



U.S. Department of Agriculture



Office of Inspector General
Great Plains Region

Audit Report

Evaluation of FSIS Management Controls Over Pre-Slaughter Activities

Report No. 24601-0007-KC
November 2008



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



NOV 28 2008

REPLY TO

ATTN OF: 24601-7-KC

TO: Alfred V. Almanza
Administrator
Food Safety and Inspection Service

ATTN: William C. Smith
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Evaluation of FSIS Management Controls Over Pre-Slaughter Activities

This report presents the results of our audit concerning management controls over pre-slaughter activities. Included is our assessment, based on the information available at the time our work was performed, of the events that took place at Hallmark-Westland Meat Packing Company in the fall of 2007. Your response to the official draft report, dated November 20, 2008, is included as exhibit D. Excerpts of the response, along with the Office of Inspector General's position, are incorporated into the Findings and Recommendations section of the report. Based on your responses, we were able to reach management decisions on all of the report's 25 recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

Executive Summary

Evaluation of FSIS Management Controls Over Pre-Slaughter Activities (Audit Report 24601-7-KC)

Results in Brief

On January 30, 2008, the Humane Society of the United States (HSUS) released videos to the public that documented the egregious abuse of cattle awaiting slaughter at the Hallmark-Westland Meat Packing Company (hereafter referred to as Hallmark) in Chino, California. These abuses, which took place in the fall of 2007, included electric shocks, spray from high-pressure water hoses, and the ramming of cattle with a forklift. The abuses were committed by employees of the establishment in an apparent attempt to force non-ambulatory cattle to rise for slaughter. On February 1, 2008, Hallmark voluntarily ceased operations pending investigation by the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) into the alleged abuses.

FSIS determined, as part of its own investigation, that Hallmark employees violated the ban¹ on slaughter of non-ambulatory disabled (“downer”) cattle by failing to notify the FSIS Public Health Veterinarian (PHV) when animals became non-ambulatory after having passed ante-mortem inspection. “Downer” animals are known to be at high risk for bovine spongiform encephalopathy (BSE).² Therefore, it is critical that they be carefully examined before slaughter (ante-mortem) and then, if appropriate, condemned. Currently, an animal that becomes non-ambulatory after ante-mortem inspection may only be slaughtered if the PHV determines through re-examination that its condition is due to an acute injury, such as a broken leg.³ On February 4, 2008, FSIS issued a Notice of Suspension to Hallmark for its failure to maintain and implement controls to prevent the inhumane handling and slaughter of animals.

On February 17, 2008, Hallmark announced that it was voluntarily recalling approximately 143 million pounds of raw and frozen beef products. This recall, the largest recall to date, was designated as Class II due to the establishment’s noncompliance with regulatory requirements and the remote possibility that the beef being recalled could cause adverse health effects if consumed.⁴ In public testimony USDA officials reinforced their determination that the recall occurred because the establishment did not comply with regulatory inspection requirements, not due to food safety concerns. To mitigate public concerns that downers may have entered the

¹ Title 9 Code of Federal Regulation (C.F.R.) 309.3 (e).

² BSE, widely referred to as “mad cow disease,” is a chronic degenerative disease of the central nervous system of cattle. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSE), which include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Cruetzfeldt-Jakob disease (CJD) in humans.

³ In May 2008, the Secretary announced plans for a total ban on the slaughter of cows too sick or weak to stand. A proposed rule to implement such a ban was published for public comment on August 27, 2008.

⁴ Class I recall involves a health hazard situation where there is a reasonable probability that eating the food will cause health problems or death.

food supply, USDA officials cited three other interlocking safeguards that protect the public even if other safeguards, such as ante-mortem inspection, should fail; these safeguards are the removal of Specified Risk Materials (SRM),⁵ BSE surveillance testing, and the feed ban.⁶ Under the Federal Meat Inspection Act (FMIA),⁷ if an establishment does not present animals for ante-mortem inspection, FSIS is unable to determine that animals are fit for slaughter as human food, and therefore cannot permit the carcasses to be marked as “inspected and passed.”⁸

The release of the videos by HSUS led Congress, USDA, and the public to question how such events could have occurred at a slaughter establishment that was under inspection by FSIS. FSIS inspection personnel are charged with enforcing the requirements of the Humane Methods of Slaughter Act, the FMIA, and the Poultry Products Inspection Act. FSIS inspects all meat, poultry, and processed egg products sold in interstate commerce to ensure that they meet U.S. food safety standards.

At the request of the Secretary of Agriculture, the Office of Inspector General (OIG) is leading the Department's criminal investigation into potential violations of the FMIA. The investigation is ongoing, and OIG Investigations is working cooperatively with FSIS' Office of Program Evaluation, Enforcement, and Review (OPEER) and other law enforcement agencies, as well as coordinating these efforts with the U.S. Department of Justice. At the conclusion of the investigation, a report of investigative findings will be issued to the appropriate USDA officials.

This audit was conducted to determine what inspection controls and/or processes may have broken down at Hallmark, and whether the events that took place there are isolated or systemic. To make that assessment, we evaluated the adequacy of FSIS' pre-slaughter controls at 10 other slaughter establishments which, like Hallmark, slaughter cull cows.⁹ We also evaluated the effectiveness of FSIS' controls over the removal of SRMs from cattle, as well as inspector-generated samples for residue testing.¹⁰ Because of the ongoing investigation, our assessment of what happened at Hallmark is limited by the information we have to date. Also, since Hallmark has ceased operations, we could not observe and validate FSIS' oversight and verification of that establishment's food safety systems. Therefore, we made

⁵ Title 9 C.F.R. 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.

⁶ In 1997, the Food and Drug Administration implemented a mandatory feed ban that prohibits feeding most mammalian protein to ruminants, including cattle. This rule was strengthened in a final rule published April 25, 2008.

⁷ 21 U.S.C. 603 and Title 9 C.F.R. 309.1.

⁸ FSIS Directive 6100.1, dated September 13, 2007.

⁹ Cows are culled from a herd for reasons such as unsatisfactory milk production or reproductive failure, a weak condition or old age, or when the cost to feed does not guarantee a profit from feeding.

¹⁰ Although all cows may be subject to residue testing, culled dairy cows are particularly likely to have been administered antibiotics and other drugs because of their age and physical condition.

our assessment as to what happened at Hallmark through interviews and review of available records, where possible.

We determined that there were deliberate actions¹¹ by Hallmark personnel¹² to bypass required inspections, as well as noncompliance with required inspection procedures by FSIS in-plant staff. Supervisory and other management controls did not detect and/or prevent these incidents. Although we found varying degrees of noncompliance and/or inconsistent implementation of required inspection procedures by FSIS inspectors in the other cull establishments reviewed during the audit, nothing came to our attention to indicate that unsuitable animals were passed for slaughter at these establishments. In addition, there was no single underlying reason why the noncompliances occurred. Therefore, we concluded that the events that occurred at Hallmark were not a systemic failure of the inspection processes/system as designed by FSIS. However, we did determine that management controls designed to provide oversight of the inspection processes, as well as organizational controls to demonstrate the sufficiency and competency of its personnel resources, can be strengthened to minimize the chance that events such as those at Hallmark could happen in the future. The observations made during this audit and conclusions reached are limited to cull slaughter operations, which are inherently higher risk due to the health and age of the animals slaughtered.

We did not observe any systemic inhumane handling incidents at the 10 establishments visited during this audit, nor did anything come to our attention that would lead us to believe any were occurring when we were not there. However, we concluded that there is an inherent vulnerability that humane handling violations can occur and not be detected by FSIS inspectors because FSIS does not provide continuous surveillance of all operating areas within a slaughter establishment at all times. Further, animals slaughtered at cull slaughter establishments, like Hallmark, are in a generally weak physical condition, which increases the risk that humane handling violations can occur as establishment employees attempt to move the animals from the unloading areas to the holding pens to slaughter. At Hallmark, egregious humane handling violations occurred when its employees attempted to move non-ambulatory cattle. In response to the events at Hallmark, on August 27, 2008, USDA announced a proposed rule to ban the slaughter of all cattle that become non-ambulatory disabled after passing ante-mortem inspection; these animals would be condemned and properly disposed of rather than slaughtered.

In addition to implementing the proposed ban on non-ambulatory cattle, and establishing appropriate oversight to ensure compliance at slaughter establishments, FSIS can also strengthen management controls and improve

¹¹ Because of the ongoing criminal investigation, no further information can be provided in this report.

¹² The San Bernardino County District Attorney in California filed animal cruelty charges against two former Hallmark employees; both were convicted.

its oversight of its inspection staff. FSIS must take action to demonstrate that the various compensating controls it has in place over its pre-slaughter inspection processes are consistently understood and implemented by its inspection and management staff. We noted the following concerns.

Sufficiency and Competency of Inspection Resources

- FSIS cannot demonstrate that the resources assigned to its offline inspection activities are sufficient to adequately perform the tasks assigned. At Hallmark, and at each of the other 10 slaughter establishments we visited, we noted inspection noncompliances of varying types and degree. The reasons for these noncompliances varied, but at three establishments, in addition to Hallmark, the PHVs stated they took shortcuts in ante-mortem inspection activities in order to complete all assigned tasks. Although we observed no adverse impact at the 10 cull slaughter establishments reviewed, such noncompliances can facilitate attempts to bypass inspection processes, as was the case at Hallmark.
- We cannot assess the reasonableness of the supervisory span of control assigned to frontline supervisors (FLS) because FSIS cannot provide supportable work measurement assumptions. The FLS is assigned a circuit of establishments for supervision and oversight and represents the first level of supervision above the in-plant level. The FLS at Hallmark, as well as the FLSs at 7 of the 10 establishments reviewed, were not aware of common practices used by in-plant inspection staff that did not meet FSIS requirements. Therefore, we concluded that FSIS needs to develop a supportable, risk-based methodology for assigning its inspection staff, and re-assess the adequacy and effectiveness of its supervisory span of control.
- FSIS does not have a formal, structured developmental program and system in place to ensure that all of its inspection and supervisory staff receive both formal and on-the-job training to demonstrate that they possess the competencies essential for its mission-critical functions. Since FSIS' inspection staff is directly involved in ensuring the safety of the food supply, we believe a structured program of continuing education, certified each year, would provide the organizational control needed to demonstrate a knowledgeable and qualified workforce.

Management Controls

- FSIS has a management control structure in place that should have identified and/or mitigated the problems disclosed at Hallmark, as well as those we identified at the establishments visited during the

audit. FSIS management, however, did not detect the inconsistent application and/or noncompliance with required inspection procedures that occurred at Hallmark, or at the establishments visited during the audit. FSIS needs to more fully utilize its management information systems to monitor compliance with its inspection requirements, as well as to obtain early alerts of potential problems.

We reported limitations with FSIS' management control systems in a prior audit, Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, dated December 2007. FSIS is in the process of re-aligning its systems in a Public Health Information System (PHIS) to better integrate and consolidate numerous applications that collect information to provide mission critical support. In addition, FSIS is continuing to enhance and implement systems designed to provide management oversight of the public health activities of its inspection workforce. We concluded that these control systems should be strengthened to minimize the potential for events such as those that occurred at Hallmark to happen in the future.

SRM Verification Activities

- FSIS cannot effectively demonstrate that its verification of establishment controls and written procedures for the removal, segregation, and disposition of SRMs is adequate to detect noncompliance. FSIS' information systems do not provide information to document the verification of each establishment's controls, nor do they readily provide data for analysis to detect trends of noncompliance or to identify areas where more in-plant oversight is needed. During our establishment visits, we observed that FSIS was verifying the removal of SRMs from each carcass that passed through the slaughter process. However, we found that inspectors did not always detect or consistently document noncompliances with SRM control requirements.

We believe FSIS needs to strengthen its overall management controls and oversight processes to provide reasonable assurance that the compensating controls FSIS has put in place for pre-slaughter inspection activities and SRM verification activities are consistently and fully implemented by its inspection staff.

Recommendations In Brief

FSIS needs to reassess the inhumane handling risks associated with cull slaughter establishments and determine if more frequent or in-depth reviews need to be conducted. Also, FSIS should establish a process to analyze available data for anomalies or variances in both establishment and inspector performance that could require additional followup by district management.

FSIS needs to develop a supportable, risk-based methodology for determining the inspection resources needed at each establishment and its appropriate supervisory structure. We also recommend that a structured training and development program, with a continuing education component, be developed for both its inspection and management resources. Further, supervisory and management oversight of in-plant performance needs to be strengthened to ensure that on-site evaluations are thorough and are conducted at the required frequencies.

We have also made numerous recommendations for FSIS to strengthen its pre-slaughter inspection processes and compensating controls over the movement and tracking of animals from ante-mortem inspection, to slaughter, and/or through proper disposal, residue testing procedures, and SRM verification activities.

Agency Response

FSIS agreed with the report's 25 recommendations. We have incorporated the FSIS response in the Findings and Recommendations section of this report, along with the OIG position. FSIS' response to the draft report is included in its entirety as exhibit D.

OIG Position

Based on FSIS' response, we were able to reach management decisions on the report's 25 recommendations.

Abbreviations Used in This Report

BSE	Bovine Spongiform Encephalopathy
CSI	Consumer Safety Inspector
DVMS	District Veterinary Medical Specialist
eADRs	Electronic Animal Disposition Reporting System
EARO	Executive Assistant for Regulatory Operations
EIAO	Enforcement Investigations and Analysis Officer
EPA	Environmental Protection Agency
FAST	Fast Antimicrobial Screening Test
FDA	Food and Drug Administration
FI	Food Inspector
FLS	Frontline Supervisor
FMIA	Federal Meat Inspection Act
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
FSRE	Food Safety Regulatory Essentials
GAO	General Accountability Office
HACCP	Hazard Analysis and Critical Control Point
HATS	Humane Activities Tracking System
HMSA	Humane Methods of Slaughter Act
HSUS	Humane Society of the United States
IIC	Inspector-In-Charge
IPPS	In-Plant Performance System
LEARN	Laboratory Electronic Application for Results Notification
MAW	Method of Assigning Work
NR	Noncompliance Record
NRP	National Residue Program
OCIO	Office of the Chief Information Officer
OFDER	Office of Food Defense and Emergency Response
OIE	Office International des Epizooties
OIG	Office of Inspector General
OPEER	Office of Program Evaluation, Enforcement, and Review
PBIS	Performance Based Inspection System
PHIS	Public Health Information System
PHV	Public Health Veterinarian
RVIS	Residue Violators Information System
SRM	Specified Risk Materials
USDA	United States Department of Agriculture

Table of Contents

Executive Summary	i
Background and Objectives	1
Findings and Recommendations.....	5
Section 1. No Systemic Failure of Inspection Processes, but Management Controls Can Be Strengthened to Mitigate Future Occurrences.....	5
Finding 1 Deliberate Actions and Inspection Control Breakdowns Contributed to the Regulatory Violations at Hallmark	6
Recommendation 1.....	14
Recommendation 2.....	15
Recommendation 3.....	15
Recommendation 4.....	16
Finding 2 Management Controls Were Not Effective in Detecting Inconsistent Application and/or Noncompliance With Required Inspection Procedures	17
Recommendation 5.....	25
Recommendation 6.....	26
Recommendation 7.....	27
Recommendation 8.....	27
Section 2. FSIS Pre-Slaughter Activities.....	29
Finding 3 Inspectors Did Not Comply With Required Inspection Procedures and/or Used Inconsistent Methods in Performing Ante-Mortem Inspections	29
Recommendation 9.....	35
Recommendation 10.....	35
Recommendation 11.....	36
Recommendation 12.....	36
Recommendation 13.....	37
Finding 4 FSIS Needs to Strengthen Controls Over Secondary Entrances to Prevent the Potential Slaughter of Unfit Animals	38
Recommendation 14.....	39
Finding 5 Effectiveness of Inspector-Generated Residue Testing as Part of the Ante-Mortem Inspection Process Needs to Be Re-Assessed	40
Recommendation 15.....	43
Recommendation 16.....	43
Recommendation 17.....	44
Section 3. Specified Risk Materials	46

Finding 6	FSIS Needs To Strengthen Its Monitoring of the Effectiveness of SRM Intervention Procedures.....	47
	Recommendation 18.....	51
	Recommendation 19.....	52
	Recommendation 20.....	52
Finding 7	FSIS Inspectors Did Not Always Detect or Document Noncompliance With SRM Regulations	53
	Recommendation 21.....	59
	Recommendation 22.....	60
	Recommendation 23.....	60
	Recommendation 24.....	61
	Recommendation 25.....	61
Scope and Methodology.....		63
Exhibit A – Pre-Slaughter Inspection Issues		67
Exhibit B – Residue Testing Issues.....		68
Exhibit C – Specified Risk Material Issues.....		69
Exhibit D – Agency Response to the Draft Report		70

Background and Objectives

Background

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency of the U.S. Department of Agriculture (USDA). As such, the agency protects consumers by ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act, FSIS inspects all meat, poultry, and processed eggs sold in interstate commerce to ensure that it meets U.S. food safety standards. FSIS is responsible for verifying that slaughter and processing establishments implement food safety systems that comply with Pathogen Reduction and Hazard Analysis and Critical Control (HACCP)¹³ standards. HACCP requires that all significant hazards with the products and production environment be identified and controlled. FSIS is also responsible for enforcing the Humane Methods of Slaughter Act (HMSA);¹⁴ its inspectors verify the humane treatment of livestock in slaughter establishments.

