | Alaska ▪ American Samoa ▪Colorado ▪ Guam Hawaii ▪ Idaho ▪ Northern Mariana Islands Montana ▪ Nebraska ▪ Oregon ▪ Utah Washington ▪ Wyoming | 5 | 18 |
| Dallas, TX | Louisiana ▪ New Mexico Oklahoma ▪ Texas | 3 | 14 |
| Total | | 24 | 83 |

# Exhibit B: List of 14 Recommendations Not Effectively Implemented from Prior Audit Reports (Audit Report 24601-0007-Hy and Audit Report 24601-0007-KC)

| **Audit 24601-0007-Hy Recommendation 12**<br>Develop and implement criteria for prioritizing the scheduling of food safety assessments. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| FSIS developed criteria for prioritizing the scheduling of food safety assessments. FSIS will conduct Food Safety Assessments at establishment once every four years. | FSIS did not conduct Food Safety Assessments at every establishment in one district once every four years, and at two other districts it did not maintain sufficient documentation to determine if an FSA was performed at every establishment.<br>(See Finding 1.) |

| **Audit 24601-0007-Hy Recommendation 13**<br>Develop and implement criteria for conducting periodic reevaluations of an establishment's food safety system to assess its progress after an initial food safety assessment. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| FSIS developed a procedure to be conducted annually by each inspector-in-charge to review each establishment's latest food safety assessment as part of the annual reassessment verification procedure. If the inspector-in-charge documents any changes, an alert will be sent to the front-line supervisor who then could decide to address the issue at his/her level or to elevate it to the district office, which may decide to send out an EIAO for review. | FSIS did not maintain documentation showing whether an FSA was performed at every establishment. In addition, FSAs were not being completed as agreed. Therefore, we could not perform an accurate analysis of how well FSIS was performing these assessments.<br>(See Finding 1.) |

| **Audit 24601-0007-Hy Recommendation 26**<br>Provide guidance to officials, particularly at the district level, to use AssuranceNet to view performance data down to the establishment level as well as the circuits and districts. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| Developed monitoring procedures and frequencies, for direction on "drilling down" into data below the circuit level. | FSIS did not ensure that all levels of district office staff actually used AssuranceNet to monitor the completion of the IPPS performance measures.<br>(See Finding 1.) |

| **Audit 24601-0007-Hy Recommendation 27** | |
|---|---|
| Modify AssuranceNet to monitor the completion and results of all required elements and sub-elements assessed during IPPS reviews. | |
| **FSIS Response** | **OIG Conclusion** |
| Develop additional guidance to supervisors reviewing IPPS assessments, instructing them to specifically focus on the extent to which these are being covered over the course of the year. | FSIS did not complete all elements and sub-elements during IPPS reviews.<br><br>(See Finding 1.) |

| **Audit 24601-0007-Hy Recommendation 28** | |
|---|---|
| Implement features within AssuranceNet that will allow the system to (1) identify employees who have not worked in an IPPS-rated position for an entire rating period (e.g., retired or new employees), and (2) identify, for corrective action, instances in which employees have not received the required IPPS reviews. | |
| **FSIS Response** | **OIG Conclusion** |
| FSIS stated that the design and implementation of an AssuranceNet feature for tracking completion of IPPS assessments has been incorporated into a contract the agency currently has in place to build onto AssuranceNet, and they are working with the contractor to finalize the requirements. The tracking feature will allow users to generate reports displaying lists of individuals who have outstanding IPPS reviews, including individuals who have not yet received an IPPS assessment in the current rating period. | FSIS did not implement an adequate process to identify employees who have not worked in an IPPS-rated position for an entire rating period. In addition, IPPS reviews were not completed. FSIS did not adequately use AssuranceNet to monitor completion of IPPS reviews.<br><br>(See Finding 1.) |

| **Audit 24601-0007-Hy Recommendation 31** | |
|---|---|
| Develop and implement requirements for inspection personnel to document their reviews of establishment testing results. At a minimum, the inspection personnel should document when they reviewed the test results, the type(s) of results they looked at (*E. coli* 0157:H7, *Salmonella*, etc.) and the time period reviewed. | |
| **FSIS Response** | **OIG Conclusion** |
| FSIS agreed to provide instructions to inspection program personnel concerning which types of industry data they should review for which types of products. They will also provide a work method for reviewing the data, for example, trends over time, and also describe documentation procedures to track the specific data, and time window, in which it was reviewed. | FSIS did not ensure in-plant personnel documented their reviews of establishment testing results.<br><br>(See Finding 4.) |

| **Audit 24601-0007-Hy Recommendation 32** | |
|---|---|
| Ensure that the inspection personnel's reviews of establishment testing are periodically verified by responsible supervisory officials and noncompliance is specifically identified in IPPS. | |
| **FSIS Response** | **OIG Conclusion** |
| FSIS agreed to add a sub-element to the IPPS form to capture the new review requirement and amend FSIS Directive 5000.2 to advise inspection personnel as to when they should alert supervisors of an establishment's trend of positive pathogen tests. | FSIS did not ensure in-plant personnel documented their reviews of establishment testing results.<br><br>(See Finding 4.) |

| **Audit 24601-0007-Hy Recommendation 33** | |
|---|---|
| Expedite the development of the specific criteria to inspection personnel that provide a basis for establishing when corrective actions are inadequate and appropriate enforcement actions should be initiated for repetitive deficiencies. The criteria should also define when progressive enforcement actions should be taken. | |
| **FSIS Response** | **OIG Conclusion** |
| FSIS agreed to revise Directive 5000.1 to include additional instructions concerning linking noncompliance records and initiating enforcement actions. FSIS noted that the revised directive would provide for more consistent and coordinated action if a noncompliance is not corrected, persists, or recurs. In addition to a revision of Directive 5000.1, FSIS noted more focus will be given to the section in the food safety regulatory essentials training for linking of noncompliance records and evaluating corrective actions). | FSIS did not always issue noncompliance reports or link noncompliance reports when warranted.<br><br>(See Finding 3.) |

| **24601-0007-KC Recommendation 1** | |
|---|---|
| Require that district veterinary medical specialist reviews evaluate the effectiveness of in-plant FSIS personnel in overseeing slaughter establishments' humane handling activities. Also, establish controls to ensure that district veterinary medical specialist review results are correlated with prior reported violations to determine whether inspection processes need to be reassessed, or other administrative actions taken. | |
| **FSIS Response** | **OIG Conclusion** |
| FSIS agreed to issue a new directive that would provide district veterinary medical specialists with additional guidance related to their reviews. This guidance will require each district veterinary medical specialist before conducting a humane handling verification visit to review the results of the prior district veterinary medical specialist review as well as noncompliance record, Memoranda of Information, and suspensions for the preceding 6 months. | We found that district veterinary medical specialist reviews were not performed as required.<br><br>(See Finding 1.) |

| **24601-0007-KC Recommendation 3**<br>Establish a process to analyze Performance Based Inspection System data for anomalies or variances in both slaughter establishment and inspector performance that could require additional follow-up by district management. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| In order to address the recommendation, Office of Food Defense and Emergency Response (OFDER)/Data Analysis and Integration Group will develop a quarterly humane handling alert based on a review of establishment noncompliance data that can be used by OFO management to identify anomalies or variances in slaughter establishment noncompliance or inspector performance that could require additional follow-up by district management. | FSIS did not have documentation to support quarterly reports provided to Congress to show the FTEs devoted to humane handling activities.<br><br>(See Finding 5.) |

| **24601-0007-KC Recommendation 7**<br>Strengthen human capital management by establishing structured training and development program with strong organization controls to demonstrate the competency of the inspection workforce in fulfilling its mission. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| FSIS will establish policies and procedures to ensure that all mission critical occupational groups (front-line supervisor, public health veterinarian, consumer safety inspector, program investigator, import inspector, and food inspector) receive formal, entry level on-the-job or classroom training based on their job description, performance standards, and agency policies and procedures within 1 year or sooner of starting their positions. Further, FSIS will require that inspection program personnel recertify this training annually. | FSIS did not implement a procedure to require the recertification of training annually. In addition, we found that slaughter establishments we visited did not take the appropriate enforcement actions against establishments that had questionable humane handling violations during ante-mortem inspections.<br><br>(See Finding 2.) |

| **24601-0007-KC Recommendation 8**<br><br>Strengthen management controls to ensure that district management teams are performing onsite evaluations of IPPS reviews at the minimum frequency required by AssuranceNet. In addition, evaluate whether the frequency of these reviews should be increased. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| FSIS stated that during the summer of 2008 district analysts had received training to allow them to make more effective use of the custom reports available through AssuranceNet. These reports allow the districts to see what percentage of IPPS reviews they have performed overall as well as broken down by circuit so that they can better monitor and target their efforts throughout each rating cycle. Also, the AssuranceNet system was enhanced during the summer of 2008 to allow district management teams to see which IPPS assessments have generated follow-up due to deficiencies identified by the rating supervisors. | FSIS did not perform onsite evaluations of IPPS reviews as required. In addition, we found IPPS reports to be unreliable.<br><br>(See Finding 1.) |

| **24601-0007-KC Recommendation 13**<br><br>Develop procedures to require public health veterinarians to verify, at least on a periodic basis, that non-veterinary inspectors perform ante-mortem inspections in accordance with FSIS directives. Also, ensure that such observations are documented. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| FSIS responded to OIG's recommendation by explaining that "they have made improvements to the IPPS Supervisory Guidelines that will result in better accountability for carrying out ante-mortem and other inspection activities. The new guidelines will contain explicit instructions for conducting IPPS assessments to test the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible and to observe their performance of inspection and verification procedures. The guideline will incorporate a 'work method' to ensure that supervisors ask the right questions and that they observe the performance of the inspection personnel on every aspect of their jobs, including ante-mortem inspections. These observations are required to be documented on the IPPS report in AssuranceNet." | FSIS did not perform the required number of IPPS reviews, and not all elements of IPPS reviews were completed.<br><br>(See Finding 1.) |

| **24601-0007-KC Recommendation 20**<br><br>Add specific fields to both AssuranceNet and IPPS for SRM-related activities and develop processes to ensure that these are adequately monitored both at the district and Headquarters levels. | |
|---|---|
| **FSIS Response** | **OIG Conclusion** |
| The Public Health Information System (PHIS) will have features that require inspection personnel to record which specific regulatory requirements are verified (during inspection) each time they are performed, even if noncompliance is not found. This data will be available to OFO supervisory personnel for them to track and ensure that inspectors are performing such verifications at the specified frequencies. PHIS policy and training will include guidelines for monitoring SRM verification frequencies and for responding to variations in frequency. As PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track the performance of tasks and to assure that the appropriate regulatory requirements are verified as required. | FSIS did not monitor in-plant inspectors' completion of SRM verification tasks. We found that SRM tasks were not being performed.<br><br>(See Findings 1 and 4.) |

# Exhibit C—Results of Prior Audit Recommendations

This exhibit lists the recommendations from audit reports 24601-0007-Hy and 24601-0007-KC that we reviewed as part of the follow up work. [184] For all corrective actions found to be not effective, see Exhibit B.