FSIS employs about 7,800 in-plant inspectors at about 6,200 Federally-inspected establishments; of these, 632¹⁵ slaughter cattle. FSIS employs public health veterinarians (PHV), food inspectors (FI), and consumer safety inspectors (CSI) who are responsible for inspecting animals prior to slaughter, as well as carcasses after slaughter, to ensure the meat is safe for human consumption. The CSI performs in a relief or trouble-shooting in-plant inspection capacity but is primarily responsible for conducting regulatory oversight activities inside establishments relating to sanitation performance standards, sanitation operating procedures, pathogen reduction verification procedures, and other food security verification procedures. The CSI and PHV both observe animal handling and the slaughter process to ensure compliance with HMSA. In 2004, FSIS implemented the Humane Activities Tracking System (HATS) to document the time spent by FSIS inspection personnel in verifying that humane handling slaughter requirements are met.

FSIS regulations¹⁶ require that all livestock offered for slaughter at an official establishment be examined on the day of and before slaughter. Livestock are inspected before slaughter (ante-mortem), resulting in one of three possible outcomes: 1) passed for slaughter; 2) “suspect,” which requires further inspection by a PHV post-mortem; or 3) condemnation. 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 a carcass-by-carcass basis in the

¹³ In 2000, FSIS completed implementation of the Pathogen Reduction and HACCP system, which required meat and poultry processing and slaughter establishments to identify critical points in the production chain where food safety hazards could be controlled, reduced, or eliminated (process control).

¹⁴ Public Law 95-445, 7 U.S.C. Section 1902, Chapter 48.

¹⁵ Of these, 103 establishments primarily slaughter cull cattle. These figures are based on FSIS 2007 slaughter data.

¹⁶ Title 9 C.F.R. 309.1 (a).

slaughter area after the animal has been humanely stunned and bled. 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. USDA 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 have been determined to be at high risk for bovine spongiform encephalopathy (BSE). USDA currently allows the slaughter of animals that become non-ambulatory because of an acute injury after passing ante-mortem inspection, but only if the PHV re-examines the animal and determines it is acceptable for slaughter.¹⁷ On August 27, 2008, USDA announced a proposed rule to impose a complete ban on the slaughter of cattle that become non-ambulatory after initial inspection by FSIS. Under the proposed rule, all cattle that are non-ambulatory disabled at any time prior to slaughter will be condemned and properly disposed of.

In 2004, FSIS declared certain beef tissues and products to be specified risk materials (SRM) and banned these products from the human food supply.¹⁸ The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older are considered SRMs, as well as the tonsils and distal ileum of the small intestine of all cattle, regardless of age.¹⁹ Establishments are required to control or prevent these SRMs from entering the food supply.²⁰ 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.²¹ Carcasses containing SRMs can be processed and shipped to other establishments for further processing, provided that proper controls are established to ensure that all SRMs are removed by these “downstream processors”²² before they are marketed for consumption.

FSIS administers the National Residue Program (NRP) in cooperation with the Environmental Protection Agency (EPA) and the Department of Health and Human Services, Food and Drug Administration (FDA) to control veterinary drug, pesticide, and environmental contaminant residues in meat, poultry, and processed egg products.²³ FSIS began administering the NRP in 1967 and follows FDA and EPA guidance on residue monitoring and tolerance action levels.

¹⁷ Title 9 C.F.R. 309.3 (e).

¹⁸ Title 9 C.F.R. 310.22.

¹⁹ Title 9 C.F.R. 310.22 (a).

²⁰ Title 9 C.F.R. 310.22 (b) and (e).

²¹ Title 9 C.F.R. 310.22 (f).

²² Title 9 C.F.R. 310.22 (g).

²³ FSIS regulations are published in Title 9 C.F.R., Chapter III. FSIS personnel collect samples at inspected establishments and analyze samples at FSIS laboratories for residues. FDA and EPA have statutory authority for establishing residue tolerances or action levels under the Federal Food Drug and Cosmetic Act, and through the Federal Insecticide, Fungicide and Rodenticide Act (as modified by the Food Quality Protection Act), respectively.

FSIS inspectors sample livestock carcasses and parts under the NRP's Domestic Sampling Plan, which is comprised of two component sampling plans. Under the first of these, the Scheduled Sampling Plan, FSIS inspectors collect random samples of healthy-appearing carcasses that have been passed for consumption to determine the exposure assessment or the prevalence of residues in the national food supply. FSIS also schedules exploratory assessments to investigate or target certain types of animals or residues for ongoing or previous exposures.

A second component of the NRP is Inspector-Generated Sampling. Inspectors judgmentally select a carcass for sampling based on several factors, including (a) signs or symptoms observed in the live animal, (b) pathological conditions or abnormalities of the carcass and/or its associated viscera,²⁴ (c) previous known residue violations by the animal's owner, (d) the animal's herd history, or (e) the fact that an animal is identified as a "high risk" type, such as bob veal²⁵ or show animals. When the inspector collects a judgmental sample, he/she is to retain (or, if necessary, condemn) the carcass and perform an in-plant screening test called FAST (Fast Antimicrobial Screening Test) on swabs from the kidney, which determines if residues of antibiotics or sulfonamides²⁶ possibly exist in the sample. If a FAST test has a positive indication of residue, inspection staff forward the related carcass samples to FSIS laboratories for confirmation and further analysis of potential residues or other contaminants.

FSIS reports the laboratory test results in the Laboratory Electronic Application for Results Notification (LEARN) system. Inspectors use LEARN for condemnation instructions if violative residue levels are found in the samples of those carcasses or parts that were retained pending test results. A sample is considered a violation when a residue is detected exceeding an FDA or EPA established tolerance or action level. If a violative level of residue is found, FSIS notifies FDA of the violation and assists in obtaining the names of producers or other parties involved in offering contaminated animals for slaughter. FDA has jurisdiction over residues on the farm and performs any necessary followup or enforcement actions with violators.

²⁴ Viscera are the internal organs of the animal.

²⁵ Cattle marketed at up to 3 weeks in age, or up to 150 pounds in weight.

²⁶ Sulfonamides are prescription animal drugs used as antibiotics to treat conditions such as bacterial pneumonia, foot rot, and acute mastitis.

Objectives

This audit was conducted to determine what inspection controls and/or processes may have broken down and whether the events at Hallmark are isolated or systemic. We evaluated the adequacy of FSIS' pre-slaughter controls and determined whether improvements are needed to identify and prevent similar incidents from occurring elsewhere. We also evaluated the effectiveness of FSIS' controls over the removal of SRMs from cattle, as well as FSIS' inspector-generated sampling program for residues at cull cow establishments.

Findings and Recommendations

Section 1. No Systemic Failure of Inspection Processes, but Management Controls Can Be Strengthened to Mitigate Future Occurrences

The events at Hallmark are the subject of an ongoing criminal investigation. Therefore, our assessment of what happened is limited to the information that is available to date. However, through investigative analyses of Humane Society of the United States (HSUS) videos, review of inspection and slaughter documentation, and interviews with managers and employees of Hallmark, as well as FSIS inspection and supervisory personnel, we concluded that there were deliberate actions²⁷ on the part of Hallmark personnel²⁸ to bypass inspection processes required by Federal regulations.²⁹ In addition, the FSIS Public Health Veterinarian (PHV) and other inspection personnel assigned to Hallmark did not always perform their inspection duties as required. These noncompliances, which were not detected or prevented by FSIS' management and supervisory controls, may have facilitated the attempts by Hallmark employees to bypass required inspection processes. Information presently available to us indicates that one non-ambulatory animal was slaughtered by Hallmark; the disposition of its carcass, however, is still under investigation.

Although we found varying degrees of noncompliance and/or inconsistent implementation of required inspection procedures by FSIS personnel at the other 10 cull slaughter establishments we visited during the audit, nothing came to our attention to indicate that unsuitable animals were passed for slaughter. The noncompliances we observed at these 10 establishments were attributable to a number of different reasons, and we did not observe any single underlying factor that caused them to occur. Therefore, we concluded that the events that occurred at Hallmark were not a systemic failure of the inspection processes/system, as designed, by FSIS. However, we did determine that management controls designed to provide oversight over the inspection processes, as well as organizational controls to demonstrate the sufficiency and competency of its personnel resources, can be strengthened to mitigate the chance that events such as those that occurred at Hallmark can happen in the future.

²⁷ Because of the ongoing criminal investigation, no further information can be provided in this report.

²⁸ The San Bernardino County District Attorney filed animal cruelty charges against two former Hallmark employees; both were convicted.

²⁹ Title 9 C.F.R. 309.1 (a).

Finding 1**Deliberate Actions and Inspection Control Breakdowns Contributed to the Regulatory Violations at Hallmark*****Is Hallmark Representative of Other FSIS-Inspected Slaughter Establishments?***HUMANE HANDLING

During 2007, there were about 632 Federally-inspected establishments nationwide that slaughtered cattle. The majority slaughter primarily younger fat cattle.³⁰ Hallmark, however, is representative of another group of 103 establishments³¹ that slaughter primarily cull cows. These are often "spent" dairy cows that have been sold off by their dairies when they can no longer produce milk in sufficient quantities to make them profitable. Because of their age and use, dairy cull cows tend to be in poorer physical condition than fat cattle.

Although FSIS regulations and directives generally do not distinguish between establishments that slaughter fat cattle and those that slaughter cull cows, we believe the risks are greater at cull cow establishment – both in terms of potential animal abuse and food safety issues. This is because cull cows are (1) more likely to have pathological conditions that would render them unfit for use as human food; (2) in generally weaker physical condition, which increases the risk of inhumane handling by slaughter establishment employees as they attempt to move them from the unloading areas to the holding pens to slaughter; and (3) more likely to have been administered antibiotics or other drugs before arrival at the slaughter establishment, thus increasing the risk that they will contain violative levels of residues.

Because of these higher risk factors, we chose 10 cull slaughter establishments to visit as part of our audit, all of which were from a group of 49 establishments that, according to FSIS data, slaughtered the greatest number of cull cows during calendar year 2007. Of these, four slaughtered cull cows exclusively, while six slaughtered both cull cows and fat cattle. Details of our findings at these 10 establishments are discussed in sections 2 and 3 of this report.

³⁰ A class of beef cattle of any age but usually greater than 1 year, judged ready for slaughter to provide prime cuts of beef.

³¹ In 2007, FSIS data show that over 50 percent of cattle slaughtered at these establishments were cull cows.

Were Systemic Humane Handling Violations Occurring at Other Slaughter Plants Reviewed?

The 10 establishments we visited, like Hallmark, slaughtered cull cows. During our visits, we did not observe any systemic inhumane handling incidents nor did anything come to our attention that would lead us to believe any were occurring when we were not there. However, we did note that an inherent vulnerability exists that such violations can occur and not be detected because FSIS does not have sufficient staffing levels to provide continuous surveillance of all operating areas within and around a slaughter establishment at all times.

Further, many slaughter establishments (including Hallmark) receive and unload animals from transport vehicles after business hours, as well as on weekends. When interviewed after the release of the HSUS videos, the PHV at Hallmark stated that he had asked permission to make unannounced humane handling visits to Hallmark after working hours. However, FSIS policy is that permission must be granted by an employee's supervisor for off-hour visits. In this case, the PHV stated that the request was disapproved because of potential liability issues.³²

On March 10, 2008, FSIS issued two notices to strengthen its oversight of humane handling compliance. One of these reinforced an existing notice that required inspection personnel to conduct verification activities randomly throughout their tour of duty. The other required inspectors to increase the time they spend verifying humane handling regulatory requirements by at least 50 percent for a 2-month period.

We concluded, therefore, that there was no evidence of systemic humane handling violations at any of the 10 establishments we visited. However, because of the limitations in FSIS' monitoring capabilities, there is an inherent vulnerability that such violations can occur and not be detected.

Did FSIS Identify Animal Handling Abuses at Hallmark and the Establishments Reviewed During the Audit?

FSIS regulations, directives and notices³³ state that if a noncompliance with humane handling requirements has occurred - even one in which the inspector has not observed animals actually being injured or abused - FSIS personnel are to document the noncompliance on FSIS Form 5400-4, Noncompliance Record (NR), and verify that the establishment takes the necessary corrective actions. If corrective actions are not taken in response to an NR, or if the inspector sees an animal being injured or treated inhumanely, FSIS is to take progressively stronger actions, such as shutting down the noncompliant portion of an establishment pending the completion of corrective actions, or requiring that an abused animal be immediately euthanized. If the observed inhumane treatment is of an egregious nature, FSIS must impose a suspension action.³⁴

³² To date, no evidence has been disclosed to indicate that the animal handling abuses at Hallmark took place after working hours.

³³ Title 9 C.F.R. 500.2 and FSIS Directive 6900.2, Revision 1, dated November 25, 2003.

³⁴ Directive 6900.2, while specifying corrective actions to be taken in cases of egregious violations, did not define an "egregious violation." Notice 12-05, dated February 18, 2005, however, addressed this need. Under this guidance, situations of active abuse such as those documented at Hallmark would be classified as egregious and would require that a suspension action be initiated.

At Hallmark, between December 2004 and February 2008, we found no evidence that in-plant inspectors wrote NRs or took suspension actions for humane handling violations. However, FSIS personnel acknowledged at least two incidents of humane handling violations that occurred during this period, both of which involved active abuse of animals. The inspectors did not write an NR or pursue any other enforcement actions; only verbal directions were provided to establishment personnel to discontinue the action or practice in question. The inspectors did not believe an NR was necessary because the specific incident was immediately resolved. We verified that both the PHV and CSI at Hallmark received training in humane handling requirements, and we further verified that this training covered the required enforcement actions under Directive 6900.2. Thus, we must conclude that both of these employees were aware of the requirements; however, we have no information beyond the statements they made as to why they failed to follow them.

In December 2005, prior to the Hallmark incidents in 2007, the District Veterinary Medical Specialist (DVMS) visited Hallmark for a humane handling verification review and issued a report documenting noncompliances with the facility, animal access to water, excessive prodding, and stunning effectiveness. The DVMS report stated that 100 animals were observed being driven into the stunning area; 33 were prodded with an electric prod, 21 of which were prodded between 2 and 3 times. According to the DVMS' report, the majority of this activity took place in the chute leading to the stunning box. The DVMS noted at least two design features of the chute that could have caused animals to balk and not move. An NR was issued as a result of the DVMS review and Hallmark was required to correct the noncompliances identified.

We believe the degree of excessive prodding of animals by Hallmark employees during the DVMS review should have raised questions as to why humane handling noncompliances had not been previously identified by the inspectors because (1) these actions were taken despite the presence of the DVMS, and (2) they may have been at least partly related to ongoing structural issues with the chute. However, there is no record that any such inquiry was made by FSIS managers. A subsequent review by the DVMS in May 2007 reported that corrective actions were taken on the prior review findings and no further noncompliances were identified at that time.

In addition to the DVMS' findings, NR data recorded in the Performance Based Inspection System (PBIS) might have also provided a warning that inspectors at Hallmark were not identifying humane handling violations. The following table shows the NRs written for humane handling violations as a percent of total NRs written from January 2006 through January 2008.

	Humane Handling NRs			All NRs	
	No. Establishments	No. NRs (2)	Percent of Establishments	No. Establishments	No. NRs
All Slaughter	346	858	52%	662	27,913
Top 49 Cull Establishments	38	156	78%	49	5,338
10 Establishments Reviewed	8	20	80%	10	814
Hallmark (1)	1	0		1	66
(1) Hallmark is one of the top 49 cull slaughter establishments. (2) Humane handling violations were noted in 3.1% of all NRs written; 2.9% written for the top 49 cull establishments; and 2.5% of the 10 establishments reviewed. Of the top 49 cull establishments, 11 (22 percent) including Hallmark had no NRs written for humane handling.					

As illustrated in the table, the top 49 cull slaughter establishments were over 50 percent more likely than slaughter establishments in general to have NRs written for humane handling violations. The cull slaughter establishments also averaged about 4 humane handling NRs per establishment, as compared to an overall average of only about 2.5 per establishment. Hallmark's unusual lack of an NR history in the humane handling area, in conjunction with the DVMS' 2005 report, should have indicated the need to further examine the humane handling oversight activities at this establishment.

Could Abuses Such as Those Shown in the HSUS Videos Take Place Without the Knowledge of FSIS Inspectors?

The abuses at Hallmark appeared to take place predominately during working hours, when FSIS personnel were on duty at the establishment.³⁵ Office of Inspector General (OIG) Investigations' analysis of the HSUS videos showed that abuses took place in the unloading areas, the pens, and between the pen and slaughter areas. FSIS personnel have access to all of these areas; however, they cannot monitor all of them at any one particular time. As a result, there is an inherent vulnerability that such violations could occur and not be detected.

At the time the HSUS videos were recorded, Hallmark slaughtered about 500 animals each day and had approximately 147 employees engaged in various aspects of slaughter and processing operations. FSIS had five inspectors onsite – one PHV, one CSI, and three FIs. The FIs performed “online” duties during slaughter operations, which meant that they were required to monitor their specific stations on the slaughter line on a continuous basis; they would not be able to observe humane handling violations in the “offline” areas.

³⁵ Based on information made available to us from the ongoing investigation, these were the only times the HSUS reporter would have been in a position to record the videos.

The PHV and CSI performed offline duties which included, but were not limited to, humane handling inspections. The PHV's duties also included performing ante-mortem and post-mortem inspections, and supervision of the other inspection staff. The CSI's responsibilities also included performing numerous verification inspection tasks required under HACCP, as well as functioning in a relief online inspector capacity. Both the PHV and CSI recorded they performed humane handling inspections in the Humane Handling Activities Tracking System (HATS). The CSI at Hallmark also provided inspection oversight at the processing operation at Hallmark-Westland Meat Packing Company.³⁶ The CSI estimated he spent equal time at each facility.

At the time the recorded abuses took place, Hallmark did not have a video monitoring system in place. Although our information indicates that such a system was in process of being installed before the establishment ceased operations, there is no assurance that this would have prevented animal abuses from occurring. Three of the 10 establishments we visited during the audit had video monitoring, but FSIS inspectors were not given access to these systems. At one of the establishments, its management stated they would not allow FSIS access even if requested. There are currently no regulations in place that require FSIS be granted access to establishment video surveillance systems. Therefore, we have no information to make an assessment as to the effectiveness of video monitoring in preventing inhumane treatment of animals.

Were Inspection Staff Knowledgeable of the Requirements of the Humane Handling Slaughter Act?

FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, provides the requirements for verifying the humane handling and slaughter of livestock. Its provisions include the requirements that (1) the driving of livestock from unloading ramps to holding pens and from holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals; and (2) electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement and injury. Any use of implements which, in the opinion of the inspector, is excessive, is prohibited. In addition to ensuring that each establishment has facilities to protect animals from inclement weather and animals have access to water, inspectors are required to verify that animals are handled humanely at the time they are presented for ante-mortem inspection. The directive requires that inspectors write NRs when humane handling violations are observed, even in cases (such as those involving structural deficiencies) where animals have not actually been injured.

³⁶ Westland Meat Packing Company was a processing establishment that was co-located with Hallmark and owned by the manager of Hallmark.

Both the PHV and CSI at Hallmark received training in humane handling. We reviewed the training modules and found that they appeared sufficiently comprehensive in terms of both the requirements and enforcement actions required, should humane handling violations be observed. Nevertheless, the inspectors did not take the proper actions when they observed violations. Neither the PHV nor CSI believed they should write an NR if an observed violation was immediately resolved. This apparently included at least two instances of egregious abuse; in one of these cases the PHV instructed the establishment to immediately euthanize the animal.

At Hallmark and at the 10 establishments we visited, all 19 PHVs assigned to those establishments received training in humane handling requirements. This topic is included as part of FSIS' Public Health Veterinarian training, a 9-week course that each PHV must complete before beginning duties in that position. All 18 CSIs also received training, either as part of Basic Livestock Slaughter Inspection training or from an online humane handling training module. These employees are the ones most likely to encounter animal abuse situations, if they occur, because of their assigned duties.

Of the 66 FIs assigned to the 10 establishments we visited, 27 (41 percent) had not received the Basic Livestock Slaughter Inspection training, which would have also provided them with humane handling training. FSIS also provides online training in Humane Handling, but only 5 (8 percent) of the 66 FIs had taken this training. Although these employees generally perform "online" duties and may not encounter humane handling situations on a routine basis, we did find that FIs are sometimes called upon to perform ante-mortem inspections, where such training would be needed.

We concluded, therefore, that based on their training, PHVs and CSIs should possess the necessary knowledge to identify and enforce humane handling requirements. However, this does not extend to the FIs, who may, or may not, be assigned offline oversight duties. The events at Hallmark demonstrate there is no assurance that even a properly trained employee will identify and report humane handling violations. FSIS has other management controls, however, that should identify noncompliance by their inspectors. In the case of Hallmark, these controls broke down. The DVMS review, as well as oversight reviews by the frontline supervisors (FLS),³⁷ indicate that FSIS failed to respond to indicators that in-plant inspectors may not have been identifying and/or reporting humane handling violations.

³⁷ See Finding 2 for our conclusions regarding the FLS' supervisory span of control.

FOOD SAFETY INSPECTION PROCEDURES NOT FOLLOWED

What Pre-Slaughter Procedures Were Not Followed at Hallmark? If Followed, Could These Have Provided Adequate Control Over the Movement of Animals to Slaughter?

The ante-mortem inspection procedure, if implemented as specified in FSIS Directive 6100.1³⁸ and associated training, can provide reasonable assurance that diseased animals unfit for slaughter are not entering the food supply. The directive requires that before livestock can be offered for slaughter, they must be presented for ante-mortem inspection. FSIS inspectors are to observe the animals both at rest and in motion for abnormalities and signs of disease or health conditions that would make them unfit for slaughter. For each animal inspected, the ante-mortem process will result in one of three possible outcomes. The animal will be either: 1) passed for slaughter; 2) marked as “suspect” for additional examination by a PHV after slaughter; or 3) condemned and immediately disposed of. “Suspect” animals are those whose condition - as observed ante-mortem - indicates the need for further examination of the animals’ carcasses and organs at post-mortem.³⁹ Suspect animals are required to be identified using a metal tag placed in the ear and be segregated from other animals and slaughtered separately. Only if the post-mortem examination satisfies the PHV as to an animal’s condition can the carcass enter the food chain. FSIS Form 6150-1, Identification Tag, Ante-Mortem, is to accompany the animal until it is either passed at post-mortem inspection or condemned as unfit.

At Hallmark, the PHV stated that he did not fill out the 6150-1 forms himself, but rather delegated this responsibility to Hallmark employees. Further, he stated that he did not require the use of the metal ear tags to identify suspect animals because it saved time not to use them. He instructed Hallmark employees to notify him when suspect animals reached the point where post-mortem inspection would be conducted so that he could make a final determination on them. These practices essentially created an “honor system” in which the inspector relied on Hallmark employees to identify suspect animals moving to, and through, slaughter. This weakened control was further exacerbated by the fact that the PHV sometimes designated entire pens of animals as suspect, depending on the supplier of the animals. This practice, when followed, would have sent large numbers⁴⁰ of suspect animals moving to slaughter without proper identification.

The PHV also stated that establishment employees were delegated the responsibility of filling out condemnation forms on animals that were to be euthanized because of their condition. FSIS inspection personnel were not observing the denaturing⁴¹ and destruction of condemned animals. FSIS

³⁸ Directive 6100.1, Ante-Mortem Livestock Inspection, updated September 13, 2007.

³⁹ Post-mortem inspection occurs in the slaughter area after the animal has been humanely stunned and bled. Inspectors look for signs of disease or pathological conditions that would render a carcass or part unwholesome or otherwise unfit for human consumption.

⁴⁰ An individual pen at Hallmark could contain over 30 animals.

⁴¹ 9 C.F.R. § 314.3, Disposition of Condemned Products at Official Establishments Having No Tanking Facilities, defines denaturing as the application by injection, or other means, of carbolic acid, cresylic disinfectant, or other specified chemicals to render the meat unusable.

regulations⁴² require that condemned products or carcasses be destroyed in the presence of an inspector by incineration, or else be denatured to prevent them from re-entering the food chain.

Another control specified in Directive 6100.1 requires inspectors to verify that the slaughter establishment has an animal identification system that accurately identifies each animal and establishes that inspection personnel have performed ante-mortem inspection on each animal.⁴³ Although no specific requirements are stated beyond this, the directive cites the pen card as one example of such an identification system. Pen cards are establishment records that identify the number of cattle in each pen presented to the PHV for ante-mortem inspection. At Hallmark, as well as the other establishments we visited, the PHV's signature on a pen card was intended to serve as evidence that the animals in the pen associated with that particular card had received ante-mortem inspection.⁴⁴

Although there is no evidence to indicate that the PHV at Hallmark ever signed pen cards in cases where he had not performed ante-mortem inspection, there is an increased risk that animals may not have been properly controlled for slaughter if proper identification is not made of suspect and condemned animals.

**Have There Been
Prior Audits and
What
Improvements
Have Been Made
by FSIS?**

In January 2004, the General Accountability Office (GAO) issued a report⁴⁵ on FSIS' implementation of the HMSA. GAO found that because of incomplete and inconsistent inspection records, it was difficult to determine the frequency, scope, and severity of humane handling slaughter violations. They also found that because guidance was not clear, enforcement actions in response to violations were inconsistent. GAO reported that because of the lack of information on how much time inspectors spend on verifying compliance with the HMSA, it was difficult to determine whether the number of inspectors was adequate.

In response, FSIS incorporated humane handling violation codes in the electronic PBIS and developed guidance to clarify when an NR should be written and when enforcement actions should be taken for repetitive violations. FSIS also developed HATS to track the time inspectors spend on verifying compliance. Further, Notice 12-05, dated February 18, 2005, and reinforced by Notice 16-08, dated March 10, 2008, now provides FSIS employees with examples of what constitutes an egregious abuse for enforcement purposes.

⁴² Title 9 C.F.R. 314.3.

⁴³ Directive 6100.1, Part VIII A, Documentation and Enforcement – Identification System.

⁴⁴ At Hallmark, the PHV did in most cases sign the pen cards. Our review of the pen cards for the period September 2007 through January 2008 showed that of 224 pen cards, 5 were not signed by the PHV. However, we have no information to validate that the PHV counted the animals in each pen to ensure the accuracy of the pen cards; the PHV stated he reviewed the pen cards for accuracy.

⁴⁵ GAO-04-247, *Humane Methods of Slaughter Act, USDA Has Addressed Some Problems but Still Faces Enforcement Challenges*.

GAO also recommended in its 2004 report that once FSIS developed a mechanism to identify the level of effort that inspectors were currently devoting to humane handling and slaughter activities, the agency also needed to develop criteria for determining the level of inspection resources that are appropriate based on establishment size, configuration, and history of compliance. However, FSIS has not developed adequate criteria for making the most effective use of its inspection resources based on HATS data. For instance, DVMS reviews are performed at the same frequency at all establishments, despite the greater risk of abuse (also cited in the 2004 GAO report) at cull slaughter establishments. In addition, FSIS has not addressed the concern that was heightened by the release of the HSUS videos – that its inspectors are not deployed to continuously monitor all areas where establishment employees could potentially be abusing sick or weak animals to move them to slaughter.

Conclusion

We have concluded that FSIS needs to re-assess its resources at cull cow establishments, so that informed decisions can be made as to the levels of staffing needed to prevent future incidents, such as those at Hallmark. Although we concluded that the events at Hallmark were not a systemic failure of the inspection processes/system, as designed, at the other cull establishments reviewed, management controls to demonstrate the sufficiency and competency of its personnel resources can be strengthened (see Finding 2). Also, we determined that FSIS’ management controls were ineffective in disclosing the “shortcuts” taken by the PHV at Hallmark (see Finding 2 and section 2 of this report for a discussion of our review of the ante-mortem processes at the 10 establishments we visited during the audit).

Recommendation 1

Require that DVMS reviews evaluate the effectiveness of in-plant FSIS personnel in overseeing slaughter establishments’ humane handling activities. Also, establish controls to ensure that DVMS review results are correlated with prior reported violations to determine whether inspection processes need to be reassessed or other administrative actions taken.

Agency Response

In the response to the official draft, FSIS agreed to issue a new directive by February 2009 that would provide DVMSs with additional guidance related to their reviews. This guidance will require each DVMS, before conducting a Humane Handling Verification visit, to review the results of the prior DVMS review as well as NRs, Memoranda of Information, and suspensions for the preceding 6 months. While at an establishment, each DVMS will discuss with in-plant inspection personnel any issues of concern that have been noted, including any which have been discussed with the establishment’s management which did not rise to the level of a noncompliance. Also through

discussion, the DVMS will ascertain the knowledge base of the FSIS in-plant inspection staff. This information will be provided in a written document to the district manager and deputy district managers, who will in turn share it with the applicable frontline supervisor to address performance issues.

OIG Position

We accept FSIS' management decision.

Recommendation 2

Reassess the humane handling risks associated with cull slaughter establishments, and determine whether DVMS reviews should be conducted on a more frequent basis at those establishments.

Agency Response

The Office of Food Defense and Emergency Response's Data Analysis and Integration Group (OFDER/DAIG) will complete an analysis of noncompliance rates for humane handling procedures at dairy cow establishments as compared to rates at establishments that slaughter other market classes of adult cattle. The analysis will be completed by August 2009 and provided to Office of Field Operations (OFO) for final determination. In addition, the new directive (see Recommendation 1) that will be provided to the DVMSs could result in more frequent Humane Handling Verification visits.

OIG Position

We accept FSIS' management decision.

Recommendation 3

Establish a process to analyze PBIS data for anomalies or variances in both slaughter establishment and inspector performance that could require additional followup by district management.

Agency Response

OFDER/DAIG 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. The process will be established by January 2009 and the first alert will be distributed in March 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 4

Determine whether FSIS-controlled in-plant video monitoring would be beneficial in preventing and detecting animal abuses at cull cow slaughter establishments.

Agency Response

In their response, agency officials stated that FSIS-controlled video cameras would not provide the definitive data needed to support enforcement of humane handling requirements, as compared to the direct, ongoing and random verification of establishment handling and slaughter practices that FSIS uses. For example, video footage might not reveal whether an animal was conscious during a certain point in the slaughter process. However, they agreed that the use of cameras to monitor humane handling compliance could be useful to the establishments themselves in deterring and detecting animal abuses, particularly if an establishment has implemented a systematic approach to meeting the humane handling and slaughter requirements.

FSIS has authority to access establishments' video records under the Federal Meat Inspection Act, specifically 21 U.S.C. 642, and FSIS has enforced access to video records when these were used to meet certain aspects of HACCP and Sanitation Standards Operating Procedures (SSOP) requirements. FSIS will issue Compliance Guidelines for Using Video Records to industry for designing, maintaining, and validating their video systems so that video records are trustworthy, accurate, and a true representation of the process. An accompanying FSIS directive will clarify FSIS inspection personnel's access to and verification of establishment video records. Both the guidelines and the directive will be issued by March 2009.

OIG Position

We accept FSIS' management decision.

Finding 2**Management Controls Were Not Effective in Detecting Inconsistent Application and/or Noncompliance With Required Inspection Procedures**

FSIS has a management control structure in place that should have identified and/or mitigated FSIS personnel noncompliances with required inspection procedures that occurred at Hallmark, as well as those that we observed at the other 10 establishments during this audit (see section 2). We concluded that management controls designed to provide oversight over the inspection processes, as well as organizational controls to demonstrate the sufficiency and competency of its personnel resources, can be strengthened to minimize the potential for these events from happening in the future.

Prior audits⁴⁶ have reported concerns with FSIS' management controls and information technology (IT) systems that generate the data necessary to provide proper oversight and management of inspection operations. FSIS has, in recent years, made significant strides in designing and developing a management control structure that will allow better monitoring by officials at the Headquarters and district office levels than was previously possible. FSIS is re-aligning its systems into the Public Health Information System (PHIS) to better integrate and consolidate its numerous applications that collect information used to provide mission critical support for inspection, surveillance, enforcement, scheduling, modeling, and analysis. PHIS is being developed, in part, to predict hazards and vulnerabilities, communicate or report analysis results, and target resources to prevent or mitigate the risk of food-borne illness and threats to the food supply. PHIS is not scheduled for full implementation until the second half of fiscal year 2009.

FSIS implemented the In-Plant Performance System (IPPS)⁴⁷ and AssuranceNet⁴⁸ as a means of providing management oversight of the public health activities of FSIS inspection personnel. These systems, in addition to various food safety and district management reviews, are important components in the implementation of an effective management control structure; they provide valuable performance data to supervisors and higher-level managers. However, FSIS is still in the process of fully and effectively enhancing and implementing these systems.