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| 24601-0007-Hy | 4 | As FSIS moves forward to develop and implement risk-based inspection, conduct and document analyses that support the data windows selected for each of the components in the risk control measure that assesses an establishment's ability to control risk. | Yes | Yes |
| 24601-0007-Hy | 5 | Ensure that the basis for decisions made regarding the components included in the risk-based inspection program are thoroughly documented and evaluated with limitations mitigated and are transparent to all stakeholders. | Yes | Yes |
| 24601-0007-Hy | 9 | As FSIS moves forward to develop and implement risk-based inspection, include the enforcement action NOIE Under Deferral in the calculation. | Yes | Yes |
| 24601-0007-Hy | 11 | Institute the appropriate oversight and control during the development of critical IT systems needed to support risk-based inspection. | Yes | Yes |

[184] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007 and Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, November 2008.

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| 24601-0007-Hy | 12 | Develop and implement criteria for prioritizing the scheduling of food safety assessments. | Yes | No |
| 24601-0007-Hy | 13 | Develop and implement criteria for conducting periodic reevaluations of an establishment's food safety system to assess its progress after an initial food safety assessment. | Yes | No |
| 24601-0007-Hy | 15 | Develop and implement procedures to ensure sufficient, timely follow-up work is performed in response to findings in food safety assessments. | Yes | Yes |
| 24601-0007-Hy | 18 | Complete the in-depth analysis of all the data information streams within FSIS. Also, establish a mechanism to assure that once the analysis is performed for a system it is updated on a regular basis and that new systems are fully analyzed before they come on line. | Yes | Yes |
| 24601-0007-Hy | 19 | Implement management controls to ensure effective distribution and full use of the results of all data analyses and reports to other affected program areas, including field operations, in order to allow for follow-up actions to correct problems identified and to establish performance goals for inspectors. | Yes | Yes |
| 24601-0007-Hy | 20 | Perform an analysis of all reports currently generated (including those generated by the Office of Policy, Program, and Employee Development) and determine if any would be beneficial to other divisions/levels in improving compliance and | Yes | Yes |

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| | | operations. Further, determine if modifications could be made to the reports to make them more beneficial to other program areas, including field operations. | | |
| 24601-0007-Hy | 21 | Provide ongoing training to district analysts on new or modified software and specific analytical techniques including the type of data to collect, standard types of analysis to perform, format to present data, frequency of reporting the results, and follow-up actions the analysts are expected to take on any adverse issues noted. Also, establish a system to track when training is taken, the type of training taken, and a system to alert the appropriate managers if the minimal levels of training are not being achieved. | Yes | Yes |
| 24601-0007-Hy | 22 | To the extent feasible, focus the activities of district analysts primarily on their data management and analysis responsibilities and promptly fill vacant district analyst positions. | Yes | Yes |
| 24601-0007-Hy | 24 | Provide officials at each level with written guidance on the use of the AssuranceNet system, particularly with regard to follow-up actions and adherence to the established system thresholds. | Yes | Yes |
| 24601-0007-Hy | 25 | Establish procedures to ensure that warning "flags" provided by AssuranceNet are timely and effectively followed up on, particularly in cases in | Yes | Yes |

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| | | which deficiencies are repeatedly noted at the same establishment, circuit, or district. | | |
| 24601-0007-Hy | 26 | Provide guidance to officials, particularly at the district level, to use AssuranceNet to view performance data down to the establishment level as well as the circuits and districts. | Yes | No |
| 24601-0007-Hy | 27 | Modify AssuranceNet to monitor the completion and results of all required elements and sub-elements assessed during IPPS reviews. | No | No |
| 24601-0007-Hy | 28 | Implement features within AssuranceNet that will allow the system to (1) identify employees who have not worked in an IPPS-rated position for an entire rating period (e.g., retired or new employees), and (2) identify, for corrective action, instances in which employees have not received the required IPPS reviews. | No | No |
| 24601-0007-Hy | 29 | Implement procedures and controls as needed to ensure that supervisors limit their use of the "followup" box on the IPPS review forms to instances involving documented performance deficiencies. | Yes | Yes |
| 24601-0007-Hy | 30 | Continue the increased diligence for achieving management decision and final action on the remaining prior recommendations. In addition, | Yes | Yes |

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| | | apply this increased diligence to future recommendations to ensure timeframes are met. | | |
| 24601-0007-Hy | 31 | Develop and implement requirements for inspection personnel to document their reviews of establishment testing results. At a minimum, the inspection personnel should document when they reviewed the test results, the type(s) of results they looked at (*E. coli* 0157:H7*, Salmonella*, etc.), and the time period reviewed. | Yes | No |
| 24601-0007-Hy | 32 | Ensure the inspection personnel's reviews of establishment testing are periodically verified by responsible supervisory officials and noncompliance is specifically identified in IPPS. | Yes | No |
| 24601-0007-Hy | 33 | Expedite the development of the specific criteria to inspection personnel that provide a basis for establishing when corrective actions are inadequate and appropriate enforcement actions should be initiated for repetitive deficiencies. The criteria should also define when progressive enforcement actions should be taken. | Yes | No |
| 24601-0007-Hy | 34 | Reassess the effectiveness of training programs for inspection personnel and front-line supervisors and revise the programs, as appropriate. | Yes[185] | Yes |

[185] Although this recommendation was implemented, FSIS did not submit all of the required documentation to Office of the Chief Financial Officer.

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| 24601-0007-Hy | 35 | Provide refresher training, at a minimum, to the inspection personnel and front-line supervisors assigned to the establishments with the recalls (i.e., United Food Group LLC and Topps Meat Company LLC). | Yes | Yes |
| 24601-0007-KC | 1 | Require that district veterinary medical specialist reviews evaluate the effectiveness of in-plant FSIS personnel in overseeing slaughter establishments' humane handling activities. Also, establish controls to ensure that district veterinary medical specialist review results are correlated with prior reported violations to determine whether inspection processes need to be reassessed or other administrative actions taken. | Yes | No |
| 24601-0007-KC | 2 | Reassess the humane handling risks associated with cull slaughter establishments, and determine whether District Veterinary Medical Specialist reviews should be conducted on a more frequent basis at those establishments. | Yes | Yes |
| 24601-0007-KC | 3 | Establish a process to analyze Performance Based Inspection System data for anomalies or variances in both slaughter establishment and inspector performance that could require additional follow-up by district management. | No | No |
| 24601-0007-KC | 4 | Determine whether FSIS-controlled in-plant video monitoring would be beneficial in preventing and | Yes | Yes |

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| | | detecting animal abuses at cull cow slaughter establishments. | | |
| 24601-0007-KC | 6 | Reassess and support the methodology used to establish the supervisory span of control for front-line supervisors. | Yes | Yes |
| 24601-0007-KC | 7 | Strengthen human capital management by establishing structured training and development program with strong organization controls to demonstrate the competency of the inspection workforce in fulfilling its mission. | No | No |
| 24601-0007-KC | 8 | Strengthen management controls to ensure that district management teams are performing onsite evaluations of IPPS reviews at the minimum frequency required by AssuranceNet. In addition, evaluate whether the frequency of these reviews should be increased. | Yes | No |
| 24601-0007-KC | 9 | Strengthen and clarify the requirements for in-plant inspection personnel to assess the adequacy of each establishment's animal identification system. In addition, strengthen FSIS guidance requiring the use of ear tags to identify suspected and condemned animals. | Yes | Yes |
| 24601-0007-KC | 10 | Require inspectors to verify the accuracy of the animal counts on pen cards and drive sheets and reconcile these to establishment slaughter records. | Yes | Yes |

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| 24601-0007-KC | 11 | Strengthen existing guidance for inspectors to observe animals both at rest and in motion during ante-mortem inspection. | Yes | Yes |
| 24601-0007-KC | 12 | Implement controls to ensure that each non-veterinary inspector has received necessary training, both formal and informal, before performing ante-mortem inspections. | Yes | Yes |
| 24601-0007-KC | 13 | Develop procedures to require public health veterinarians to verify, at least on a periodic basis, that non-veterinary inspectors perform ante-mortem inspections in accordance with FSIS directives. Also, ensure that such observations are documented. | Yes | No |
| 24601-0007-KC | 14 | Require that secondary entrances to slaughter areas, stunning boxes, and winches not used as part of establishments' normal slaughter operation be placed under FSIS control to ensure that they can be used only under the supervision of inspection personnel. | Yes | Yes |
| 24601-0007-KC | 15 | Develop specific guidance and procedures for in-plant FSIS personnel to use herd history as a basis for performing residue tests. | Yes | Yes |
| 24601-0007-KC | 16 | Develop a process that provides ongoing monitoring and analysis of inspector-generated residue sampling. Initiate follow-up actions when | Yes | Yes |