⁴⁶ Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, December 2007.

⁴⁷ IPPS was implemented in October 2002. IPPS is a tool used by supervisors to assess the work of non-supervisory in-plant inspection personnel. The IPPS review process provides a framework and guidelines for supervisors to use in evaluating employee performance.

⁴⁸ AssuranceNet did not become functional until approximately February 2007. AssuranceNet tracks and monitors the performance of FSIS personnel in key functional areas and measures performance against predetermined thresholds. We made six recommendations in a prior audit, Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, dated December 2007, to improve the data used in the system for an effective management control structure.

SUFFICIENCY OF INSPECTION RESOURCES

Were FSIS Resources Adequate at Hallmark to Effectively Fulfill Its Pre-Slaughter Regulatory Responsibilities?

FSIS has staffing models/standards to demonstrate that resources assigned to online and CSI functions are adequate to fulfill their required duties and responsibilities.⁴⁹ However, there are no staffing models to identify the number of PHVs needed for ante-mortem and post-mortem inspection functions, as well as other offline inspection tasks.

FSIS regulations⁵⁰ provide guidelines for maintaining online inspection staffing based on line speed. The Inspector-In-Charge (IIC) has the authority to require the establishment to reduce line speeds where, in his/her judgment, inspection procedures cannot be adequately performed. CSIs, who perform HACCP verification activities, are assigned based on a model called MAW, Method of Assigning Work. MAW was developed in 2003/2004 and replaced prior work measurement standards developed in the 1960's. The MAW is based on the number of tasks assigned by the PBIS and an annualized estimate of the time needed to perform these tasks (including administrative time associated with the task). MAW's staffing model, however, does not take into consideration the type of slaughter establishment (i.e., fat or cull cattle) or the number of animals slaughtered.

For ante-mortem inspection and other offline functions (pre-slaughter and humane handling activities), no staffing models and/or standards exist. FSIS officials stated that it is up to the district managers to decide – within the limitations of the authorized resources for each district – how each establishment should be staffed based on the conditions at the establishment. An FSIS Human Resource official stated that one factor district managers should use to assign PHVs is the number of cattle requiring veterinary disposition; he would expect a cull slaughter establishment to need more PHV time because they would suspect more cattle.

At Hallmark, there was one PHV and one CSI. The FLS informed us that prior to 1998, there were two PHVs assigned to the establishment. The PHV stated that he took “shortcuts” in the ante-mortem process to save time, and stated that he had complained in the past about lack of staffing.

At each of the other 10 slaughter establishments we visited, we noted inspection noncompliances of varying types and degree (see section 2). The reasons for these noncompliances also varied, but at three establishments, the PHVs admitted they took shortcuts in inspection activities in order to complete all tasks. One of these establishments had a vacant PHV position; therefore, one PHV was providing inspection coverage that, in the past, had been performed by two.

⁴⁹ The scope of this audit was limited to pre-slaughter activities; this audit did not review or analyze the basis for these standards.

⁵⁰ Title 9 C.F.R. 310.1.

Without a risk-based, supportable methodology for assigning its inspection staff, FSIS cannot demonstrate that the resources assigned to its offline inspection activities are sufficient to adequately perform the tasks assigned.

Was Sufficient Oversight Provided to the Inspection Activities at Hallmark and Other Plants Reviewed?

The reasonableness of the span of control assigned to FLSs⁵¹ cannot be assessed because FSIS cannot provide supportable work measurement assumptions. Therefore, we cannot determine whether FSIS assigns adequate supervisory oversight to in-plant inspection activities. We found that the FLS responsible for Hallmark, as well as the FLSs at 7 of the 10 establishments reviewed, were not aware of common practices used by in-plant inspection staff that did not meet FSIS requirements (see section 2). Therefore, we concluded that oversight of in-plant operations is adversely impacted by the supervisory span of control assigned to the frontline supervisor.

FSIS assigns each FLS a circuit of establishments for supervision and oversight. The circuit represents the first level of supervision above the in-plant level. The FLS is responsible for managing, coordinating, and supervising the inspection and enforcement activities at each assigned establishment through a subordinate supervisory structure. The FLS' duties include, but are not limited to: overseeing and coordinating the review, implementation, and assessment of in-plant inspection programs; determining the adequacy of inspection resources; ensuring the comprehensive analysis of corrective actions to resolve noncompliances; managing and implementing program and organizational changes; utilizing FSIS information systems and other analytical records to oversee establishment compliance with HACCP and other regulatory requirements; providing oversight of food safety assessments and in-depth verification compliance reviews; ensuring proper implementation of sampling initiatives; and utilizing IPPS to guide, direct and assess the overall performance of non-supervisory inspection personnel. This position is an interdisciplinary position that is classifiable as either a Supervisory Veterinary Medical Officer or a Supervisory Consumer Safety Officer.

In 1990 (prior to implementation of HACCP), FSIS updated its 1984 circuit maintenance guidelines.⁵² Circuits were assigned based on a "structured workload" of 13 to 15 supervisory workdays a month,⁵³ to include allowances for travel between establishments. Two supervisory days per month were provided for establishments with three or more inspectors on each of two shifts.

⁵¹ Frontline supervisors oversee the in-plant inspection activities within each circuit in a district. They generally report to a deputy district manager.

⁵² FSIS Directive 1010.2, Revision 1, dated June 25, 1990.

⁵³ It was expected that the remainder of the month would be spent on administrative and other duties not related to direct in-plant supervision.

FSIS officials recognized that these guidelines needed to be updated, and in December 2005 published a “Frontline Supervisor Study” based on input from 91 percent of the agency’s 156 FLSs on-board at that time. The purpose of the study was to obtain input on the importance of the FLS’s responsibilities, the time allocated to them, what the FLSs felt was needed to better fulfill their responsibilities, as well as their thoughts on the role of the FLS in the future. Some of the concerns identified by the FLSs were as follows.

- They were responsible for too many direct reports and too many establishments which made it difficult for them to conduct quality IPPS reviews and to perform their management control activities.
- Some FLSs had double the workload and responsibilities for long periods (sometimes 1-2 years) because of vacancies.
- Circuits that covered large geographical areas made it difficult to conduct IPPS reviews.
- Some FLSs found it difficult to allocate time for training because of their workload.

At Hallmark, the FLS was not aware of the inspection practices that were not being followed. At the time of our audit, this FLS was responsible for 60 establishments and 17 employees who reported directly to him (direct reports).⁵⁴ FLSs for 2 of the establishments we reviewed were responsible for 2 circuits representing 69 and 88 establishments, and 31 and 28 direct reports, respectively. Both of these assignments were temporary, and were due to vacancies in other circuits; however, two other FLSs in our sample covered over 50 establishments each, and two had a comparable or larger number of direct reports as the Hallmark FLS. We question whether the FLS can provide an adequate level of oversight with such a wide supervisory span of control.

In August 2008, FSIS issued a draft revision to its Circuit Maintenance Guidelines.⁵⁵ The supervisory workload of the circuit remained at 13 to 15 workdays a month, while the standards specified for a circuit were set as 45 establishments and 16 direct reports. Circuit workloads were based on computed allowances for supervision, the number of establishments, and travel on a monthly average basis of 20.5 workdays. The computation allows an average of 29 minutes for an establishment, regardless of shift, type, or size, and .5 day for each direct report. According to FSIS Headquarters

⁵⁴ An FLS’ direct report would generally include any employee who is not directly supervised by another in-plant FSIS supervisor such as an IIC or Supervisory Public Health Veterinarian.

⁵⁵ These guidelines do not specify what work an FLS is expected to perform on any given visit to an establishment. According to one district manager, a typical visit might include a review of NRS, a walk through of all or part of the facility, discussions with the IIC, and performance of any needed IPPS reviews.

officials we interviewed, the determination of how many establishments and direct reports a FLS should have, as well as the amount of time allocated, is not documented through formal studies. Rather, these guidelines are based on the judgment of the officials who drafted the guidelines, and on-going discussions with FSIS field personnel. In the absence of a documented methodology to support its work measurement assumptions, we cannot determine whether FSIS assigns adequate supervisory oversight to in-plant inspection activities.

The following table illustrates the span of control assigned to the FLS who was assigned to Hallmark and the 10 establishments reviewed.

Establishment	No. of Establishments	Direct Reports	FLS Not Previously Aware of Conditions Disclosed by Audit
Hallmark	60	17	Yes
Establishment 1	88	28	Yes ⁵⁶
Establishment 2	69	31	Yes ⁵⁷
Establishment 3	54	19	No
Establishment 4	14	16	No
Establishment 5	53	16	Yes
Establishment 6	44	16	No
Establishment 7	29	14	Yes
Establishment 8	25	15	Yes ⁵⁸
Establishment 9	14	11	Yes
Establishment 10	24	17	Yes

At 7 of the 10 establishments visited, the FLSs were not aware of some or all of the conditions we noted. Based on discussions with the FLSs, we concluded that they were not aware of the conditions we noted because of the number of establishments they oversaw and their inability to spend sufficient time at each establishment.⁵⁹

The revised Circuit Maintenance Guidelines Directive has not been formally issued, and its effect on the structure of circuits nationwide cannot yet be assessed because we have not been provided the support and methodology for the assumptions used in the staffing guidelines. However, we did note the following when comparing the draft guidelines to the existing circuit structures for Hallmark and the 10 establishments reviewed during this audit.

⁵⁶ Due to a vacancy in another circuit, this FLS was assigned oversight over 2 circuits for a period of 6 months at the time of our audit.

⁵⁷ Due to a vacancy in another circuit, this FLS was assigned oversight over 2 circuits for a period of 6 weeks at the time of our audit.

⁵⁸ The circuit for this establishment did not have an FLS at the time of our audit; the deputy district manager was providing supervision until the position could be filled.

⁵⁹ There are no guidelines describing the specific amount of time an FLS should spend at an establishment on any given visit.

- The FLS for Hallmark exceeded both the recommended numbers of establishments and direct reports provided by the draft guidelines.
- At 7 of the 10 establishments we visited, we noted that the FLSs had not been aware of conditions that we noted, a situation we attributed at least in part to the FLS' supervisory span of control. Of these, three exceeded the recommended number of establishments in the draft directive while three exceeded the recommended direct reports.⁶⁰

We concluded that supervision and oversight at Hallmark was not adequate to prevent or detect the inspection deficiencies identified to date. This was clearly evident by the IPPS reviews of the PHV; these reviews did not identify deficiencies in his work. In addition, we concluded that supervision and oversight of inspection operations can be strengthened by re-assessing supervisory span of control.

Why Did FSIS' Management Controls Not Provide an Alert of Potential Problems at Hallmark?

As noted previously, FSIS has made significant strides in the development of an overall management control system through the use of IPPS and AssuranceNet. These systems should have notified FSIS managers of potential problems at Hallmark. However, there are inherent limitations in both systems, as designed, because they depend heavily on reliable, in-plant observations by FSIS' in-plant inspectors and the FLS.

The IPPS system is a tool for supervisors to assess the work of non-supervisory inspection personnel. The IPPS review process provides a framework and guidelines for supervisors to use in evaluating employee performance; it also allows higher-level supervisors at the district and Headquarters levels to review and evaluate the adequacy of the performance assessments. The IPPS reviews performed by the FLS at Hallmark – particularly those documenting the performance of the PHV – should have disclosed the fact that required procedures for ante-mortem inspection were not being followed.

In an interview following the release of the HSUS videos, the FLS who oversaw Hallmark stated that he had not been aware of the noncompliant practices being followed by the PHV, such as allowing establishment employees to fill out required paperwork or the suspecting of entire pens of animals. Therefore, these problems were not reflected in his IPPS review of the PHV.⁶¹

⁶⁰ We did not assess the number of indirect reports at these establishments because we were not aware, at the time of fieldwork, this would be one of the measurement criteria in the draft guidelines.

⁶¹ The investigation is still ongoing, and we do not have complete information as to why the FLS did not become aware of these issues. However, based on interviews taken as part of the investigation, the FLS noted that some of his onsite reviews were very limited. He cited the number of establishments he was responsible for as one contributing factor.

The AssuranceNet system is the second and broader component of FSIS' management control process. This system tracks and monitors the performance of FSIS personnel in several key functional areas related to food safety and security; each functional area contains one or more monitored performance measure in which current performance is measured against predetermined thresholds. For instance, AssuranceNet monitors whether district management teams⁶² are reviewing at least 10 percent of the IPPS reviews performed within their districts each year; at least 1 percent of these must be done on-site, by accompanying the FLS or other supervisor.

AssuranceNet is primarily designed to monitor performance trends at the circuit level and higher. We reported limitations with FSIS' management control systems in a prior audit, Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, dated December 2007. In that audit, we reported that AssuranceNet was not used to review the performance of individual establishments unless the entire circuit failed to meet a particular performance measure. We recommended that FSIS provide guidance to its management officials to view performance data down to the establishment level, as well as the circuits and districts. In response, FSIS issued new guidance⁶³ for managers to use in reviewing AssuranceNet's performance indicators. However, the new guidance still characterizes AssuranceNet as a monitoring tool at the circuit level and higher; managers are only expected to "drill down" to individual establishments when issues are identified at the circuit level.

The effectiveness of both systems can be reduced if district management teams⁶⁴ do not ensure that IPPS reviews are being adequately performed. AssuranceNet data for the period July 1, 2007, through August 28, 2008, showed that only 6 of 15 districts had met or exceeded their targets for reviewing 10 percent of the completed IPPS reviews. Of the remaining nine districts, five completed half or fewer of the required reviews.⁶⁵ Also, district management teams in 3 of 15 districts had not performed the required onsite reviews during the performance of IPPS reviews at establishments.⁶⁶ Of our six sampled districts, we found that only one met its 10 percent review requirement, with three completing fewer than half. Two districts had not completed any onsite reviews with the FLSs. If these reviews are not performed, FSIS district managers cannot assure that FLSs are providing the proper oversight of in-plant inspectors.

⁶² The district management team consists of the district manager and the deputy district managers.

⁶³ FSIS Notice 19-08, issued on March 26, 2008.

⁶⁴ For AssuranceNet purposes the district management team in each district is composed of the district manager and the deputy district managers.

⁶⁵ In 2008, FSIS extended the end of its rating cycle from June 30 to September 30 to meet the Departmental requirement for all USDA employees to be on the same rating cycle; for this year, therefore, the rating period was not yet complete.

⁶⁶ This includes the district where Hallmark is located.

What Other Controls Should Have Alerted FSIS to Potential Problems at Hallmark?

In fiscal year 2001, Congress provided funds to establish 17 District Veterinary Medical Specialist (DVMS) positions dedicated to the oversight of compliance with the Humane Methods of Slaughter Act (HMSA). About 75 percent of the DVMS' time is to be spent on field reviews and correlations, which include visiting slaughter establishments to observe humane handling practices. If violations are observed, the DVMS may recommend that the inspector write NRs or administer suspensions.

A DVMS review was performed at Hallmark in December 2005, more than 2 years before the release of the HSUS videos. The DVMS report documented serious offenses and recommended an NR be written by the PHV. However, there is no evidence in the report that the DVMS ever questioned why such activities had not been previously identified by the PHV or CSI (see Finding 1 for a further discussion of this problem). FSIS needs to establish a control to ensure that DVMS reviews are correlated with prior reported violations to determine whether inspection processes need to be reassessed or other administrative actions taken.

What Controls Should Be Strengthened to Ensure Its Personnel Possess the Skills and Knowledge Needed for the Tasks Assigned?

FSIS offers a variety of training courses, both formal classroom and online, to develop the competencies of its inspection staff. PHVs are required to take a 9-week PHV course before they can assume that position in the field. CSIs are provided Food Safety Regulatory Essentials (FSRE) training that covers HACCP oversight duties. FIs are given Slaughter Inspection Training that includes, among other subjects, training on humane handling requirements and ante-mortem inspection. Other training is available online to inspectors through AgLearn,⁶⁷ including three courses that deal with SRMs and the removal of SRMs from carcasses.

FSIS, however, does not have a formal, structured developmental program in place to demonstrate and ensure that all of its employees receive both formal and on-the-job training. Since FSIS' inspection staff is directly involved in ensuring the safety of the food supply, we believe a structured program of continuing education, certified each year, would provide the organizational control needed to demonstrate a knowledgeable and qualified workforce.

FSIS training requirements are not clearly defined in FSIS' written policy or directives. FSIS Directive 4338.1, dated March 4, 2004, Training as a Condition of Employment, requires that the PHV, CSI, and Enforcement Investigations and Analysis Officer (EIAO)⁶⁸ receive training within one year of entry into their positions. However, the type of training the CSI is to receive is not specified, and the FI position is not covered in the directive. Although FSIS has a system in place to track the training each employee

⁶⁷ USDA's online training system.