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| | | there are variances in inspector performance and/or residue test results. | | |
| 24601-0007-KC | 17 | Clarify the written requirements for the collection of test samples. In addition, strengthen monitoring to ensure that inspectors properly safeguard samples against possible tampering. | Yes. | Yes |
| 24601-0007-KC | 19 | Implement procedures for district offices to monitor and analyze SRM-related noncompliance records as part of the agency's overall management control process. Provide district level users access to all information including OFDER's monthly exception reports. | Yes | Yes |
| 24601-0007-KC | 20 | Add specific fields to both AssuranceNet and IPPS for SRM-related activities and develop processes to ensure that these are adequately monitored both at the district and Headquarters levels. | No | No |
| 24601-0007-KC | 21 | Provide specific guidance to FSIS personnel at all slaughter establishments to verify that HACCP, SOP, and pre-requisite plans are in compliance with FSIS regulations and directives. Ensure that this covers key provisions that each establishment's plans must address. Further, require the Inspector-in-Charge at each establishment to certify completion of this review to the district office. | Yes | Yes |

| Audit Number | Recommendation | Prior Recommendations | Corrective Action Implemented? | Corrective Action Effective? |
|---|---|---|---|---|
| 24601-0007-KC | 22 | Incorporate steps in future FSAs to verify that establishments' HACCP, SOP and pre-requisite plans are in compliance with FSIS regulations and directives regarding SRMs. | Yes | Yes |
| 24601-0007-KC | 23 | Implement procedures to require that, as part of their supervisory visits, front-line supervisors provide ongoing oversight to FSIS inspectors in their SRM-related inspection duties. | Yes | Yes |
| 24601-0007-KC | 24 | Strengthen guidance to clarify when noncompliance records should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment prerequisite plans. | Yes | Yes |
| 24601-0007-KC | 25 | Assess the level of training needed by both front-line supervisors and in-plant inspectors on SRM verification responsibilities and develop controls to ensure that such training is provided in a timely manner. | Yes | Yes |

# Exhibit D—Noncompliance Records Not Issued and/or Linked by FSIS Inspectors at Establishments

Table 1 shows the number of establishments where inspectors did not issue or link noncompliance records, but OIG determined that the establishment violated inspection procedures for the statistically and non-statistically selected establishments in our sample.

**Table 1—Summary—Noncompliance Records Not Issued, Not Linked, or Both—22 of 83 Establishments**

| Method of Selection | Number of Establishments | | | TOTAL |
|---|---|---|---|---|
| | Did Not Issue a Noncompliance Record | Did Not Link Noncompliance Records | With Both Exceptions | |
| Statistical | 9 | 5 | 3 | 17 |
| Non-statistical | 2 | 1 | 2 | 5 |
| **TOTAL** | **11** | **6** | **5** | **22** |

Table 2 below lists examples of actions taken by inspectors for similar noncompliance violations.

**Table 2—Examples of Noncompliance Records Issued Versus Not Issued and Noncompliance Records Not Linked**

| *One inspector issued a noncompliance record for…* | *Another inspector did **not** issue a noncompliance record for…* | *Inspector did not link the following noncompliance records…* |
|---|---|---|
| Residue found in six different areas. | Residues in four different areas. | Seven noncompliance records issued for flaking paint, all in different areas. |
| Residue on equipment. | Residue on two pieces of equipment. | Three noncompliance records issued that related to rust on the wheels of a table. |
| A few bits of meat residue were on a conveyor belt. | Small bit of meat residue on a conveyor belt. | Three noncompliance records issued for condensation in the ready-to-eat/chicken salad area. |
| Flake of paint observed on product contact surface. | A small piece of plastic found in a box of chicken about to be ground. | Three noncompliance records were issued for meat and fat residue found on vacuum packing equipment. |
| Chicken carcass found from the previous day. | Pounds of product found on the floor. Line was stopped. | Two noncompliance records were issued for fat residue found on production equipment. |
| Dirty cooking trays, utensils. | Trash from a bottle inner seal left in a bin with food contact tables. | Two noncompliance records were issued within four days concerning unclean surfaces in several areas. |

# Exhibit E—Issues with Front-Line Supervisors' Oversight

*The following three tables summarize the front-line supervisor oversight issues at the statistically and non-statistically selected establishments in our sample.*

Table 1 provides an overall summary showing the total number of front-line supervisors, and related establishments, with in-plant inspectors that did not complete required HAV, SRM Control Verification, or Update the Establishment Profile tasks, or did not document in-plant testing results.

**Table 1—Summary of Issues with Front-Line Supervisor Oversight**

| | | Number of Establishments | | | | |
|---|---|---|---|---|---|---|
| **Method of Selecting Establishments to Review** | **Number of Front-Line Supervisors with issues** | **with issues[186]** | **HAV Task Incomplete[187]** | **SRM Task Incomplete** | **Establishment Profile Not Updated** | **In-Plant Testing Not Documented** |
| Statistical | 40 | 46 | 16 | 28 | 3 | 22 |
| Non-Statistical | 4 | 9 | 5 | 0 | 0 | 6 |
| **Totals** | **44** | **55** | **21** | **28** | **3** | **28** |

[186] Establishments may have more than one issue and front-line supervisors may serve multiple establishments.
[187] During the last three quarters of CY 2014 (April through December 2014).

**Table 2—Details for 46 Statistically Selected Establishments with Front-Line Supervisor Oversight Issues**

Table 2 provides a detailed listing of the 46 statistically selected establishments with inadequate front-line supervisor oversight resulting in in-plant inspectors that did not complete required Hazard Analysis Verification (HAV), SRM Control Verification, or Update the Establishment Profile tasks, or did not document in-plant testing results.

| | Establishment Number | HAV Tasks Incomplete[188] | SRM Control Verification Task Incomplete | Profile Not Updated | In-Plant Testing Not Documented | Type of Establishment |
|---|---|---|---|---|---|---|
| 1 | 3 | X | | | | Processing |
| 2 | 4 | X | X | | X | Processing |
| 3 | 5 | X | | | | Processing |
| 4 | 7 | | X | | | Processing |
| 5 | 10 | | | | X | Processing |
| 6 | 12 | | | X | X | Processing |
| 7 | 13 | | X | | X | Processing |
| 8 | 14 | | X | | X | Processing |
| 9 | 15 | X | X | X | X | Processing |
| 10 | 16 | X | | | | Processing |
| 11 | 18 | | | | X | Processing |

[188] During the last three quarters of CY 2014 (April–December 2014).

| | Establishment Number | HAV Tasks Incomplete[188] | SRM Control Verification Task Incomplete | Profile Not Updated | In-Plant Testing Not Documented | Type of Establishment |
|---|---|---|---|---|---|---|
| 12 | 19 | | X | | | Slaughter |
| 13 | 26 | | X | | X | Slaughter |
| 14 | 27 | | | | X | Processing |
| 15 | 28 | | X | | X | Processing |
| 16 | 30 | | | | X | Slaughter |
| 17 | 31 | X | | | | Processing |
| 18 | 33 | X | X | | X | Slaughter |
| 19 | 34 | | X | | | Processing |
| 20 | 35 | X | | | | Processing |
| 21 | 37 | | | | X | Processing |
| 22 | 38 | | X | | | Processing |
| 23 | 39 | X | | | | Slaughter |
| 24 | 43 | | X | | | Processing |
| 25 | 44 | X | X | | X | Slaughter |

| | Establishment Number | HAV Tasks Incomplete[188] | SRM Control Verification Task Incomplete | Profile Not Updated | In-Plant Testing Not Documented | Type of Establishment |
|---|---|---|---|---|---|---|
| 26 | 45 | X | | | | Processing |
| 27 | 49 | | X | | | Processing |
| 28 | 51 | | | | X | Processing |
| 29 | 52 | X | X | | | Processing |
| 30 | 53 | | X | | | Processing |
| 31 | 56 | | X | X | X | Processing |
| 32 | 57 | | | | X | Slaughter |
| 33 | 58 | | | | X | Slaughter |
| 34 | 59 | | | | X | Processing |
| 35 | 60 | | X | | | Processing |
| 36 | 63 | | X | | | Processing |
| 37 | 64 | | X | | | Slaughter |
| 38 | 66 | X | X | | | Processing |
| 39 | 67 | | X | | | Processing |

| | Establishment Number | HAV Tasks Incomplete[188] | SRM Control Verification Task Incomplete | Profile Not Updated | In-Plant Testing Not Documented | Type of Establishment |
|---|---|---|---|---|---|---|
| 40 | 68 | X | | | | Processing |
| 41 | 69 | X | X | | | Processing |
| 42 | 71 | | X | | | Processing |
| 43 | 74 | | X | | X | Processing |
| 44 | 77 | | X | | X | Processing |
| 45 | 79 | | X | | | Processing |
| 46 | 82 | X | X | | X | Slaughter |
| **Totals** | | **16** | **28** | **3** | **22** | |

**Table 3—Details for Nine Non-Statistically Selected Establishments with Front-Line Supervisor Oversight Issues**

Table 3 provides a detailed listing of the non-statistically selected establishments with inadequate front-line supervisor oversight resulting in in-plant inspectors that did not complete required HAV, SRM Control Verification, or Update the Establishment Profile task(s), or did not document in-plant testing results.

| Establishment Number | HAV Verification Task Incomplete[189] | SRM Control Verification Task Incomplete | Establishment Profile Not Updated | In-Plant Testing Not Documented | Type of Establishment |
|---|---|---|---|---|---|
| 1[190] | X | | | X | Processing / Slaughter |
| 2 | | | | X | Processing / Slaughter |
| 6 | X | | | | Processing / Slaughter |
| 8 | X | | | X | Processing / Slaughter |
| 20 | X | | | | Slaughter |

[189] During the last three quarters of CY 2014 (April through December 2014).
[190] This front-line supervisor was included in the statistically selected establishments noted above; therefore, we did not count this supervisor in this section.

| Establishment Number | HAV Verification Task Incomplete[189] | SRM Control Verification Task Incomplete | Establishment Profile Not Updated | In-Plant Testing Not Documented | Type of Establishment |
|---|---|---|---|---|---|
| 25 | | | | X | Processing / Slaughter |
| 70 | | | | X | Processing / Slaughter |
| 72 | | | | X | Processing / Slaughter |
| 81 | X | | | | Slaughter |
| **Totals** | **5** | **0** | **0** | **6** | |

# Exhibit F—PHIS Connectivity Issues

The following tables summarize the results of our visits to 75 establishments and our evaluation of whether the inspectors could connect to PHIS and some of the reasons why inspectors were unable to connect.