⁶⁸ The EIAO serves as a consumer safety officer and conducts onsite food safety and other verification activities, as well as investigations and analysis for administrative and civil enforcement matters.

receives, there is no requirement in place for managers to validate and certify that all mandatory training has, in fact, been received.

FSIS Headquarters officials stated that FIs should receive Slaughter Inspection Training during the first year of their employment. According to FSIS officials, this training would, among other things, give them the basic knowledge for performing ante-mortem inspections. However, of the 66 FIs that had been assigned to Hallmark and the 10 establishments we visited during our audit, only 39 (59 percent) had ever taken this training. Although the PHV at Hallmark did not allow FIs to perform ante-mortem inspection, the PHVs at four of the other establishments we visited did.

We noted similar concerns regarding the training provided for the removal of SRMs from carcasses of cattle over 30 months of age. Although FSIS officials stated that they attempt to provide each PHV and offline inspector with one of the SRM courses available online from AgLearn, we found that 7 of 18 CSIs did not have this training.

FSIS officials stated that an important component of their overall training program is the on-the-job training provided by the PHV and/or IIC in each establishment. However, no formal program has been developed for demonstrating what specific on-the-job training should be provided, nor are PHVs required to maintain any specific documentation of the training provided.

Given the critical public health mission of FSIS, we believe that FSIS needs to strengthen its human capital management by establishing a structured training and development program, with strong organizational controls, to demonstrate the competency of its workforce in fulfilling its mission. These organizational controls should be comparable to the continuing education requirements for other technical and scientific professions.

Recommendation 5

Develop a documented, supportable methodology for assigning in-plant inspection staff for offline inspection activities, including a basis for assignment at different types of plants.

Agency Response

Concurrent with the effort to strengthen its public health infrastructure through the development of PHIS, FSIS is planning changes to its offline inspection personnel work. Models are being designed to estimate time, procedures, and frequency of tasks required by establishment shift. These are inclusive offline work assignments that include ante-mortem and post-

mortem inspection responsibilities. Testing of the new method of offline inspection is scheduled for the spring of 2009, and the work assignment assumptions used to develop the models will also be available at that time. FSIS expects to implement this process by June 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 6

Reassess and support the methodology used to establish the supervisory span of control for frontline supervisors.

Agency Response

FSIS officials stated that the primary objective of revising the Circuit Maintenance Guidelines was to provide agency managers with key parameters to use in determining the optimum numbers of FLS positions based on the number of establishments, employees, and travel within a district. They stated that the directive implementing the guidelines was not an attempt to develop a work measurement instrument for the FLS position, nor could it determine the absolute span of control of the FLS position due to the highly variable nature of their work. Revising the Circuit Maintenance Directive created 17 additional circuits; this resulted in fewer establishments per circuit, fewer direct and indirect reporting lines to the FLSs, and reduced travel time.

They stated that the increase in the total number of FLS positions will provide management with the opportunity to strengthen management controls over in-plant inspection activities, including the application of HACCP programs, and allow for more routine on-site reviews of in-plant operations and ongoing assessments of inspection data generated at the in-plant level. The new Circuit Maintenance Guidelines Directive was completed in September 2008, and FSIS will fully implement the directive during the second quarter of FY 2009. Further, FSIS will perform an assessment of the new guidelines by the end of March 2010 to determine, among other things, the impact of the reduction of the FLS span of control.

OIG Position

We accept FSIS' management decision.

Recommendation 7

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.

Agency Response

FSIS will establish policies and procedures to ensure that all mission critical occupational groups (FLS, PHV, CSI, 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. These policies and procedures will be implemented in a directive or notice to be issued by September 2009.

In the interim, to ensure that inspection program personnel demonstrate the appropriate level of competency, the IPPS Supervisory Guide has been modified to include explicit instructions to conduct an IPPS assessment to observe and evaluate the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible. The guidelines provide a “work method” to ensure that supervisors ask the right questions and observe the inspection personnel on every aspect of their jobs. These observations are required to be documented in the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken and perform a follow-up IPPS review within 60 days. The draft IPPS Supervisory Guide is out for comment with the districts and FLSs, and FSIS plans to issue the revised guideline by December 2008.

OIG Position

We accept FSIS’ management decision.

Recommendation 8

Strengthen management controls to ensure that district management teams are performing on-site evaluations of IPPS reviews at the minimum frequency required by AssuranceNet. In addition, evaluate whether the frequency of these reviews should be increased.

Agency Response

FSIS officials stated that 4 of the 15 districts had not met the requirement for reviewing 10 percent of IPPS assessments performed during the last rating cycle, while one district had not met the 1 percent standard for onsite reviews of IPPS assessments. They stated also 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 followup due to deficiencies identified by the rating supervisors. Following the next IPPS cycle, an assessment will be performed on these improvements to determine whether they resulted in the districts meeting the required IPPS frequencies. A report will be prepared of the results of this assessment. This is expected to be completed in November 2009.

OIG Position

We accept FSIS' management decision.

Section 2. FSIS Pre-Slaughter Activities

Under the FMIA and FSIS regulations and directives, FSIS inspectors are required to examine and inspect all livestock before slaughter. The purpose of this process, called ante-mortem inspection, is to ensure that animals accepted for slaughter are only those that are healthy, without non-violative levels of chemical and drug residues, and otherwise suitable for conversion into safe, wholesome products. This part of the overall inspection process is critical because certain animal health conditions⁶⁹ can only be assessed while animals are still alive. If performed properly, ante-mortem inspections can be expected to remove obviously diseased animals from the food supply prior to slaughter and to identify animals that require a more extensive post-mortem examination by an FSIS veterinarian.

Thus, if an establishment fails to present animals for ante-mortem inspection, or if these inspections are not carried out in accordance with FSIS directives,⁷⁰ a vital safeguard to prevent diseased or otherwise unfit cattle from entering the food chain may be compromised; this was one of the related concerns raised about the egregious humane handling incidents at Hallmark.

Finding 3

Inspectors Did Not Comply With Required Inspection Procedures and/or Used Inconsistent Methods in Performing Ante-Mortem Inspections

Our reviews at 10 cull slaughter establishments found varying degrees of noncompliance and/or inconsistent implementation of required ante-mortem inspection procedures. While nothing came to our attention to indicate that unsuitable animals were being passed for slaughter at these establishments, some of the practices we observed would reduce the level of assurance that unsuitable animals would be detected and effectively controlled for proper disposition. In our visits, we found that 8 of the 10 establishments were not following required accountability procedures designed to ensure that only animals that had passed ante-mortem inspection are slaughtered. In addition, at 5 establishments we questioned the adequacy of the practices used in the ante-mortem inspection process itself. The observations made during this audit, and the conclusions reached, are limited to operations that slaughter cull cows since these animals are of higher risk for pathological conditions and the presence of drug residues.

⁶⁹ Conditions of the central nervous system can only be detected when the animal is alive.

⁷⁰ 21 U.S.C. 603 and 9 C.F.R. 309.1 and FSIS Directive 6100.1, dated September 13, 2007.

Management controls designed to provide proper oversight of the inspection process, as well as organizational controls to demonstrate the sufficiency and competency of the inspection staff, were not sufficient to identify and enforce compliance. In at least two cases, the inspectors did not follow required procedures because they felt the conditions at their establishments allowed for deviations. This was particularly true at smaller establishments, where inspection personnel believed they could visually track and monitor individual animals through the ante-mortem inspection and slaughter processes. In one instance, the PHV stated that there was insufficient time or personnel to perform ante-mortem inspection in the manner required by Directive 6100.1; in others, the inspectors cited limitations or restrictions resulting from the physical layout of the slaughter establishments. FSIS supervisory personnel were either unaware of these situations or did not believe they were problems that needed to be corrected. The concerns we noted in the ante-mortem inspection procedures at the 10 cull establishments are described below.

***Inadequate
Tracking of
Animals***

At five establishments, FSIS inspectors allowed establishment employees to control the required accountability process that is designed to provide assurance that only animals that have received ante-mortem inspection are allowed to go to slaughter. Directive 6100.1 requires FSIS inspectors to verify that slaughter establishments have animal identification systems in place to identify each animal, and ensure that ante-mortem inspection is performed on each animal.

The directive does not provide specifics on the required animal identification systems, but does cite the “pen card” system as an example. Under this method, each pen of animals presented for ante-mortem inspection is accompanied by a pen card⁷¹ which, at minimum, lists the number and type of animals being presented. At the discretion of individual establishments, other information such as owner identification can be included. The signature of the FSIS PHV on a pen card is used to provide evidence that the associated pen of animals has received ante-mortem inspection.

Inspectors did not effectively use the pen cards or other techniques to ensure that all animals moved to slaughter receive ante-mortem inspections. Specifically, we noted the following.

⁷¹ One of the 10 establishments we visited used an equivalent form called a drive sheet, which combined information from multiple pens of animals rather than separating them on individual cards.

- At three of the five establishments, inspectors did not verify that the number of animals shown on each pen card reflected the number of animals being presented for ante-mortem inspection and passed for slaughter. As noted in Finding 1, inaccurate data on pen cards could potentially be used by establishment employees to bypass the accountability system and move uninspected animals to slaughter.
- At four of the five establishments, inspectors did not, even on a periodic basis, reconcile the pen cards to establishment slaughter records to ensure that the number of animals slaughtered did not exceed the number on which ante-mortem inspection had been performed. Since FSIS, in its training, recommends that PHVs maintain pen cards for one week, the only record remaining to document the number of animals passing ante-mortem inspection and approved for slaughter are the establishment slaughter records. Therefore, reconciliation of this accountability system by the inspector is a critical control.
- At one establishment, the inspector simply pre-signed blank pen cards and provided these to establishment personnel for later use. When interviewed, the inspector claimed not to have understood the purpose or significance of these cards.⁷²

The failure to properly control, verify, and reconcile animals approved for slaughter could potentially facilitate deliberate acts to bypass inspection processes.

Animals Were Not Consistently Observed at Rest and in Motion

Ante-mortem inspection procedures were either incorrectly or inconsistently implemented at 5 of the 10 establishments we visited. Animals were not always observed both at rest and in motion, nor were they always observed individually. Inspection personnel attributed their actions to either a lack of sufficient time or personnel to conduct the inspection procedures as required, or to limitations in the physical structure and layout of the establishments.

At three establishments, inspectors did not always observe cattle both at rest and in motion, as required,⁷³ when performing ante-mortem inspection. FSIS training materials⁷⁴ state that certain abnormal signs, such as labored breathing, are easier to detect while the animals are at rest. However, other abnormalities, such as lameness, may not be detected until the animals are in motion. Either of these conditions are potential signs that animals may be suffering from pathological conditions, violative drug residue levels, or central nervous system conditions, which would require that they be either condemned and immediately euthanized, or else designated as “U.S. Suspect”

⁷² Inspection operations at this establishment are currently the subject of an OIG Investigation.

⁷³ FSIS Directive 6100.1, Ante-Mortem Livestock Inspection, dated September 13, 2007.

⁷⁴ FSIS Training Module, Basic Livestock Slaughter and Inspection.

so that their fitness for human consumption can be evaluated during post-mortem examination.

Animals Not Observed on Both Sides

We noted inconsistent practices for viewing animals on both sides during ante-mortem inspection. At three establishments, inspectors did not observe both sides of the animal. Although regulations do not require in-motion inspection from both sides, this procedure is taught to new inspectors as the proper method of inspection. FSIS training materials citing this procedure are available to the public from FSIS' website. Observation of both sides of the animal is important at establishments that slaughter older cattle that are more susceptible to disease.

FSIS Headquarters officials stated that there is no requirement, nor is it necessary, to view the animals on both sides. However, inspectors at 7 of the 10 establishments we visited were, in fact, viewing both sides of the animals during ante-mortem inspection. Our discussions with a representative of the World Organization for Animal Health, Office International des Epizooties (OIE),⁷⁵ disclosed that while there are no specific guidelines for observing animals from both sides during ante-mortem inspection, OIE considers it preferable to view animals from both sides for a more complete examination in regards to clinical conditions that may be visible from only one side of the animal. We also consulted two independent experts, who believed that viewing both sides of an animal was important for identifying eye tumors, abscesses, open cuts or other wounds that might not be apparent at post-mortem.

Animals Not Observed Individually

At four establishments, inspectors did not observe the animals individually. Instead, animals moved past the inspector concurrently in rows or groups of three to four animals deep, effectively obscuring the observation of potential injuries and abnormalities of each animal. Inspection personnel cited a variety of reasons for not observing the animals individually, such as lack of time or because they did not believe it was required. Although FSIS Directive 6100.1 does not specifically require the individual inspection of each animal, FSIS training materials state that inspection personnel should direct the establishment to move all of the animals slowly and individually so inspection personnel can identify any abnormalities. We discussed this issue with experts in veterinary medicine, whose opinions were that in order to identify animal maladies during ante-mortem inspection, it is important that animals be viewed on an individual basis.

⁷⁵ OIE (also referred to as the World Organization for Animal Health) is an international animal health organization based in France that has developed the Terrestrial Animal Health Code which contains guidelines for use by importing and exporting countries to avoid the transfer of agents pathogenic for animals or humans, while avoiding unjustified sanitary barriers.

**Suspect Animals
Not Properly
Identified or
Segregated for
Slaughter**

FSIS requires that animals exhibiting signs of disease during ante-mortem inspection be segregated for further examination by a PHV. Regulations require that animals identified as “U.S. Suspect” be identified with a serially numbered ear tag and be slaughtered separately from healthy animals.⁷⁶

At six establishments, however, we noted that inspectors did not properly use ear tags to identify suspect or condemned⁷⁷ animals. The PHV at one establishment considered ear tags to be inhumane, while two others told us they visually tracked the animals. Two other PHVs used alternate systems that did not include ear tags,⁷⁸ and one PHV did not feel they were necessary because he considered every animal “suspect.” At four establishments, inspectors were not using the required FSIS Form 6150-1 to document animals designated as suspect; two of these were also not using Form 6150-1 to document when animals became non-ambulatory in the chute. The FLSs were not aware FSIS procedures were not being followed; in at least one instance, however, the FLS was aware of the situation but allowed the PHV to continue this practice. Without proper tagging of suspect and condemned animals, there is reduced assurance that inspectors are properly identifying and tracking the animals through the inspection and slaughter processes.

At two of these establishments, we also observed that suspect animals were not set apart and slaughtered separately from other healthy animals as required by regulations. At both establishments we identified issues with other aspects of the control systems designed to properly identify and control the movement of suspect animals. Inspectors at both establishments were not using ear tags to identify suspects, nor were they performing a reconciliation to slaughter records. The FLSs for these establishments stated they were not aware of these noncompliances because they had responsibility for more than one circuit and had not been able to spend significant time at any one establishment.

**Non-
Veterinarians
Have Performed
Ante-Mortem
Inspection
Without Formal
Training or Direct
Supervision**

Information published by FSIS states that the PHV is either performing or verifying ante-mortem inspection on every animal.⁷⁹ However, this is not an FSIS requirement. In our visits to 10 cull cow slaughter establishments, we observed that the PHVs at 7 establishments allowed the CSI and/or FI to perform ante-mortem inspections on either a regular or occasional basis. We found that while the PHVs at these seven establishments always performed follow-up examinations of animals the inspectors recommended be either suspected or condemned, no such check was performed on animals that had been passed for slaughter. FSIS does not have a system in place to reliably

⁷⁶ Title 9 C.F.R., Part 309, Ante-Mortem Inspection (309.2(n) and 309.18 (a)), issued January 2008.

⁷⁷ Title 9 C.F.R 309.18(c) requires that animals classified as “condemned” be identified with a serially numbered ear tag.

⁷⁸ At one establishment, the PHV attached the FSIS Form 6150-1 Identification Tag, directly to the pen card until the animal was slaughtered; after slaughter, the tag was attached to the tongue. At another establishment, the PHV used a U.S. Retained Tag, in lieu of a suspect ear tag. Neither of these methods complies with Directive 6100.1 and increase the risk that suspect carcasses may be misidentified at post-mortem inspection.

⁷⁹ BSE Rules Being Strictly Enforced, August 2005.

demonstrate that these non-veterinary employees have either the training or knowledge to perform ante-mortem inspections.