**Table 1—Overall Summary—Connection to PHIS**

| **PHIS Connection Method** | | **Were Inspectors Able to Connect on Day of Our Visit?** | | **Inspectors Used DCU** | |
|---|---|---|---|---|---|
| *Type*[191] | *Responses* | *Yes, No, or Not Determined* | *Responses* | *Yes or No* | *Responses* |
| DSL | 24 | Yes | 59 | Yes | 14 |
| EVDO | 33 | No | 12 | No | 61 |
| MiFi | 11 | Not Determined | 4 | | |
| T1 | 6 | | | | |
| Alternate Site[192] | 8 | | | | |
| Cable Internet | 1 | | | | |
| **Totals** | **75** | | **75** | | **75** |

[191] The various connection methods include: Digital Subscriber Line (DSL), Evolution-Data Optimized (EVDO), Mobile Wi-Fi (MiFi), T-carrier 1 (T1), or cable internet. We did not have any issues at establishments relating to T1 and cable internet.

[192] These alternate sites were used in addition to the assigned device such as MiFi or EVDO.

**Table 2—PHIS Connectivity Issues**

Table 2 below outlines the connectivity issues observed by OIG during our site visits.

| Establishment Numbers[193] | Connection Method | Was Inspector Able to Connect? | Reason Why Inspector Was Not Able to Connect | Does the Inspector Use DCU? |
|---|---|---|---|---|
| 1 | DSL | No | PHIS was down. | No |
| 3 | EVDO | Yes | | No |
| 4 | DSL | Yes | | Yes |
| 5 | EVDO | Yes | | No |
| 7 | EVDO | Yes | | No |
| 9 | EVDO | Yes | | No |
| 10 | MiFi | Yes | | No |
| 11 | DSL | Yes | | No |
| 12 | EVDO | Yes | | No |
| 13 | DSL | Yes | | No |
| 14 | DSL | Yes | | Yes |
| 15 | DSL | Yes | | No |

[193] The gaps in the numbers represent the eight establishments we visited during the survey phase of this audit where we did not assess PHIS connectivity. For the remaining 75 establishments, we determined whether FSIS inspectors had issues with connecting to FSIS' PHIS.

| Establishment Numbers[193] | Connection Method | Was Inspector Able to Connect? | Reason Why Inspector Was Not Able to Connect | Does the Inspector Use DCU? |
|---|---|---|---|---|
| 16 | MiFi | Yes | | No |
| 17 | DSL | Yes | | Yes |
| 18 | EVDO | Yes | | Yes |
| 19 | DSL | Yes | | No |
| 21 | EVDO | Not Determined | The establishment was not in operation on the day of our visit. | No |
| 22 | DSL | Yes | | Yes |
| 23 | EVDO | Yes | | No |
| 24 | T1 | Yes | | No |
| 25 | DSL | Yes | | No |
| 26 | DSL | Yes | | Yes |
| 27 | EVDO | Yes | | No |
| 28 | EVDO | Yes | | No |
| 29 | EVDO | Yes | | Yes |
| 30 | DSL | No | We observed PHIS was down for about a half a day during our visit. | Yes |
| 31 | EVDO | Yes | | No |

| Establishment Numbers[193] | Connection Method | Was Inspector Able to Connect? | Reason Why Inspector Was Not Able to Connect | Does the Inspector Use DCU? |
|---|---|---|---|---|
| 32 | EVDO | Yes | | No |
| 33 | EVDO | No | The inspector does not attempt to connect at this location because of poor connection. Connects at a different location with a DSL connection. | No |
| 34 | MiFi | No | The inspector was unable to connect to PHIS during our visit. We were onsite from 4:00 pm to 10:00 pm. | No |
| 35 | EVDO | Yes | | No |
| 36 | MiFi | No | The inspector experienced issues with new LincPass card. Inspector had sent an email and made calls to the help desk to get access to PHIS. OIG observed that the inspector could not access PHIS; inspector received an error message. | No |
| 37 | EVDO[194] | Not Determined | The inspector prefers to connect at headquarter plant where it uses a T1 line. The T1 line is better than the EVDO card. The inspector stated that the EVDO card does not have the best connectivity. | No |
| 38 | MiFi [195] | Yes | | No |
| 39 | EVDO | Yes | | No |
| 41 | DSL | Yes | | No |

[194] Inspector at establishments 37, 52, and 65 had EVDO cards available, but chose to connect to PHIS at a different plant with a stronger connection.
[195] The inspector was using an EVDO card the day of our visit.

| Establishment Numbers[193] | Connection Method | Was Inspector Able to Connect? | Reason Why Inspector Was Not Able to Connect | Does the Inspector Use DCU? |
|---|---|---|---|---|
| 42 | MiFi | Yes | | No |
| 43 | DSL | Yes | | No |
| 44 | T1 | Yes | | No |
| 45 | EVDO | Yes | | No |
| 46 | MiFi | Yes | | No |
| 47 | EVDO | No | The inspector stated that the connection to the internet is poor because of the metal building. | No |
| 49 | EVDO[196] | No | The inspector stated that there is no connectivity at this establishment. Inspector relies on a T1 connection at another establishment. | Yes |
| 50 | EVDO | Yes | | No |
| 51 | DSL | Yes | | No |
| 52 | EVDO | Not Determined | The inspector chose to connect at home plant with T1 line instead of the EDVO card assigned. | No |
| 53 | DSL | Yes | | Yes |

[196] This establishment relied on a T1 connection at an alternate site. While the inspector did not have any other means of connection the day of our visit, he/she received an EVDO card from FSIS 30 days later.

| Establishment Numbers[193] | Connection Method | Was Inspector Able to Connect? | Reason Why Inspector Was Not Able to Connect | Does the Inspector Use DCU? |
|---|---|---|---|---|
| 54 | EVDO | No | The inspector stated there are connectivity issues because the establishment is located in a rural area. | Yes |
| 55 | T1 | Yes | | No |
| 56 | EVDO | No | | No |
| 57 | DSL | Yes | | No |
| 58 | T1 | Yes | | No |
| 59 | EVDO | Yes | | No |
| 60 | Cable | Yes | | No |
| 61 | DSL | Yes | | Yes |
| 62 | DSL | Yes | | No |
| 63 | EVDO | Yes | | No |
| 64 | T1 | Yes | | No |
| 65 | EVDO | Not Determined | The inspector had a dedicated site with a T1 line. At this particular establishment there is no T1 line. As a result, the inspector does not use the connection there. The inspector notes all issues and later enters information at dedicated site. | No |
| 66 | EVDO | Yes | | No |

| Establishment Numbers[193] | Connection Method | Was Inspector Able to Connect? | Reason Why Inspector Was Not Able to Connect | Does the Inspector Use DCU? |
|---|---|---|---|---|
| 67 | MiFi | Yes | | No |
| 68 | MiFi | No | The establishment is located in a rural, mountainous area. The inspector stated that he usually just enters the task when he visits a different establishment with better connectivity. | Yes |
| 69 | MiFi | Yes | | No |
| 71 | EVDO | No | The inspector's EVDO card has not worked since the inspector began using the LincPass. The inspector accesses PHIS at one of his other establishments with a T1 line. | No |
| 72 | DSL | Yes | | No |
| 73 | T1 | Yes | | No |
| 74 | EVDO | No | The inspector does not have internet connection at this establishment. The inspector uses the DSL connection at another establishment. | No |
| 75 | EVDO | Yes | | No |
| 76 | EVDO | Yes | | No |
| 77 | EVDO | Yes | | No |
| 79 | DSL | Yes | | No |
| 80 | DSL | Yes | | No |

| Establishment Numbers[193] | Connection Method | Was Inspector Able to Connect? | Reason Why Inspector Was Not Able to Connect | Does the Inspector Use DCU? |
|---|---|---|---|---|
| 81 | DSL | Yes | | No |
| 82 | DSL | Yes | | No |
| 83 | MiFi | No | The MiFi device does not work in the establishment due to the construction of the building. | Yes |

# Exhibit G—Sampling Methodology for FSIS Follow Up on the 2007 and 2008 Audit Initiatives

## Objective

This statistical sample is designed to support OIG Audit Number 24016-0001-23. The objective of this audit is to evaluate the corrective actions taken by FSIS to implement prior OIG audit recommendations in Audit Report 24601-0007-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, and Audit Report 24601-0007-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments.* Based on the recommendations in the prior OIG reports, these corrective actions include improving (1) internal controls, (2) staffing and supervision of in-plant inspectors, (3) inspection activities in accordance with the Humane Methods of Slaughter Act, and (4) the removal of specified risk materials (e.g., brain, skull, spinal cord, distal ileum, etc.).

The audit team also addresses questions/concerns received in a Congressional request related to FSIS' staffing and management decisions for livestock slaughter establishments. Specifically, the audit team will address whether FSIS has controls in place to ensure that the right mix of human capital is in place, adequately trained, and properly performing pre-slaughter and humane handling activities.

To help achieve this objective, we developed a representative random statistical sample of establishments for review.

## Audit Universe

FSIS' inspection operations are overseen by 10 district offices nationwide—Alameda, California; Atlanta, Georgia; Chicago, Illinois; Dallas, Texas; Denver, Colorado; Des Moines, Iowa; Jackson, Mississippi; Philadelphia, Pennsylvania; Raleigh, North Carolina; and Springdale, Arkansas.[197]

Our audit universe consists of 5,092 establishments inspected by the 10 FSIS district offices. However, one of the establishments in our data was in the process of an active litigation. We removed it from our review, for a new total of 5,091 establishments.

## Sample Design

Given the data structure diversity in the audit programs (data factors) and audit resource requirements (resource factors), we developed several design ideas to help us make informed decisions about which design would be feasible for the objective of this audit. We considered various sample designs—simple random, stratified, multi-stage selections, etc. To achieve

[197] Additionally, FSIS enters into cooperative agreements with States to operate their own meat and inspection programs, referred to as the State Meat and Poultry Inspection program. Currently, there are 27 States participating in this program that provides inspection to about 1,900 meat and poultry establishments. These State-regulated establishments are not included in our audit universe and sample.

universe representation and lower travel expenses, we are using a multi-stage stratified sample of establishments. At the first stage, we chose five out of the ten district offices at random. At the second stage, 3 percent of establishments within each district office chosen at the first stage were selected at random.[198] The total sample size is 66 establishments inspected by 5 district offices.

In addition to the randomly selected establishments, our audit team judgmentally picked 17 establishments for review. This was done to follow up on specific audit findings we had published in our 2007/2008 audit initiatives.[199] The 17 establishments selected will not be used for estimation, but their error count will add to the total estimated values for relevant findings. These 17 establishments are placed in a census stratum.

In addition to the removal of the census stratum from our projectable universe, we removed a few establishments from our sample and universe (the sample units were then replaced with the next establishments on the list of random selection in the district office) as fieldwork progressed.[200]

In total, after these adjustments were made, our projectable universe consisted of 5,091 establishments in ten district offices with a sample size of 66 statistically selected and 17 judgmentally selected for a total sample count of 83 establishments.

The sample size of our statistical sample was calculated based on the following factors:

- Audit Universe—5,074 establishments.
- Expected Error Rate—Because we had no historical information about an expected error rate, we assumed a 50 percent value in attribute testing scenario, i.e., each unit tested has a 50/50 chance of a "pass" or a "fail." This is the most conservative assumption for this factor and leads to a higher sample size than any other assumed percentage.
- Precision—We wanted to be able to report our estimates with a +/-10 percent precision in an attribute testing scenario.
- Confidence Level—We are using a 90 percent confidence level for the reporting our estimates.

[198] Each establishment in the universe was assigned a random number using a spreadsheet function "randbetween." The universe was then ordered in ascending order of random numbers. The first 3 percent of establishments in that order within each district office were chosen for review.

[199] Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk Based Inspection at Meat and Poultry Establishments*, December 2007, and Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities,* November 2008.

[200] For the Raleigh District, we replaced establishment 84 with establishment 85 due to an active litigation hold at the establishment as a result of an investigation. We were unable to visit establishment 85 because it was not operating due to seasonal closure and replaced this establishment with establishment 16. In the Denver District we replaced 86 with 51 because the plant was suspended. In the Des Moines District, we replaced 87 with 21 because it was no longer a Federal inspected plant. In the Dallas District we replaced 88 with 47.

**Results**

All of the results presented below are projected to the audit universe of 5,091 establishments, except for one estimate. The projections below include the error count of the issues we found at the census (judgment) stratum. Those census results were not projected to the statistical universe, but they were simply added to the estimated error.

After fieldwork began, our audit team found out that one of the issues we would report on was relevant only to a subset of our universe—humane treatment of animals is relevant to slaughter facilities only. In this case, we isolated the part of the sample and universe which contained slaughter facilities only and estimated from the relevant sample to that sub universe only. The sample size for this issue decreased from 83 to 32 establishments and the size of the universe it projects to change from 5,091 to 1,025.

All estimates and universe counts are presented in detail in the table below. A narrative interpretation of the results is included below the table.

*Table 1: Statistical Estimates*[201]

| Criteria Tested | Estimate | Standard Error | 90% Confidence Interval | | Coefficient of Variation | Actuals found | Universe size | Achieved Precision |
|---|---|---|---|---|---|---|---|---|
| | | | Lower | Upper | | | | |
| HAV task not completed | 1,081 | 360 | 410 | 1,752 | .373 | 21 | 5,074 + 17 census = 5,091 | 13% |
| as a percentage of the universe | 21% | | 8% | 34% | | | | |
| Noncompliance records not linked | 547 | 202 | 206 | 887 | .372 | 11 | | 7% |
| as a percentage of the universe | 11% | | 4% | 17% | | | | |
| Noncompliance records not written | 820 | 193 | 496 | 1,144 | .237 | 16 | | 6% |
| as a percentage of the universe | 16% | | 10% | 22% | | | | |

[201] All numbers greater than 1 are rounded to the nearest whole number. All decimals presented are rounded to the nearest one thousandth.

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Establishment count with at least one issue | 2,029 | 372 | 1,408 | 2,649 | .184 | 38 | | 12% |
| as a percentage of the universe | 40% | | 28% | 52% | | | | |
| Inhumane treatment observed and proper actions not taken | 198 | 47 | 88 | 308 | .236 | 3 | 1,008 + 17 census = 1,025 | 11% |
| as a percentage of the universe | 19% | | 9% | 30% | | | | |

**Interpretation of the results**

Based on our sample, we estimate that:

- 1,081 establishments (21 percent) had an incomplete HAV task. We are 90 percent confident that the number of establishments with this issue is between 410 (8 percent) and 1,752 (34 percent).

- 547 establishments (11 percent) had noncompliance reports that were not linked. We are 90 percent confident that the number of establishments with this issue is between 206 (4 percent) and 887 (17 percent).

- 820 establishments (16 percent) had noncompliance reports that were not written. We are 90 percent confident that the number of establishments with this issue is between 496 (10 percent) and 1,144 (22 percent).

- 2,029 establishments (40 percent) have at least one of the issues listed above. We are 90 percent confident that the number of establishments with at least one issue is between 1,408 (28 percent) and 2,649 (52 percent).

- At 198 establishments (19 percent), inhumane treatment might have been observed without proper actions taken. We are 90 percent confident that the number of establishments with this issue is between 88 (9 percent) and 308 (30 percent).

# USDA'S
# FOOD SAFETY AND INSPECTION SERVICE'S
# RESPONSE TO AUDIT REPORT

United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW, Washington, D.C. 20250

TO: Gil H. Harden
Assistant Inspector General
Office of Inspector General

FROM: Alfred V. Almanza /s/ April 18, 2017
Acting Deputy Under Secretary, Food Safety
Administrator, Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Food Safety and Inspection Service Follow-up on the 2007 and 2008 Audit Initiatives, Audit Number 24016-0001-23

We appreciate the opportunity to review and comment on this Official Draft report. The Food Safety and Inspection Service (FSIS) reviewed the Official Draft report and has general comments followed by a response to each recommendation.

**FSIS' General Comments**

FSIS has already taken action on many of the recommendations. FSIS made several significant changes and improvements to its processes and systems in 2015-2017, yet much of this audit work focuses on the 2012-2014 timeframe. FSIS appreciates the efforts OIG took to update the report with some of our newer processes. However, the report still uses criteria and FSIS policy and operations information from 2007-2008 for developing audit findings, and in some cases, the issues are significantly less relevant than a decade ago.

For example, under Finding 3, OIG suggest FSIS "should take a more conservative approach to issuing and linking noncompliance records (NRs) since these noncompliance records relate to the establishments' food safety system." In response, OIG recommends FSIS issue a Directive on when NRs are justified. FSIS has issued many such Directives, and we do not find Finding 3 relevant to the present day and reflective of an appropriate solution. We have changed our processes as outlined in a memo FSIS sent to OIG on March 24, 2016 (Enclosure 1). FSIS has strengthened our approach to noncompliance and made it more data-driven. FSIS utilizes Early Warning Alerts in the Public Health Information System (PHIS), which are based on adverse trends in Public Health NRs and give inspection program personnel (IPP) the data to be able to determine trends and take appropriate actions. As outlined in Notice 13-16 (see Enclosure 2) issued in Feb. 2016, FSIS calculates Public Health Regulation (PHR) non-compliance rates for each meat, poultry, and egg products official establishment. Every year FSIS establishes cutpoints at 2 levels, Tier 1 and Tier 2. Tier 2 is the lower threshold at which IPP will be notified with an Early Warning Alert that an

establishment has a non-compliance rate that is elevated and is at or exceeds the Tier 2 cut point. Tier 1 is the higher threshold at which FSIS will consider the establishment for a Public Health Risk Evaluation (PHRE), a new methodology for which was established in May 2015. When IPP and Frontline Supervisors (FLS) receive the Early Warning Alert, they are to take a number of steps as directed in Notice 13-16. We find this enhanced approach to be more robust and evidence-based than the approach we were using in 2008 following OIGs prior audits. FSIS believes our current strategies, defined by the rules of practice and paired with the Early Warning Alerts, provides our workforce with real-time enforcement capabilities.

FSIS would also like to acknowledge in our response, under Finding 3, the discussions the audit team had with FSIS about the development of the Public Health Regulations approach to identifying important trends or patterns in non-compliance that may warrant further review and more serious enforcement action. FSIS explained to OIG how it had developed an alternative approach to identifying and prioritizing adverse trends in regulatory non-compliance. This Public Health Regulation (PHR) criterion is based on a set of regulations that are closely associated with adverse outcomes such as positive pathogen test results or enforcement actions. This criterion has the advantage of identifying repeated non-compliance across a set of regulations and inspection tasks rather than a more limited linking of pairs of NRs. Furthermore, this approach is reevaluated annually to ensure that the most current data informs the algorithm. This process also automatically includes multiple non-compliances that cite the same set of PHR regulations. The PHR criterion also helps to prioritize those cases of repetitive non-compliance where the public health risk is greatest. All of this was developed after the audits in 2007 and 2008 and have served to move FSIS beyond the linking issue originally identified a decade ago. Fundamentally, this approach is more protective of public health than that of a decade ago.