FSIS procedures are not specific as to the level of supervision that a PHV should exercise over non-veterinarian inspectors during ante-mortem inspections. FSIS Headquarters officials stated that it is an acceptable practice to leave the determination as to who can conduct ante-mortem inspection to the individual PHV. They stated that non-veterinarians can be trained to identify signs that indicate an animal's possible unfitness for slaughter. These signs are taught as part of FSIS' Basic Livestock Slaughter Inspection training, which FSIS officials stated that they attempt to provide to all newly-hired food safety inspectors during their first year on the job. Further, the PHV is responsible for assuring that their subordinate inspectors are adequately trained to perform ante-mortem inspection. The PHVs we interviewed stated that as long as the inspector had proper on-the-job training, they did not have to be physically present when the inspector conducts ante-mortem inspection.

Based on our observations, however, we question whether even a fully trained non-veterinary inspector can be expected to identify clinical signs that might warrant further examination. For example, the PHV at one establishment stated that cows with retained fetal membranes may have a metritis⁸⁰ condition and should be designated as "suspect" animals. This would require further examination by a PHV at both ante-mortem and post-mortem inspection. However, we observed that the CSI at this establishment passed three such animals for slaughter without further examination by the PHV. Discussions with FSIS personnel and a review of disposition guidelines revealed that a number of factors would have to be considered when determining whether to pass such an animal for slaughter. The guidelines provide for consideration of factors such as discharges, temperature, and other clinical signs. We question whether an inspector without veterinary training can make such determinations. At another establishment, the PHV allowed an entry-level FI, who had been on the job four months, to perform ante-mortem inspection without formal training. The on-the-job training was not documented but we were informed by the FI that his training encompassed "hands-on observations and review of photographs."

In addition, FSIS could not demonstrate that all of its employees who performed ante-mortem inspection had received the required formal training. Although all 18 CSIs at the 10 plants we visited had received formal training, this was not the case for 10 of the 25 FIs, at 2 of the 4 establishments⁸¹ where the PHVs assigned FIs ante-mortem inspection responsibilities. FSIS officials stated that formal training was of less importance in an employee's development than on-the-job training provided by the PHV. However, there is

⁸⁰ Bacterial infection of the uterine tract.

⁸¹ At the other 6 establishments of the 10 in our sample, the PHVs or CSIs performed all ante-mortem inspections.

no evidence or system that documents either the type or extent of training given to each employee by the PHV. Also, there is no structured training program that documents and certifies that non-veterinary employees are being trained in a consistent manner (See section 1 for a discussion on this necessary organizational control).

Ante-mortem inspection is a critical part of FSIS' overall system of controls to prevent unfit animals from being slaughtered for human food. Adequate controls must be established and implemented to ensure that ante-mortem inspections: (1) are being performed on every animal that goes to slaughter; (2) comply with the procedures required under FSIS directives; and (3) are either performed by trained veterinarians, or by properly-trained inspectors.

Recommendation 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.

Agency Response

FSIS is writing a new notice pertaining to verification of an establishment's identification records and to reconciling livestock numbers between ante-mortem and slaughter. The notice will clarify that the establishment is responsible for providing livestock data to inspection program personnel when requesting ante-mortem inspection. It will also explain that inspection program personnel are to verify this data when performing ante-mortem inspections, as well as the verification method to be used. In April 2009, FSIS will revise and reissue FSIS Directive 6100.1 (Ante-Mortem Livestock Inspection) to permanently capture the content of the new notice. The directive will also provide clarified tagging instructions for livestock that is determined to be U.S. Suspect or U.S. Condemned.

OIG Position

We accept FSIS' management decision.

Recommendation 10

Require inspectors to verify the accuracy of the animal counts on pen cards and drive sheets, and reconcile these to establishment slaughter records.

Agency Response

FSIS is writing a new notice pertaining to verification of an establishment's identification records and the reconciliation of livestock numbers between ante-mortem and slaughter. This notice will clarify that the establishment is responsible for providing livestock data to inspection program personnel when requesting ante-mortem inspection. The notice will explain that inspection program personnel are to verify the establishment's data when performing ante-mortem inspection as well as the verification method to be used. After livestock have passed this verification process during ante-mortem inspection, they may be moved to slaughter. The notice is expected to be issued in December 2008, and will be incorporated into Directive 6100.1 in April 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 11

Strengthen existing guidance for inspectors to observe animals both at rest and in motion during ante-mortem inspection.

Agency Response

FSIS will revise and reissue FSIS Directive 6100.1, Ante-Mortem Livestock Inspection, to clarify that inspection program personnel are to observe animals both at rest and in motion during ante-mortem inspection. The revised directive is expected to be issued in April 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 12

Implement controls to ensure that each non-veterinary inspector has received necessary training, both formal and informal, before performing ante-mortem inspections.

Agency Response

On September 10, 2008, FSIS implemented a structured on-the-job (OJT) training program for all food inspectors and other non-veterinary inspectors performing ante-mortem inspections. The new OJT program is one of six modules contained in the 2008 Interim Employee Development Guide which

provides resources to supervisors and trainers to aid in their training efforts in the first phase of a new inspector's career. The module contains several topics for which new inspectors must demonstrate basic proficiency, including Sanitation and SSOPs, and ante-mortem and post-mortem inspection. The module also includes forms which both the inspector and the supervisor/trainer must initial when the inspector has attained basic proficiency on each subject. The supervisor/trainer is required to add comments on each form reflecting both the inspector's strengths and weaknesses, and include their plan for improving any deficiencies in knowledge and/or execution. When all subjects in the module are completed, the forms are to be submitted to the district office so that formal classroom training can be scheduled.

Newly hired inspectors will be required to complete the classroom training in a timely manner, within 1 year of entering on duty. FSIS will also require that these inspectors recertify this training annually. To ensure that inspection program personnel have received the necessary training, OFDER/DAIG will conduct quarterly analyses of this training data and provide a report to the Office of Outreach, Education, and Employee Training and to the districts so that they can follow up on any instance where required training has not been received. The first report that will include a status of inspection program personnel who have received the structured OJT will be completed by September 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 13

Develop procedures to require PHVs 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.

Agency Response

FSIS officials stated 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. If supervisors find deficient performance, they are to ensure that remedial action is taken such as correlation or re-training, and to perform a follow-up within 60 days. The revised IPPS Supervisory Guidelines are currently out in draft, and FSIS expects to issue them in December 2008.

OIG Position

We accept FSIS' management decision.

Finding 4

FSIS Needs to Strengthen Controls Over Secondary Entrances to Prevent the Potential Slaughter of Unfit Animals

Eight of the 10 establishments we visited had usable, secondary access points (commonly called downer doors) to the establishments' slaughter areas, of which only three were secured under FSIS lock. Such entrances could, if not adequately monitored by FSIS, facilitate the movement of non-ambulatory or uninspected animals to enter the slaughter areas without FSIS' knowledge. Prior to 2004, establishments could use these special access areas to bring in animals for slaughter that were too weak to walk through the regular serpentine chutes to the stunning boxes. FSIS' ban of the slaughter of non-ambulatory animals made these structural features either obsolete or else usable only in very limited circumstances. However, FSIS has no policy in place for determining how, or if, these areas should be controlled.⁸²

We also noted that 4 of 10 establishments had winches above the primary stunning box that were not under FSIS lock. These winches could be used to drag non-ambulatory cattle into the establishment.⁸³ These secondary entrances and winches were generally not observable from FSIS' online inspection stations, and could serve as routes into the slaughter areas that could potentially bypass FSIS inspection. The lack of adequate animal accountability systems (see Finding 3) further increases the risk that such entry points can be misused, if not properly controlled.

In some instances, these doors and other facilities are needed as part of the slaughter process. For example, secondary stunning boxes might be used on healthy, ambulatory animals that cannot fit through the serpentine chute because of their size or other factors (e.g., longhorn cattle). However, controls should be put into place to ensure the establishment cannot easily move animals into the processing areas that potentially may not have passed inspection. FSIS has the authority to require that establishments only use

⁸² At Hallmark, such a secondary access area was padlocked; we could not determine when this occurred.

⁸³ Two establishments had both an unsecured winch and an unsecured downer door.

facilities and equipment that are essential to inspections.⁸⁴ FSIS can control secondary entrances and related work areas and equipment through the use of FSIS-controlled locks at all times when the doors or other facilities are not being used by the establishment.

As a result of our reviews, FSIS inspectors at one of the cited establishments informed us that they would implement this practice and affix locks to the establishments' secondary access door to ensure that they could only be used under FSIS supervision. We believe that FSIS needs to require that, at all establishments, these doors and other facilities be secured and maintained under FSIS control to ensure that they are used only under FSIS supervision.

Recommendation 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.

Agency Response

FSIS officials stated that the agency does not have statutory or regulatory authority to require that secondary entrances and equipment be placed under FSIS control. However, FSIS does recognize the need to ensure that these entrances and pieces of equipment are not used in violation of the statutes or regulations. By May 2009, FSIS will either issue a new FSIS notice or revise FSIS Directive 6900.1 Revision 1, "Humane Handling of Disabled Livestock," to clarify that inspection program personnel, through ongoing verification activities, are to ensure that secondary entrances and equipment are not used by official establishments to adulterate product, create unsanitary conditions, handle livestock inhumanely, or to violate the statutes or regulations in any other way. The issuance will instruct inspection program personnel to take regulatory control or other actions if official establishments misuse secondary entrances or equipment in such a manner.

OIG Position

We accept FSIS' management decision.

⁸⁴ Title 9 C.F.R. 305.3 and Title 9 C.F.R. 307.2

Finding 5**Effectiveness of Inspector-Generated Residue Testing as Part of the Ante-Mortem Inspection Process Needs to Be Re-Assessed**

FSIS administers the National Residue Program (NRP) in cooperation with EPA and FDA to control veterinary drug, pesticide, and environmental contaminant residues in meat, poultry, and processed egg products. The NRP encompasses two domestic sampling programs. One, Scheduled Sampling, tests randomly-sampled cattle that exhibit no signs of illness to determine the exposure assessment or the prevalence of residues in the national food supply. The other, Inspector-Generated Sampling, involves a rapid, in-plant screening test called FAST (Fast Antimicrobial Screening Test) on any carcass that, based on herd history, ante-mortem, or post-mortem inspection findings, there is reason to believe may have an illegal drug residue.⁸⁵ Cull cows, because of their age and general weakened health condition, have a higher risk for violative⁸⁶ residues than fat cattle.

FSIS publishes a Repeat Violator List as a means to assist in-plant inspectors in the identification of problem producers who repeatedly offer animals with violative residues for slaughter. If violative results occur, the PHV is to condemn the carcass and/or parts.

At Hallmark, we identified concerns with the implementation of the NRP. Through interviews with inspection staff conducted during the on-going investigation, we determined that the process for sampling for residues was not being followed, nor were test samples properly controlled. We also found these same noncompliances at 6 of the 10 additional cull slaughter establishments visited. Although required procedures were not followed, we were able to confirm that carcasses and/or parts identified as violative by inspector-generated samples at these six establishments were properly condemned and disposed of.

However, we did identify additional concerns with the design and implementation of the NRP that are outside the scope of this audit. Therefore, we will conduct a more in-depth review of the effectiveness of the NRP in a future audit effort.⁸⁷ This report is limited to a review of the process for obtaining and testing inspector-generated samples, as well as the management controls associated with this segment of the NRP.

⁸⁵ FSIS Directive 10,800.1, dated July 12, 2007.

⁸⁶ FSIS uses guidance from FDA and EPA for residue monitoring and tolerance action levels.

⁸⁷ This review was begun as part of the current audit, and will continue following issuance of this report.

***Clearer Direction
Is Needed for
Residue Testing
Based on Herd
History***

At 8 of the 10 establishments visited, inspection personnel (inspectors and PHVs) did not use herd history to select animals for residue testing.⁸⁸ Inspectors at two establishments relied solely on the establishment to inform them when animals from a past violator arrived for slaughter. FSIS has not provided clear direction on how to use repeat violator information as a basis for testing, nor did we find any monitoring of compliance with this program by FSIS. PHVs told us that it is difficult and too time consuming to check the data on manual pen or drive cards for repeat violators. In addition, the farm source of the herd is not usually documented when cattle are purchased through an auction facility. As a result, there is reduced assurance that meat products have been sufficiently tested for violative levels of residues from those producers determined to be most at risk.

***FSIS Cannot
Effectively
Monitor Residue
Test Results***

FSIS has not developed a process to monitor FAST test results, either to identify issues that need corrective action or to determine how the testing program itself might be improved. district officials do not have access to FAST test data in a usable format to facilitate oversight of the NRP.

For recordkeeping purposes, FSIS in-plant inspection personnel record the results of each sample test (whether positive or negative) on the 3-part FAST Worksheet. Once the worksheet (which has space for test results from 25 samples) is completed, the original is sent to the FSIS Financial Processing Center and a copy to the district office. The Financial Processing Center enters the information from the FAST Worksheet into a database, which is transmitted to FSIS Headquarters. We found, however, that this data may not always be complete. Staff at the Financial Processing Center stated that data from the FAST Worksheets are not entered when: (1) the establishment identification number is not included; (2) the data are not readable; or (3) the information is from the prior fiscal period. We found no evidence that followup was made to obtain clarification on the data reported.

The automated FAST test residue information is not shared with district offices, nor are all district officials even aware of its existence. An official with the FSIS Office of the Chief Information Officer (OCIO), which receives the data in Headquarters, stated that while their offices can run reports for the districts from the database upon request, there is no process in place to distribute it to the district offices on a recurring basis. We found three instances in which district offices were manually entering FAST test data into their own databases. One district, for instance, was attempting to use the data in conjunction with Electronic Animal Disposition Reporting System (eADRS) to determine what pathologies indicated a greater need for residue testing; another was attempting to assess the overall effectiveness of the agency's residue testing. In interviews, officials at one district stated that they were not aware that this data already existed in electronic format. Officials at

⁸⁸ FSIS Directives 10.800.1 and 10.220.3 state that herd history and prior residue violations are two of many factors that PHVs can take into consideration when selecting animals for in-plant testing.

another, however, stated that they had attempted to obtain the data from FSIS' Financial Processing Center but were not given access. We believe that to efficiently utilize this information, FSIS needs to implement an ongoing process to analyze FAST test results to monitor trends and to identify the need for enforcement action.

We also noted that because there are insufficient guidelines as to the extent of FAST testing a PHV in any given establishment should perform, the levels of testing varied greatly between even similar establishments. For example, we reviewed FAST test information maintained by the PHVs at two of our sampled establishments that had very similar operations and found significant variations in their testing programs. Establishment 1 and 6 received most of their cattle for slaughter from the same sources, and slaughtered 648,364 and 712,040 head of cattle, respectively, between January 2006 and April 2008. However, Establishment 1 performed 1,607 FAST tests and found 25 violations while Establishment 6 performed at least 41,837 FAST tests with 550 violations. In contrast to both of these, Establishment 10 performed no FAST tests at all for a period of more than 1 year, a fact that was not noted by the district office.

The analysis of FAST results can provide a basis for monitoring and verifying the effectiveness of residue testing performed by individual establishments. Without such analyses by the district offices or higher management levels, there is reduced assurance that the inspector-generated testing programs are being carried out in the most effective manner; or, as in the case of Establishment 10, are being carried out at all.

***Inspectors Did
Not Follow
Custody
Requirements for
Test Samples***

At six establishments (see exhibit B), inspectors did not adequately maintain custody of test samples. At four establishments, inspectors allowed establishment staff to obtain FSIS samples from carcasses or the associated viscera.⁸⁹ For example, at one establishment we observed establishment staff collecting tissues, placing the tissues and a USDA retain tag in clear plastic bags, inserting a swab into the kidney, tying the sample bags together, and placing the sample bags into a bucket located at an FSIS station. At three establishments, inspection personnel left test samples unsecured. For example, at one establishment, kidney and liver samples were placed on trays, tagged, and placed into a cooler that was not locked or under FSIS control. The inspectors stated that samples are often kept in the cooler overnight for testing the following day. Establishment staff has access to the cooler, and could easily tamper with, or switch, the samples. The district manager agreed that the samples should have been better safeguarded, and stated that they would need to discuss this issue at the district level.

⁸⁹ Viscera are the internal organs of an animal.

FSIS directives state that agency personnel are to collect tissue samples from slaughtered animals for residue testing and maintain adequate security over them until they can be shipped to the laboratory. The directive requires that inspection program personnel collect tissue samples every time there is reason to suspect that a violative residue is present.⁹⁰

FSIS requirements for securing test samples are clear, and FSIS needs to monitor compliance with these requirements. However, the requirements for collecting samples were less clear and could be misinterpreted. We believe these need to be clarified to prevent the use of non-FSIS personnel to perform this function.

Recommendation 15

Develop specific guidance and procedures for in-plant FSIS personnel to use herd history as a basis for performing residue tests.

Agency Response

FSIS receives a weekly report from USDA's National Information Technology Center that identifies establishments that have purchased, on more than one occasion, animals from the same supplier that have violative residues as confirmed by FSIS laboratories. Currently, upon receipt of this report, FSIS Headquarters notifies the district offices about these establishments through the shared Outlook residue mailbox files. By December 2008, FSIS will issue a notice instructing the district offices to inform all IICs (and their FLSs) at establishments known to have purchased livestock from repeat violators about new violations involving the violating firms. The notice will advise inspection program personnel about their responsibilities when they are informed that an establishment has repeatedly purchased animals from the same supplier with violative levels of residues. The notice will also give instructions to PHVs regarding additional residue sampling if an establishment continues to purchase livestock from these suppliers.

OIG Position

We accept FSIS' management decision.

Recommendation 16

Develop a process that provides on-going monitoring and analysis of inspector-generated residue sampling. Initiate follow-up actions when there are variances in inspector performance and/or residue test results.

⁹⁰ FSIS Directive 10,800.1, "Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program," dated July 12, 2007, and FSIS Directive 7335.1, "Use of Sample Seals for Laboratory Samples and Other Applications," Revision 2, dated December 3, 2002.

Agency Response

FSIS will implement the eSample system by June 2009 which, among other things, will be used to collect FAST or other rapid test results used in inspector generated sampling. The eSample database will eliminate any duties that FSIS' Office of Management currently has related to the collection of these test results at the Federal Processing Center in Urbandale, IA.

The Office of Public Health and Science (OPHS) Residue Branch will analyze data from eSample and the eADRS to include production volumes (number of head slaughtered), number of in-plant screening tests conducted and test results, both positive and negative, for each establishment on a quarterly basis. OPHS has identified and will implement the following parameters as part of this process: 1) select and monitor in-plant screening tests with acceptable sensitivity and low specificity (close to tolerance and low numbers of "false" positives); 2) improve inspector generated sampling criteria; and 3) establish uniform in-plant sampling between establishments. The estimated completion date for the first analysis is August 2009. Once the data are analyzed, OPHS will provide OFO and other FSIS program managers with a report indicating any discrepancies in in-plant screening testing procedures so that appropriate action can be taken.

OIG Position

We accept FSIS' management decision.

Recommendation 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.

Agency Response

FSIS has selected a new in-plant residue test screening method to be used by inspectors in all slaughter establishments. By April 2009, FSIS will draft a directive to provide instructions to field personnel regarding comprehensive criteria for performing in-plant residue screen tests (herd history, current health of animal presented for inspection, etc.). The directive will also provide directions on how to collect and submit samples to ensure sample integrity and how to secure samples onsite prior to their submission to the FSIS laboratories. To further ensure that inspectors are fully aware of the protocol for shipping samples, FSIS will link the new directive to the current FSIS Directive 7355.1, Revision 2, "Use of Sample Seals for Laboratory Samples and Other Applications."

OIG Position

We accept FSIS' management decision.

Section 3. Specified Risk Materials

To mitigate public concerns that downer cattle from Hallmark or other slaughter establishments can enter the food supply, FSIS cited four interlocking safeguards that would protect the public health even if other controls to prevent unfit animals from being slaughtered should fail. These are the feed ban,⁹¹ BSE surveillance testing, the prohibition of non-ambulatory or disabled “downer” animals from the food supply, and the removal of Specified Risk Materials (SRMs) from cattle at the time of slaughter. USDA requires the removal of SRMs because these tissues have been identified as vectors for BSE. Beef slaughter and processing facilities are required to incorporate controls for handling such materials into their food safety systems.⁹² FSIS provided interim guidance for controlling SRMs in January 2004, and published a final SRM rule on July 13, 2007. In addition to affirming the interim rule, the final rule added regulations for monitoring the removal of SRMs by downstream processors.⁹³

Under these requirements, establishments must remove specified parts such as tonsils and distal ileum from the carcass of each animal.⁹⁴ Establishments must also have procedures in place to ensure that carcasses of younger animals are not cross-contaminated with SRMs from older animals, and also to ensure that unused parts containing SRMs are destroyed or denatured to prevent their possible re-use. Because of the importance which USDA places on the SRM removal process, and because cull establishments such as Hallmark predominately slaughter older animals (over 30 months old) for which SRM removal is most critical, we reviewed the effectiveness of FSIS’ controls over SRM removal at the 10 establishments we visited.

During our establishment visits, we observed FSIS’ methods of providing oversight of the SRM removal process and verified that FSIS inspectors were, in fact, observing the removal of SRMs from each carcass that passed through the slaughter process. However, we noted several areas where we believe FSIS can strengthen its management controls to ensure adequate oversight and enforcement of SRM requirements. These areas are described below.

⁹¹ The Food and Drug Administration has primary responsibility for preventing the introduction of BSE from animal feed.

⁹² SRM controls can be incorporated in either HACCP, SSOP, or pre-requisite plans.

⁹³ An establishment that does not slaughter, but receives carcasses from a slaughter establishment for further processing.

⁹⁴ For animals over 30 months of age, additional parts are classified as SRMs. These include the brain, eyes, and vertebral column.

Finding 6**FSIS Needs To Strengthen Its Monitoring of the Effectiveness of SRM Intervention Procedures**

In recent years, FSIS has made significant strides in the development of management control processes to accumulate and analyze food safety data and to strengthen the agency's monitoring of food safety activities. However, despite the level of importance that agency officials attribute to removing SRMs from the food supply and in preventing the contamination of edible carcasses and parts, FSIS' management control systems provide little information for oversight of these activities. We found that neither PBIS, AssuranceNet, nor IPPS are currently designed to provide managers at the Headquarters and district office levels with data to detect trends of noncompliance or to identify areas where more in-plant oversight is needed. In addition, we noted that managers are not always using all available data as part of their monitoring efforts. As a result, FSIS cannot effectively demonstrate that its verification of establishment controls and written procedures for the removal, segregation, and disposition of SRMs is adequate to detect noncompliance.

FSIS' overall management control structure depends upon several key systems to provide managers with information to monitor the performance of food safety operations in slaughter establishments. These systems include:

- PBIS, which assigns inspection tasks in support of HACCP, and which records both the performance of those tasks and the extent of noncompliance at each establishment;
- IPPS, which provides a framework and guidelines for supervisors to use in evaluating the performance of non-supervisory employees; and
- AssuranceNet, which uses data from PBIS, IPPS, and other sources to track and monitor the performance of FSIS inspectors in several key functional areas.

OIG identified the need for FSIS to strengthen these management control systems in several prior audits.⁹⁵ We also raised concerns relating to the monitoring and control of SRMs in an audit issued in January 2006.⁹⁶ Although FSIS has implemented corrective actions in response to our recommendations, we found that additional actions are needed as described below.

⁹⁵ These audits include 24601-3-Ch, *Use of Information Technology Systems*, issued in September 2004; 24601-6-Ch, *In-Plant Performance Systems*, issued in March 2006; and 24601-7-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, issued in December 2007.

⁹⁶ Report 50601-10-KC, *Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II and Food Safety and Inspection Service Controls Over BSE Sampling, Specified Risk Materials, and Advance Meat Recovery Products – Phase III*, dated January 2006.

PBIS Does Not Contain Specific SRM Inspection Tasks

The inspection tasks conducted by FSIS inspectors are partly assigned by PBIS. PBIS creates a list of tasks each morning that direct the inspectors to review different aspects of an establishment's operation. The system has codes that may include SRM handling procedures and practices, but nothing that specifically directs the inspectors to examine them. Instead, an inspector can choose to examine another part of the establishment's operation that falls within the general inspection task category. We previously reported⁹⁷ that because of the lack of any specific PBIS tasks relating to SRMs, and because all of the establishments we reviewed elected to incorporate their SRM procedures into pre-requisite plans⁹⁸ rather than into HACCP, we could not determine the extent to which this area was being monitored or evaluate the effectiveness of FSIS' controls over SRM removal.

In our previous audit,⁹⁷ we recommended that FSIS establish specific tasks within PBIS to verify SRM control procedures. FSIS proposed, and OIG accepted, an alternative action to facilitate more comprehensive searches of PBIS data through the use of dropdown menus (see next topic).

In our current audit, 8 of the 10 cull slaughter establishments we visited elected to place their SRM control procedures in pre-requisite plans. Inspectors at the establishments we visited stated that they performed the necessary SRM procedures, but could not provide documentation of what was done. Although we did not observe any SRMs entering the food supply, FSIS officials cannot demonstrate that the level of its inspection efforts for SRMs is adequate.

FSIS' Ability to Review and Analyze SRM Noncompliance Records Continues To Be Limited

In response to our previous audit,⁹⁷ FSIS enhanced PBIS by adding a dropdown menu of keywords and regulatory citations. The dropdown menu allows inspection personnel to select from a list of regulatory citations and choose the appropriate provisions to describe the types of noncompliance that could be found while performing a given PBIS verification procedure. However, work performed as part of a more recent OIG audit⁹⁹ disclosed that over 50 percent of the SRM-related NRs did not cite the appropriate provisions of Title 9 C.F.R. 310.22 that would allow noncompliances to be readily identified by reviewers, such as by Executive Assistants for Regulatory Operations (EARO)¹⁰⁰ or district analysts. We found, during this audit, that while most inspection personnel were aware of the dropdown menu, many stated they did not use it when documenting SRM noncompliances because they lacked knowledge and experience in dealing with this particular type of noncompliance.

⁹⁷ Report 50601-10-KC, *Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II and Food Safety and Inspection Service Controls Over BSE Sampling, Specified Risk Materials, and Advance Meat Recovery Products – Phase III*, dated January 2006.

⁹⁸ Pre-requisite programs are practices and conditions needed prior to and during the implementation of HACCP. They are often facility-wide programs rather than process or product-specific.

⁹⁹ Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, dated December 2007.

¹⁰⁰ The EAROs are the next level of management above the district level. Each district manager reports to one of the three EAROs.

District officials we interviewed during the current audit stated that although they are able to access NRs through PBIS, their ability to analyze them is limited.¹⁰¹ In some cases, district officials stated that they did not know how to perform keyword searches; others cited the difficulty in searching technical terms that may be spelled in various ways by in-plant inspectors in the NR narratives.¹⁰² This limitation, combined with the lack of regulatory citations on the NRs themselves, make it difficult to identify which NRs are SRM-related without a lengthy manual review. All of the officials we interviewed stated that they were not performing such reviews.

FSIS has not enhanced PBIS to facilitate the monitoring of SRM control compliance due to the current focus on developing the replacement PHIS system. However, without some type of district-level monitoring of SRM-related NRs, district managers and other officials cannot determine whether in-plant inspection staffs are adequately monitoring and enforcing SRM requirements. When implementing PHIS, FSIS officials need to ensure that NRs for SRMs can be readily accessed and analyzed by managers in the same manner that NRs for other types of violations presently can be.

We also noted that FSIS inspectors at the establishments we visited were not always writing NRs, even when they observed violations. This problem, if not corrected, can also limit managers' awareness of the true extent these violations are occurring. This condition is discussed in Finding 7.

**Managers Are
Not Using
Available Data**

Although the district offices reviewed were not performing analyses of SRM-related NRs, the Office of Food Defense and Emergency Response (OFDER)¹⁰³ was performing such analyses on a monthly basis and compiling this data into a monthly SRM Noncompliance Report. Because of the system limitations previously noted, OFDER officials stated that a significant manual review effort is needed to produce these reports. For example, use of keyword searches allowed FSIS to identify about 240 NRs that appeared to be SRM-related out of a total of 7,800 NRs written in December 2007. However, each of the 240 had to be read manually to identify the 23 NRs that, in OFDER's assessment, actually represented SRM noncompliances.

We reviewed the SRM Noncompliance Reports from January 2007 forward, and found that they contained valuable information that could have been used for monitoring at the district level. For example, one report showed that in March 2008, FSIS issued 55 SRM-related NRs compared to only 35 in the previous month. This report also identified the fact that 51 percent of the NRs

¹⁰¹ One difficulty in performing keyword searches for SRM-related NRs – as noted by the Office of Food Defense and Emergency Response – is the probability that technical terms such as *distal ileum* and *dorsal-root ganglia* can be misspelled by those who enter the NRs.

¹⁰² For example, when performing keyword searches, OFDER uses 75 different keywords that represent known misspellings of technical terms.

¹⁰³ This office, created in 2002, coordinates and manages all homeland security activities within FSIS. Its function is to ensure that policy makers, scientists, field staff, and management are prepared to prevent and respond to any food security threat.

(28 of 55) related to deficiencies in establishments' HACCP systems. It would be reasonable to conclude that had this information been disseminated to the districts, district managers could have increased monitoring of establishments' systems relevant to the removal and control of SRMs.

However, district managers are not provided these reports. Instead, under the policy of the Office of Field Operations, these reports are reviewed by the EAROs. We interviewed two of the three EAROs, and were told that they do not review these reports. One stated that they are waiting for the development of PHIS, since the new system is expected to generate reports and perform trend analysis.

**Management
Control Systems
Are Not Designed
to Monitor SRM
Compliance**

As noted in Finding 2, much of FSIS' efforts in the area of management controls have been directed to the development of AssuranceNet and IPPS. Both of these systems were referenced in FSIS' response to OIG's most recent audit that reported SRM issues.¹⁰⁴ FSIS, in its response to that audit, stated that its multi-layered management control system (AssuranceNet) would address SRM controls in its performance measures for HACCP procedures and control of condemned and inedible material. FSIS stated that these performance measures would be integrated with system design control functions via Food Safety Assessments (FSA)¹⁰⁵ and IPPS. We agree that both AssuranceNet and IPPS provide some information in this area. However, neither provides distinct data on inspectors' performance in SRM verification activities for managers to assess on a district or nationwide basis.

The Supervisory Guide for IPPS references validation of SRM controls, in that it instructs the FLS to determine the PHV's knowledge of how each establishment is controlling SRMs. However, we found that the IPPS rating forms for PHVs, CSIs, and FIs do not contain any performance element specifically related to SRM verification activities. As a result, reviewing officials such as district managers or EAROs cannot determine how, or whether, a supervisor has addressed an employee's performance in this area, as required for other performance elements.

We also noted that AssuranceNet, which FSIS officials use to monitor performance in various food safety areas, does not contain any performance elements specifically related to SRM verification activities. In January 2006, before the system was implemented, FSIS stated that AssuranceNet would include "performance measures for HACCP procedures and control of condemned and inedible material that would encompass verification of an establishment's control of SRMs." We found that AssuranceNet does monitor completion of certain PBIS tasks, as well as an element that monitors whether

¹⁰⁴ Report 50601-10-KC, *Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II and Food Safety and Inspection Service Controls Over BSE Sampling, Specified Risk Materials, and Advance Meat Recovery Products – Phase III*, dated January 2006.

¹⁰⁵ FSAs are FSIS district-level reviews to assess the design and validity of an establishment's HACCP plan, SSOPs, and pre-requisite plans. They are generally conducted by an EIAO.

“100 percent of condemned animals and inedible product (are) identified and properly disposed of.” However, these elements encompass a much broader range of activities than SRM removals, and do not provide any specific information on the effectiveness of SRM removals and interventions. This is particularly true since AssuranceNet is primarily designed to monitor trends at the circuit level and higher, rather than at individual establishments.

Given the importance placed upon SRM removal and intervention as a means of protecting the public even in instances where other FSIS controls may fail - as at Hallmark - FSIS needs to demonstrate that it provides an appropriate level of monitoring through the agency’s management control systems. We have been advised that this may partly be addressed by the new PHIS system when it becomes operational. However, managers will still need to have sufficient data to ensure that tasks necessary to verify SRM controls and interventions are being accomplished as intended.

Recommendation 18

Develop processes, as part of the new PHIS system, to verify that inspectors are regularly performing SRM-related tasks as part of their inspection duties. Incorporate features in PHIS that will allow managers to track and evaluate the extent to which such tasks are being performed at the establishment, circuit, and district levels.

Agency Response

The PHIS, currently being developed, will have features that require inspection personnel to record which specific regulatory requirements are verified each time they are performed, even if noncompliance is not found. For example, when inspection personnel perform HACCP verifications at beef plants and verify that establishments handle SRMs in accordance with their plans and regulatory requirements, the regulatory requirements that inspection personnel verified will be recorded in the PHIS database. The data will be available to OFO supervisory personnel for them to track to ensure that inspectors are performing such verifications at the specified frequencies. PHIS policy and training will include guidelines for monitoring SRM verification and for responding to apparent anomalies. As PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track whether tasks are performed and that the appropriate regulatory requirements are verified as required. This feature will apply to all regulatory requirements, not only those related to SRMs. PHIS will be in full production readiness by March 2010.

OIG Position

We accept FSIS' management decision.

Recommendation 19

Implement procedures for district offices to monitor and analyze SRM-related NRs as part of the agency's overall management control process. Provide district-level users access to all information, including OFDER's monthly exception reports.