Another example is Specified Risk Material (SRM) controls. The Bovine Spongiform Encephalopathy (BSE) situation in the U.S. is different than when OIG conducted work on BSE surveillance and industry SRM controls more than a decade ago. OIG completed its first BSE-related report in August 2004, and OIG issued another report February 2006. The World Organization for Animal Health (OIE) places the U.S. as a "Negligible BSE risk."[1] In the present day, there are a number of animal diseases of concern to FSIS, yet the report seems to single out BSE and related SRM control verification tasks above others, and overlooks the change of the level of risk of BSE in the U.S.

In addition, throughout the official draft report OIG uses vague, imprecise language that may imply to readers that certain actions by the Agency are not occurring at all, or are rarely, if ever, performed. This is not the case as will be evident in the examples cited below.

[1] http://oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/

On Page 10, 4th paragraph, 1st sentence reads, "FSIS needs to ensure that district veterinary medical specialist reviews are completed on time (32 percent were not)." The report cites this figure of 32 percent in several places; however, the methodology used to calculate it is never explained and the figure is not given much context. FSIS strongly disagrees with OIG's statement that DVMS reviews were not taking place on time. This implies that FSIS is negligent in completing these reviews, which is not the case at all. For the 18-month window ending in FY 2016, 98 percent (see Enclosure 3) of all active slaughter plants had a current Humane Handling Verification Visit within an 18-month window. The remaining 2 percent constitute either plants that newly came on board during this period or plants that slaughter infrequently.

On Page 10, 4th paragraph, 3rd sentence reads, "FSIS was also completing only 34 percent of the humane handling tasks at 12 of the slaughter establishments we visited…" FSIS believes this is a highly misleading statement, as it implies that FSIS is not performing humane handling tasks appropriately and that livestock are not adequately observed by FSIS. FSIS Directive 6900.2 states "PHVs and other trained IPP are to perform verification of the establishment's humane handling activities during each shift that animals are slaughtered, or when animals are on site, even if it is during a processing only shift." Using PHIS data, FSIS compared the days when humane handling tasks were performed to the days when federally inspected livestock slaughter was occurring and found that this task was performed on approximately 99 percent of the days when slaughter was occurring at the 12 slaughter establishments OIG visited (see Enclosure 4). PHVs are doing what they need to do to ensure that livestock presented for slaughter are treated humanely.

On Page 10, 4th paragraph, 4th sentence reads, "We found that FSIS could not reliably track the full-time equivalent (FTE) hours for performing humane handling activities, data which the agency must report to Congress." Again, FSIS believes this is a highly misleading statement. FSIS is on target to meet the annual 148 FTEs/year in Humane Handling oversight and has exceeded the required number of hours since the Congressional mandate was implemented. FSIS has controls in place in PHIS to ensure the integrity of the HATS data. When personnel need to make a change to this data, they must provide a justification and only then will the system allow them to make the change. The system maintains a history of justifications, date the edit was made, and who made it, all of which is accessible to the personnel's chain of command. In regards to the method used to track humane handling-related activities in HATS, FSIS uses the same method as that used at the Department-level and records time in 15 minute increments. This is also a standard practice in many industries. In regards to OIG's finding that the system allows data to be changed retroactively, FSIS believes OIG's portrayal to be an exaggeration of what is actually occurring. Furthermore, FSIS re-extracted the FY13 and FY14 HATS data in February 2017, recalculated the FTE times, and compared today's results to what was provided to OIG. The data are within 1 FTE of the originally reported values. Out of a total of more than 170 FTEs reported to Congress for FY13 and FY14 this represents less than a 1 percent change (approximately 0.6 percent). FSIS believes the ability to

compute the same staff year total to within 1 FTE several years after the reporting period indicates that 1) the reported data are reasonably consistent and 2) the data was accurately reported as exceeding the Congressional mandate.

Additionally, OIG makes mention of positions that can and cannot enter data on humane handling activities into the system. Throughout paragraph 4 on Page 12, OIG makes references to a position entitled "non-public health veterinarian." It is important to note that such a position does not exist at FSIS. OIG's citing of a position that does not exist to make its finding makes the Agency question the merit of the finding, as it is unclear what exactly OIG is referring.

On Page 14, 1st paragraph, OIG states that "deficiencies identified for…14 [prior] recommendations continue to exist." As stated earlier, FSIS has made improvements to its processes and systems, which addresses most if not all the prior recommendations. The corrective actions proffered a decade ago to these recommendations for the most part are not relevant today. Thus the Agency should not be assessed on whether it continues to implement outdated methods. FSIS has sought better, more effective and data-driven methods that address these prior recommendations, and the updated actions and measures that FSIS has in place now address recommendations that OIG made a decade ago.

On Page 16, 4th paragraph, 3rd sentence reads, "…[OIG's] audit found that the agency did not implement the controls to ensure district officials performed all IPPS reviews." OIG makes a number of statements similar to this regarding the IPPS that simply are not relevant to the present day given the IPPS was reengineered in 2016, and on top of that FSIS has reinforced in-plant supervisory responsibilities in FY 2017 performance standards (see Enclosure 5).

As part of the above finding, OIG also inappropriately uses projections, stating that some of these prior recommendations "were related to FSIS oversight at 83 FSIS-inspected establishments…[OIG] reviewed…[and that OIG] estimates that 40 percent of all establishments (2,029) have weaknesses with these areas of FSIS oversight." Later in the report OIG makes another projection stating "[OIG] estimate[s] that FSIS inspectors at 198 establishments (19 percent) may not be ensuring that humane slaughter requirements are consistently enforced." OIG uses a small amount of data, outdated, and inaccurate information to make projections like these throughout the report. These projections make generalizations that simply may not be correct or misleading.

OIG's use of projections raises questions for FSIS that are not addressed in the report. For example, the estimate of establishments where IPP are not appropriately linking NRs seems to assume that all 5,091 establishments should have "linkable" NRs. This assumption may not be valid and therefore the estimate of 547 may be an overestimate. OIG also doesn't acknowledge the uncertainty in their estimates until the very last pages of the report. For the same example, OIG doesn't acknowledge until the very end of the report that the true number of establishments where IPP are not appropriately linking

NRs could be as low as 206 or as high as 887, a four-fold range of possibilities. FSIS is concerned about how OIG has aggregated information about tasks into a binary result about the establishment. Tasks are performed many times, sometimes tens of thousands of times or more at an establishment and so one instance of a task not being performed (or performed inadequately in OIG's opinion) does not necessarily mean that the establishment is not inspected adequately.

Lastly, in its report OIG seems to be making policy judgments that FSIS should be making, and in other cases substituting its policy judgment for FSIS's. For example, on Page 28 and 29 of the report OIG cites an example of a hair being left on a carcass, raising issue with the fact that the inspector did not issue an NR and stated that it was not a contaminant. A hair left on a carcass is not considered a food safety issue that would be addressed in a HACCP plan, it is a quality issue. Additionally, findings 2 and 3 make reference to "progressive enforcement action" on pages 27, 28, and 30. It appears as if the findings and recommendations make the assumption that the Agency has agreed with this approach to enforcement; however we have not. FSIS maintains that each violation needs to be judged on its own merit. Again, FSIS relies on the judgment of our inspection personnel to make these decisions.

We recognize that the timing and long duration of this audit was somewhat inopportune for OIG, and the evaluability of our activities perhaps difficult, because FSIS has already enhanced and updated its program. FSIS has already put in place substantive measures or operational approaches based on inspection findings and data that fully achieve or go beyond the substance of what the recommendation requests.

**Recommendation 1:**
Require the Office of Investigation, Enforcement, and Audit (OIEA) to augment their current process to include periodic reviews on the effectiveness of the Districts implementation of corrective actions from prior audit recommendations in the 2007 and 2008 audit initiatives.

FSIS Response:
As part of FSIS' comprehensive management controls program, FSIS will assess and verify the effectiveness of corrective actions within 12 months of implementation.

Estimated Completion Date: May 2018

**Recommendation 2:**
Require district offices to enhance their controls to ensure that district veterinary medical specialist reviews are completed within the required timeframe.

FSIS Response:
For the 18-month window ending in FY 2016, 98 percent of all active slaughter plants had a current Humane Handling Verification Visit within an 18-month window (see

Attachment 2). The remaining 2 percent constitute either plants that newly came on board during this period or plants that slaughter infrequently. Additionally, District Veterinarian Specialists (DVMS) are held responsible for these visits as well as a timeframe to complete them in FSIS Directive 6910.1. These DVMS's humane handing verification visits were also measured annually as part of a corporate measure in FSIS's Annual Plans between FY 2012 and FY 2016, targets for which were exceeded every year (see Enclosure 6). Finally, the requirement to complete the humane handling verification visits are included in the FY 2017 performance plans for DVMSs (see Enclosure 7). Therefore, FSIS has fully addressed the intent of this recommendation.

Estimated Completion Date: Complete

**Recommendation 3:**
Develop and implement a process to monitor and track the completion of all of the required elements and sub-elements of employees' In-Plant Personnel System (IPPS) reviews. This process should include procedures for FSIS management to verify that all the required elements and sub-elements for an IPPS review are completed.

FSIS Response:
The IPPS reviews were reengineered and implemented in January 2016. The IPPS is aligned with performance elements (e.g. Mission Results, Communication). The new IPPS focuses on assessing whether IPP understand and can execute inspection methodology, providing supervisors with more direction on what to assess. Under this new IPPS, supervisors are required to review and document all critical performance elements during the rating cycle per the revised Directive 4430.3. Field supervisors are held accountable to supervisory responsibilities, including performance of the IPPS per Agency policy, in their FY 2017 performance plans under the Supervision element (see Enclosure 5). Along with the IPPS, they are required as supervisors to also conduct performance evaluations, which they are to document in the Performance Rating Tool (PRT). Their performance of each of these supervisory functions is dictated by FSIS policy. Furthermore, the ability to track that supervisors have completed IPPS assessment of all required performance elements during the rating cycle is part of requirements for the ongoing enhancement being made to AssuranceNet (see Enclosure 8), the system that houses the IPPS. Thus, FSIS has fully addressed the intent of this recommendation.

Estimated Completion Date: Complete

**Recommendation 4:**
Make improvements to the AssuranceNet system, as necessary, to ensure data reliability.

FSIS Response:
FSIS received feedback from its field supervisory personnel that AssuranceNet was not performing at the optimal level. To make AssuranceNet a better and more reliable tool

for our employees, FSIS brought on a contractor to enhance the system. Business requirements for this project are attached (see Enclosure 8). Among the enhancements are improving the speed of the system, fixing the database to accommodate for district consolidation that occurred in 2010, improving its reporting feature and programming the new IPPS form. The contractor is currently working on programing for the enhancements. Although this project will take more than a year to complete, FSIS anticipates a number of the IPPS enhancements to be delivered toward the end of 2017.

Estimated Completion Date: May 2018 (for some IPPS enhancements only)

**Recommendation 5:**
Require district offices to improve their controls to ensure supervisors adequately monitor completion of specified risk material-related (SRM) tasks and implement appropriate corrective actions when those tasks are not completed.

FSIS Response:
Per FSIS Directive 6100.4, plants slaughtering cattle, or receiving carcasses with SRMs, must have a written program describing how they will remove them. This can either be in their Hazard Analysis and Critical Control Point (HACCP) plan, their Sanitation Standard Operating Procedures (SSOPs), or other prerequisite program. Supervisors ensure completion of the SRM-related tasks, as well as other tasks in PHIS as part of their preparation for an IPPS assessment, as stated in Directive 4430.3. In addition, SRM verification is assessed under the SSOP, HACCP, or especially for Food Inspectors, under the Ante-Mortem/Post-Mortem categories of the IPPS. Furthermore, District management personnel are held accountable to perform this function in their FY 2017 performance plans under the Mission Results element (see Enclosure 9). Therefore, FSIS has fully addressed, and gone beyond the intent of this recommendation.

Estimated Completion Date: Complete

**Recommendation 6:**
Assess whether the new FSA review process, in Directive 5100.4, requires that (1) all establishments are considered for the selection process for a public health risk evaluation (PHRE) risk assessment, and (2) a timeframe is included for completing a food safety assessment after an establishment is determined to be at high-risk.

FSIS Response:
FSIS will perform an assessment. As FSIS has mentioned previously, all establishments are considered for the selection process for a PHRE. All establishments are considered by ODIFP to determine the PHRE schedule sent to Districts. In addition, Directive 5100.1 rev 4 explicitly sets a timeframe (5-7 production days) for completing each FSA, as explained in the very first significant change at the start of the directive.

Estimated Completion Date: December 2017 (for assessment)

**Recommendation 7:**
Implement a process that requires FSIS inspectors to receive annual recertification on humane handling requirements. This process should require specific ongoing training to all staff including front line supervisors on current and new program requirements and the applicable directives, including examples of how to apply those requirements at the district and establishment levels. This recertification training should also include guidance on issuing the various disciplinary tools (e.g., noncompliance records and notice of intended enforcement (NOIE)).

FSIS Response:
The Agency holds itself accountable by adding humane handling training metrics to the FY 2017 Annual Plan. In the FY 2017 Annual Plan specifically, FSIS has committed to deliver humane handling refresher training to 40 percent of Public Health Veterinarians (PHVs) in livestock slaughter establishment by September 30, 2017. Further, the Agency will be adding humane handling content to the IPP Help Button, a real-time reference resource, to refresh IPP knowledge on humane handling requirements whenever needed. The IPP Help Button has proven to be a useful tool for FSIS employees, receiving an average of 25,680 hits per month (see Enclosure 10). Humane handling-related requirements for establishments do not change frequently enough to require an annual recertification process. As seen above, FSIS has a process in place to train inspectors on humane handling requirements, and to provide refresher training. Thus, FSIS has fully addressed the intent of this recommendation.

Estimated Completion Date: May 2018

**Recommendation 8:**
Require district offices to enhance their controls to ensure the front-line supervisors routinely assess each employee's knowledge and practical application of program requirements during the performance of their duties as it relates to humane handling. These controls should provide for the retraining of those employees who do not demonstrate minimal knowledge, skills, and abilities.

FSIS Response:
The reengineered IPPS process implemented in January 2016 fulfills this function, as it is a tool by which Frontline Supervisors (FLS) and other in-plant supervisors routinely assess each employee's knowledge and execution of inspection methodology, including humane handling requirements. District management personnel are also required per FSIS Directive 4430.3 to perform oversight of the IPPS completed by the FLS's. Furthermore, District management personnel are held accountable to perform this function in their FY 2017 performance plans under the Mission Results element (see Enclosure 9). This information demonstrates that FSIS has fully addressed the intent of

this recommendation.

Estimated Completion Date: Complete

**Recommendation 9:**
Issue immediate appropriate communication to FSIS personnel to emphasize the importance of and requirements for issuing Noncompliance Records (NRs), and linking those NRs if applicable, when regulatory violations occur. In addition, develop and implement specific policy that provides examples detailing when NRs should be written for noncompliance with food safety requirements.

FSIS Response:
FSIS has numerous directives and notices that outline how inspection program personnel (IPP) are to determine whether establishments are meeting regulatory requirements (e.g., FSIS Directives 5000.1, 5100.1, 5000.4, 5000.6, 5030.1, 5100.1, and others). Similarly, the directives and notices state that when noncompliance is found, IPP are to issue an NR to the establishment. The directives or notices typically state which regulation to cite on the NR. Therefore, FSIS disagrees that an additional Notice or Directive on this is necessary. Additionally, it should be mentioned that FSIS has strengthened its approach to noncompliance and made it more data-driven. FSIS utilizes Early Warning Alerts, an additional tool for employees, which is based on adverse trends in Public Health NRs and gives IPPs the data to be able to determine trends and take appropriate actions. As outlined in Notice 13-16 issued in February 2016, (see Enclosure 2), FSIS calculates Public Health Regulation (PHR) non-compliance rate for each meat and poultry (including processed eggs) official establishment. Every year FSIS establishes cut points at 2 levels, Tier 1 and Tier 2. Tier 2 is the lower threshold at which inspection program personnel (IPP) will be notified with an Early Warning Alert that an establishment has a non-compliance rate that is elevated and is at or exceeds the Tier 2 cut point. Tier 1 is the higher threshold at which FSIS will consider the establishment for a Public Health Risk Evaluation (PHRE). Early Warning Alerts provide our workforce with real-time enforcement capabilities.

However, the report notes concerns about NRs for foreign contaminants and sanitation. FSIS implemented provisions of the Food, Conservation, and Energy Act of 2008 by amending the Federal meat and poultry products inspection regulations to require official establishments to promptly notify the appropriate District Office that an adulterated or misbranded meat or poultry product has entered commerce; Under 9 CFR 418.2, establishments are required to report to FSIS when they have shipped or received adulterated or misbranded product, including product that is adulterated because it contains foreign contaminants. FSIS intends to issue instructions to inspectors to clarify how to enforce this requirement. FSIS also intends to issue guidance to industry or work with industry to provide comments on industry guidance on how to address foreign contaminants.

Estimated Completion Date: May 2018

**Recommendation 10:**
Issue guidance to clarify that FSIS inspectors are to remove contaminated product (in accordance with the principles of Hazard Analysis and Critical Control Point (HACCP)) for product that is allowed to pass the critical control point, or the inspector observes adulteration and the establishment has failed to observe it or act on it.

FSIS Response:
FSIS's regulations on HACCP and SSOP define these responsibilities for regulated establishments and inspection program personnel (IPP). IPP complete thorough regulatory training, including HACCP principles, during their inspection methods course. IPP knowledge and execution of inspection methodology is verified through IPPS assessments twice a year. Additionally, the IPP Help Button provides information on HACCP in real-time (see Enclosure 11), and has proven to be an effective tool getting an average of 25,680 hits per month (see Enclosure 10). In addition, as noted in response to recommendation 9, FSIS intends to issue instructions to inspectors to clarify how to enforce requirements that establishments notify FSIS when they have shipped or received adulterated or misbranded product, as required under 9 CFR 418.2.

Estimated Completion Date: May 2018

**Recommendation 11:**
Provide training to all FSIS district and establishment personnel on issuing NRs, and linking NRs if appropriate. This training should include a module that specifically addresses concerns that warrant an NR, and when it is appropriate to link two or more NRs.

FSIS Response: FSIS has already fulfilled the intent of this recommendation through the launch of the IPP Help Button. It is available on all FSIS computers including those that are used in the field and contains helpful interactive tools to guide employees in their understanding of FSIS policy. The Help Button contains an array of information on noncompliance records (see Enclosure 12). The Help Button has proven to be a useful tool for our employees, getting an average of 25,680 hits per month (see Enclosure 10). Additionally, it should be mentioned that FSIS has strengthened its approach to noncompliance and made it more data-driven. FSIS utilizes Early Warning Alerts, an additional tool for employees, which is based on adverse trends in Public Health NRs and gives IPPs the data to be able to determine trends and take appropriate actions. As outlined in Notice 13-16 issued in Feb. 2016, (see Enclosure 2), FSIS calculates Public Health Regulation (PHR) non-compliance rate for each meat and poultry official establishment. Every year FSIS establishes cut points at 2 levels, Tier 1 and Tier 2. Tier 2 is the lower threshold at which inspection program personnel (IPP) will be notified with

an Early Warning Alert that an establishment has a non-compliance rate that is elevated and is at or exceeds the Tier 2 cut point. Tier 1 is the higher threshold at which FSIS will consider the establishment for a Public Health Risk Evaluation (PHRE). Early Warning Alerts provide our workforce with real-time enforcement capabilities. Thus, FSIS has addressed this recommendation.

Estimated Completion Date: Complete

**Recommendation 12:**
Develop and implement procedures for district officials to follow and document when performing oversight and monitoring of front-line supervisors' activities.

FSIS Response: District management officials are held accountable to supervisory responsibilities in their FY 2017 performance plans (see Enclosure 13). They are required as supervisors to conduct performance evaluations of subordinate employees, including FLSs, and document these evaluations in the Performance Rating Tool (PRT). Additionally, district management officials are required to review 10 percent of IPPS assessments conducted field supervisors, including those performed by FLSs. FSIS has the procedures in place, between its performance management system and IPPS, for district management personnel to verify FLSs are completing their supervisory responsibilities. Given this, FSIS believes it has fully addressed the intent of this recommendation.

Estimated Completion Date: Complete

**Recommendation 13:**
Develop and implement a policy that requires front-line supervisors to document their monitoring and oversight activities (separate from the twice per year In-Plant Personnel System (IPPS) review requirement) at assigned establishments on a periodic basis.

FSIS Response: What OIG is recommending is largely fulfilled by the IPPS, which field supervisors are required to document per Directive 4430.3, which was issued in January 2016 and fully addresses this recommendation. In addition, FLSs are held accountable to these supervisory responsibilities in their FY 2017 performance plans (see Enclosure 14). They are required as supervisors to also conduct performance evaluations on top of the IPPS, which they are to document in the Performance Rating Tool (PRT). Their performance of each of these supervisory functions is dictated by FSIS policy. FLSs have been effective in carrying out these supervisory responsibilities, as evidenced by performance rate of PHIS tasks. For example, the Hazard Analysis Verification (HAV) task performance rate in CY 2016 was over 90 percent, well above FSIS's management control (See Enclosure 15). Thus, the Agency has fully addressed the intent of this recommendation. FSIS must note that OIG's statement in Finding 4 related to this recommendation that "FSIS did not develop sufficient oversight controls to ensure its

supervisors adequately monitored the completion of tasks…" is not supported by evidence, but rather is OIG's opinion. As stated above, the fact is FSIS holds FLSs responsible for monitoring and oversight activities not only through the IPPS Directive 4430.3, but also through our performance management system.

Estimated Completion Date: Complete

**Recommendation 14:**
Provide the front-line supervisors with training on managing their circuits and using system-generated reports to monitor and oversee inspection activities at assigned establishments. This training should include guidance on preparing adequate documentation of these activities.

FSIS Response: PHIS contains 100+ standard reports (see Enclosure 16) as well as an alerting function that provides FSIS's FLSs with information to manage and oversee the inspection activities in their circuits. PHIS has a complete directory of all of the reports available, with details of what is contained in each report. ODIFP field analysts are available to help field personnel with PHIS. In addition, ODIFP has provided presentations to Frontline Supervisors at national meetings and district meetings highlighting what reports are available and how to access the reports. Additionally, FSIS is in the process of developing a Supervisory Help Button, similar to the IPP Help Button. FSIS anticipates it will be available to field supervisors by September 30, 2017. Thus, FSIS has fully addressed the intent of this recommendation.

Estimated Completion Date: Complete

**Recommendation 15:**
Complete an assessment of the process used for recording Humane Handling Activities Tracking System (HATS) verification activities (rounding methodology and minimum reporting requirements) and evaluate whether the current process provides the most accurate representation of the agency's time devoted to monitoring humane handling activities. This assessment should document the analysis performed to reach the conclusions. If the assessment shows that a different process is needed, establish timeframes for implementing the new process and also establish a process to verify that the actions are completed within the established timeframes.

FSIS Response: As stated earlier in FSIS's response, the Agency uses the same method as that used at the Department-level and records time in 15-minute increments. This is also a standard practice in many industries. FSIS is on target to meet the annual 148 FTEs/year in Humane Handling oversight and has exceeded the required number of hours since the Congressional mandate was implemented.

That being said, FSIS will perform an assessment of the process used for recording Humane Handling Activities Tracking (HATS) verification activities and evaluate whether the current process provides the most accurate representation of the agency's time devoted to humane handling activities. The assessment will identify ways for district officials to help ensure the accuracy of the time reported in HATS and ways to identify anomalies and trends in the data. The assessment will also evaluate when edits can be made to HATS data and the necessary approvals.

Estimated Completion Date: May 2018

**Recommendation 16:**
Develop and implement guidance for district management to help ensure the accuracy of the time reported in HATS and to identify anomalies and trends in the data.

FSIS Response: As outlined in response to recommendation 15, FSIS will perform an assessment of the process used for recording Humane Handling Activities Tracking (HATS) verification activities and evaluate whether the current process provides the most accurate representation of the agency's time devoted to humane handling activities. The assessment will identify ways for district officials to help ensure the accuracy of the time reported in HATS and ways to identify anomalies and trends in the data. The assessment will also evaluate when edits can be made to HATS data and the necessary approvals. If the agency determines, based on the results of the assessment, that additional oversight by district management is needed, FSIS will develop the necessary guidance to the field.

Estimated Completion Date: May 2018

**Recommendation 17:**
Develop and implement policies and procedures that detail when edits can be made to HATS data and indicate that these edits can only be made by certain officials with justifications approved by headquarters.

FSIS Response: FSIS has controls in place in PHIS to ensure the integrity of the HATS data. When personnel need to make a change to this data, they must provide a justification and only then will the system allow them to make the change. The system maintains a history of justifications, date the edit was made, and who made it, all of which is accessible to the personnel's chain of command.

Additionally, FSIS re-extracted the FY13 and FY14 HATS data in February 2017, recalculated the FTE times, and compared today's results to what was provided to OIG. The data are within 1 FTE of the originally reported values. Out of a total of more than 170 FTEs reported to Congress for FY13 and FY14, this represents less than a 1 percent change (approximately 0.6 percent). FSIS believes the ability to compute the same staff year total to within 1 FTE several years after the reporting period indicates that 1) the

reported data are reasonably consistent and 2) the data was accurately reported as exceeding the Congressional mandate. Thus, FSIS believes it has the measures in place already that address this recommendation.

As outlined for recommendations 15, and 16, FSIS will perform an assessment of the process used for recording Humane Handling Activities Tracking (HATS) verification activities and evaluate whether the current process provides the most accurate representation of the agency's time devoted to humane handling activities. The assessment will identify ways for district officials to help ensure the accuracy of the time reported in HATS and ways to identify anomalies and trends in the data. The assessment will also evaluate when edits can be made to HATS data and the necessary approvals.

Estimated Completion Date: May 2018

**Recommendation 18:**
Develop and implement an action plan to resolve the connectivity issues preventing inspectors from using the Public Health Information System (PHIS) at every establishment. This plan should include a nationwide assessment that identifies establishments with connectivity issues and provides specific dates for resolving the connectivity issues.

FSIS Response: FSIS has been working on solving connectivity issues for its field employees for a number of years now, and has made great strides. Connectivity is vastly better today, as FSIS has upgraded all 3G devices to 4G, installed hundreds of T1 connections, and has distributed thousands of MiFi devices in the field. FSIS is aware of 60 federally-inspected establishments remaining nationwide (see Enclosure 17) that do not have connectivity. The Agency worked with each district to identify these locations, and has been deploying innovative connectivity solutions to each site, such as Cradlepoint, Cisco 819, and portable satellite. FSIS anticipates having connectivity addressed at these locations by May 31, 2017. Once this occurs, the Agency will sunset the Disconnected State Application in PHIS, as it will no longer be needed by its employees.

Estimated Completion Date: May 31, 2017

Enclosures

List of Enclosures for FSIS Response to OIG Official Draft Report

Enclosure 1: FSIS Comments to OIG on Preliminary Findings for Follow-up Review of 2007-2008 Audit Initiatives, March 24, 2016

Enclosure 2: FSIS Notice 13-16, "Public Health Regulations and Alerts for Use in Determining Inspection Program Personnel (IPP) Actions and Food Safety Assessment Scheduling in Meat, Poultry Establishments and Egg Product Plants", February 11, 2016

Enclosure 3: Excel spreadsheet listing humane handling reviews conducted by District Veterinary Medical Specialists (DVMSs) during the 18-month window ended in FY2016

Enclosure 4: Table of livestock slaughter days and the corresponding days when Humane Handling Tasks were or were not performed on the same shift (2012 – 2015)

Enclosure 5: In-plant Supervision Element of Supervisory Public Health Veterinary FY2017 Performance Plans

Enclosure 6: 2012-2016 Results of FSIS Strategic Plan Performance Measure 2.2.1 - % of slaughter plants identified during DVMS humane handling verification visits as having an effective systematic approach to humane handling

Enclosure 7: FY2017 Performance Plan, Progress Review and Annual Appraisal Worksheet for DVMSs

Enclosure 8: AssuranceNet Project Requirements from Statement of Work, March 2017

Enclosure 9: Mission Results Element of District Manager and Deputy District Manager FY2017 Performance Plans

Enclosure 10: Graph of IPP Help Button Hits, March 2017

Enclosure 11: Screen Shot of IPP Help Menu options, including HACCP

Enclosure 12: Screen shots of IPP Help Menu Topics, PHIS Home Help Menu options, and Inspection Verification Menu options including Non-Compliance Records

Enclosure 13: Supervisory Element of District Manager and Deputy District Manager FY 2017 Performance Plans

Enclosure 14: Supervisory Element of Front Line Supervisor FY2017 Performance Plans

Enclosure 15: CY 2016 Hazard Analysis Verification Task Performance

Enclosure 16: PHIS Report Directory, April 2017

Enclosure 17: List of Establishments with Connectivity Issues, April 2017

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