Agency Response

FSIS will modify PBIS by adding a drop down menu that will provide the districts with a tool to sort and search all NRs by regulatory citations. This will enable them to monitor and analyze specific SRM-related NRs. This proposed PBIS modification is an interim measure pending PHIS implementation. In addition, OFDER/DAIG prepares quarterly exception reports that are distributed to Office of Policy, Program and Employee Development (OPPD) and OFO. The EAROs will share these reports with each corresponding district. Information contained in these reports will provide each district with data for correlation purposes, and they can further use such information and data to follow up on particular issues of concern. FSIS will provide the districts with guidance in the form of an FSIS directive or notice that will explain how and what to do with both the PBIS data and OFDER's report to monitor and analyze SRM-related NRs as part of the agency's overall management control process. The modifications to PBIS will be made and the FSIS directive or notice will be published by March 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 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.

Agency Response

FSIS believes that general performance elements and measures are the most effective approach to ensure that inspection personnel understand the broad concepts and thought processes they are to use in performing their verification activities, regardless of the pathogen or adulterant in question. However, agency officials agreed that FSIS should provide specific guidance

to supervisors on how to assess employees' knowledge and performance of those verification activities with reference to specific hazards, like SRMs or *E. coli* O157:H7, as they apply to the inspector's assignment. The revised IPPS Supervisory Guidelines will provide specific instructions to supervisors for determining the knowledge and proficiency of their inspection personnel on various aspects of their jobs. The sections dealing with HACCP verifications, SSOP verifications, and pre-requisite program verifications specifically direct the supervisor on how to assess the employee's knowledge and proficiency in carrying out verifications of SRM control activities. This is expected to facilitate supervisors in assessing the performance of in-plant inspection personnel in their verification of SRM controls, as well as other performance areas.

PHIS will have features that require inspection personnel to record which specific regulatory requirements are verified 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. These features will apply to all regulatory requirements, not just SRMs. PHIS will be in full production readiness by March 2010.

OIG Position

We accept FSIS' management decision.

Finding 7

FSIS Inspectors Did Not Always Detect or Document Noncompliance With SRM Regulations

Inspectors at 5 of the 10 establishments we reviewed did not detect instances of noncompliance with FSIS requirements for the removal and disposition of SRMs (see exhibit C). The deficiencies we noted included establishment pre-requisite plans that did not contain required SRM procedures, and the failure of establishment employees to follow in-plant intervention procedures or to ensure that SRMs were being removed from products shipped to other processing establishments. This occurred, in part, because FSIS inspectors misinterpreted applicable regulations and directives. In some cases, we noted that FSIS inspectors had not received up-to-date training on SRM requirements. Finally, we noted that inspectors at three of these establishments were reluctant to write NRs even after the noncompliances had been noted by the auditors. If FSIS in-plant inspectors do not detect such

noncompliances, or do not document them with NRs, the ability of FSIS to demonstrate the effectiveness of SRM removal and intervention processes is greatly reduced.

FSIS Did Not Always Ensure That Establishments Adequately Reassessed Their HACCP System for SRM Control

In August 2007, FSIS issued a notice that directed inspection personnel at slaughter establishments to conduct awareness meetings with establishment management.¹⁰⁶ These meetings were to (1) make establishment managers aware of changes to regulatory requirements for handling SRMs, (2) advise management that because changes might affect the establishment hazard analysis or alter the critical control points they should reassess the adequacy of their HACCP plan, and (3) ask them specific questions that their controls and procedures would be expected to address. Beginning October 1, 2007, inspectors were to use FSIS Directive 6100.4, Verification Instructions Related to SRMs to verify that the establishment's plans had incorporated the appropriate controls and procedures.

However, at two establishments, we found that the pre-requisite plans did not address the requirements of 9 CFR 310.22 and Directive 6100.4, which state that any slaughter establishment which ships carcasses containing SRMs to "downstream" processing establishments must (1) assure that the carcasses are accompanied by documentation stating that the SRMs must be removed, and (2) maintain documentation to show that the downstream establishment has received the carcasses and has certified to the subsequent removal and disposition of the SRMs. In both of these cases, FSIS personnel had documentation that the awareness meetings had been held as required by Notice 56-07. However, in one case the PHV misinterpreted the directive's requirements, stating that he believed it sufficient that the processing establishment's own SRM plan required their removal. In the other case, the inspectors stated they understood the requirement but had failed to notice that the pre-requisite plan did not contain the required controls. In both cases, the PHVs had received training on SRMs; however, this training took place before the training modules were updated to reflect the requirements for shipments to downstream processors.

At one of these two establishments, an FSA conducted in April 2008 also failed to disclose that the establishment's pre-requisite plan did not address the requirements for transporting carcasses containing SRMs. The district manager stated that because of the way FSA reports are formatted,¹⁰⁷ the district officials who reviewed the report could not determine the extent to which SRM procedures had been covered. She noted that the FSA did not concentrate on SRM-related issues, but rather on HACCP compliance in general.

¹⁰⁶ FSIS Notice 56-07, Final Regulations for Non-Ambulatory Disabled Cattle and SRMs, dated August 31, 2007.

¹⁰⁷ We reported this in audit 24601-7-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Establishments*. Until July 2008, FSAs were presented in an inconsistent, text-based format that did not allow FSIS managers to fully analyze the results of the FSAs.

**One
Establishment
Did Not Properly
Carry Out SRM
Removal**

At one establishment we visited, an investigation by FSIS OPEER disclosed that the establishment had not been properly removing the tonsils from market heads that it began shipping in 2003. Establishment personnel stated that at that time, the PHV instructed them in the method for tonsil removal. They continued using that method until a State inspector in Iowa discovered tonsil material during a routine inspection of cattle heads shipped by the establishment in 2008. Continuous review by FSIS inspection personnel during the previous 4 years, however, failed to identify this deficiency. The establishment issued a voluntary recall of over 400,000 pounds of product - about half of the cattle heads it shipped since 2003. Because the PHV who initially instructed establishment employees in tonsil removal was no longer with the agency, we could not validate that incorrect instructions were given to the establishment. The current PHV and FLS stated that they had not monitored tonsil removal sufficiently to have discovered that the establishment failed to remove all SRMs. We noted that both the CSI and the FLS received training in SRM tonsil removal after this noncompliance at this establishment had been disclosed.

**Establishments
Did Not Use
Dedicated or
Properly-Cleaned
Equipment When
Cutting Products
That Contained
SRMs**

Title 9 C.F.R. 310.22 and FSIS Directive 6100.4 require that precautions be taken when establishments slaughter cattle of mixed ages (over-and-under 30 months of age) to prevent cross-contamination by SRMs. If establishments do not segregate the carcasses and parts from the older and younger cattle, FSIS inspectors are required to verify that the establishment is either using dedicated equipment for each age group to cut through the SRMs, or cleaning and sanitizing the equipment before it is again used on carcasses or parts from cattle under 30 months old. However, at two establishments we found that these requirements were not being followed.

Establishment 1's pre-requisite plan called for cattle, following the initial splitting of the carcass in the slaughter area,¹⁰⁸ to be processed in order of their age with all cattle under 30 months of age being processed on any given day before any of the over-30-month cattle. Under this plan, it would have been unnecessary to either use dedicated equipment or to break down and clean the saws and other equipment until the next day's slaughter operations began. However, we found that by the time the carcasses reached the processing area, they had been graded by USDA Agriculture Marketing Service; and from that point forward, the establishment first grouped the carcasses by USDA grade (e.g., USDA Prime, Choice, or Select) for further processing, and only then by age. Under this system, an over-30-month old carcass of one grade would be sawed before an under-30-month carcass in the next grade-grouping. Because it was not specified in the pre-requisite plan, the establishment did not break down and clean the equipment during this process (although each saw had a low-pressure "sanitizer" spray installed).

¹⁰⁸ In the slaughter area, the establishment's pre-requisite plan called for the use of dedicated equipment for sawing under-and-over 30-month-old carcasses, and we found the establishment to be in compliance with that requirement.

The FLS was not aware that this had been occurring, while the Supervisory Public Health Veterinarian stated that this would not warrant writing an NR because there were no “visible SRMs” on the equipment.¹⁰⁹ During the audit, establishment management agreed to change their pre-requisite plan to “rinse and sanitize” the equipment. Although we observed establishment employees actually breaking down the equipment for cleaning during our visit, the FLS stated that the pre-requisite plan – even as revised – did not specifically require anything beyond the “continuous sanitation” provided by the sanitation sprayers attached to the saws.

FSIS Headquarters officials also agreed that an NR was unnecessary because they believed the sanitizer spray was sufficient to address the problem. We do not agree with this position because the establishment was not following its own pre-requisite plan, and this alone should have generated an NR.

We observed a similar situation at Establishment 10 where its employees used a single set of knives for removing the heads from carcasses of mixed ages. In addition, the establishment was using a single split saw to cut through the vertebral columns of these carcasses; and although establishment employees sprayed off the saw when switching from older carcasses back to under-30-month old carcasses, they did not break down the equipment and remove all visible debris as required by their pre-requisite plan. FSIS had not been aware that this was occurring, and agreed that the establishment was out of compliance. The PHV immediately dealt with the issue and the FLS stated a meeting would be held with establishment management to address the issue regarding the knives. The establishment took immediate corrective actions. However, FSIS again determined that an NR would not be written for the noncompliance.

We also observed that at Establishment 1, the automatic denaturant system did not disperse denaturant in sufficient amounts to ensure that inedible materials – including SRMs – were clearly identified as being inedible. This system should spread denaturant evenly across the inedible material and be readily visible. However, during our visit, the denaturant was barely visible. FSIS agreed that the system malfunctioned, but stated that the system appeared to be functioning properly the last time they had checked. Title 9 C.F.R. part 314.3 states that denaturant must be deposited in all portions of the carcass or product to the extent necessary to preclude its use for food purposes. The PHV agreed with this following our discussion, and wrote an NR to document the noncompliance.

¹⁰⁹ We noted – as we found at Establishment 10 – that there was a buildup of material inside the closed saw casing. Unlike at Establishment 10, however, the PHV and FLS did not believe this qualified as “visible SRMs.”

***FSIS Did Not
Take Consistent
Enforcement
Actions on SRM
Violations***

During the audit, when we pointed out apparent SRM noncompliances, FSIS inconsistently issued regulatory citations (NRs). We attributed this to an inadequate understanding of SRM requirements, which in turn indicates a need for additional training. For instance, Establishment 3 and 4 both had deficiencies in their pre-requisite plans that resulted in similar noncompliances regarding the shipping and tracking of carcasses that contained SRMs. At Establishment 4, the PHV agreed with our assessment and immediately wrote an NR. At Establishment 3, however, the CSI stated that he believed the establishment had “met the intent” of Directive 6100.4 and refused to write an NR. He was subsequently overruled by the district manager, who stated that an NR would be written.¹¹⁰

At Establishment 2, which was located in another district, we found that although the establishment’s pre-requisite plan was in compliance, it was not being followed. In this case, although the establishment was properly identifying the shipped carcasses as containing SRMs, they were not ensuring that downstream processors provided the required certifications that the SRMs had been removed. FSIS inspectors were not aware of the noncompliance before the audit, but did issue an NR when we notified them as to what we found. However, we were subsequently notified by the district office that the NR had been rescinded. An FSIS Headquarters official stated that the establishment was generally following their written procedure and the OIG finding represented only a “minor variation,” despite the fact that nearly half of the downstream shipments we reviewed (23 of 43 shipments, involving over 540,000 pounds of product shipped) did not contain the required certification. The FLS for this establishment stated, however, during our visit that any deviation from an establishment’s written plan would justify an NR.

Establishment 3 and 4 were both in the same district; and while both ultimately took equivalent enforcement action, in one case this only came about through the intervention of the district office. However, despite the fact that an FSA had recently been performed at Establishment 4, the district office only became aware of the deficiencies in the establishments’ pre-requisite plans as a result of our audit. Establishment 2 was in another district, which took a markedly different position on the enforcement of a situation similar to that found at the other two establishments. We believe that such inconsistencies further highlight the need for more effective management controls and training.

¹¹⁰ FSIS Directive 6100.4 requires, among other provisions, that when an establishment ships meat products containing SRMs to other establishments for additional processing, the shipping establishment must obtain written certifications from the processors that the SRMs have been removed before the products are marketed. Neither of these two establishments reflected this in their pre-requisite plans; therefore, the required procedures were not being followed.

At Establishment 4, we also noted that FSIS inspectors did not require the establishment to obtain age verification documentation for animals it slaughtered. Although the establishment's normal practice was to consider all animals as over 30 months of age, it also occasionally slaughtered under-30-month-old animals for one of its buyers. We found that the establishment did not comply with its pre-requisite plan, which required age verification of under-30-month old animals. The inspectors at this establishment disagreed with the need to write an NR, stating that "the establishment treated all animals as over 30 months of age, so aging is not necessary." District officials, when they became aware of the situation, instructed the PHV to write an NR.

As noted above, we found that Establishment 1 and 10 were not following their pre-requisite plans in that they cut and/or sawed carcasses of mixed ages but did not use dedicated equipment for each group or clean and sanitize the saws when switching from older to younger cattle. However, neither of these noncompliances resulted in inspectors writing an NR. Establishment 10 took corrective actions, including the requirement that the saws be actually broken down and cleaned rather than simply sprayed – a process which had left visible SRMs in the enclosed areas of the saw casings. However, no NR was written. An FSIS official stated that these issues "did not deal with deviations from critical control points within the HACCP plan." However, Directive 6100.4 requires that FSIS inspection personnel issue an NR in any instance where the establishment has failed to develop and implement procedures that comply with 9 C.F.R. 310.22. Although Establishment 10's procedures were in compliance with the regulation, their implementation clearly was not. As a result, we believe an NR should have been issued.

Likewise, at Establishment 1, FSIS declined to write an NR on the basis that the low-pressure sprayers on the saws – a measure that the establishment's revised pre-requisite plan referred to as "rinsing and sanitizing" – met the requirements of Directive 6100.4. This action appeared inconsistent with the actions taken at Establishment 10, since in both cases a buildup of material was noted inside the closed saw casings. In any case, the presence of the sprayer did not change the fact that Establishment 1 mixed the age groups when sawing carcasses, which clearly violated the controls specified in its pre-requisite plan.

We discussed these issues with two of the four EAROs, and asked how, or if, they monitored the effectiveness of SRM verification activities. One stated that SRM controls are primarily monitored through the FSAs, and that they review some – but not all – of these. The other EARO stated that they do not have a large role in monitoring SRM compliance because this is done at the establishment level. Moreover, they do not have major concerns about SRMs because they see relatively few NRs being written on these issues.

The noncompliances we observed at 5 of the 10 establishments visited occurred for various reasons. In some cases, we noted that the PHVs did not have up-to-date training on SRM issues – the training record for the PHV at Establishment 2, for instance, did not list any SRM training at all. However, it is uncertain whether lack of formal training can explain why in-plant personnel were not aware of ongoing noncompliance, or did not recognize them as such. However, we believe that the conditions noted during this audit support the need for greater management control over SRM verification activities. We question how EAROs can effectively use FSAs as the primary tool to monitor compliance with SRM requirements. Also, we believe the EARO’s lack of concern regarding SRM noncompliance because “relatively few NRs are written” may be questionable because, as disclosed during the audit, there is inconsistent interpretation as to when NRs should be written. Without documentation that there has been noncompliance, FSIS has no means to assess risk and monitor trends in compliance with SRM control and interventions.

Thus, under the current management control structure, there is reduced assurance that district offices can become aware of situations that require their intervention; the same would apply to the EAROs who supervise them. Without adequate monitoring tools, FSIS may not become aware of situations that require intervention until these reach a stage that requires a recall or other enforcement action.

Recommendation 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 (IIC) at each establishment to certify completion of this review to the district office.

Agency Response

FSIS will issue an FSIS notice or revise Directives 6100.2, “Post-Mortem Livestock Inspection,” and 6100.4, “Verification Instructions Related to Specified Risk Materials,” to require the IIC at each slaughter establishment to verify that his or her staff has reviewed the regulatory requirements and verification instructions in the directives relative to SRM controls and the establishment’s HACCP, Sanitation SOP, and prerequisite programs. These issuances will contain a reporting or notification process that captures whether the IIC at the establishment completes the review. The new instructions will be issued by April 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 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.

Agency Response

FSIS agreed that it was necessary to incorporate mechanisms into the FSA process to ensure compliance with SRM requirements, and has modified the FSA documentation to include these requirements. As part of the PHIS data infrastructure enhancement initiative, the FSA documentation process has been improved to a question and answer format and includes an SRM section within the 03J meat slaughter FSA tool. These questions lead the EIAO to verify that slaughter establishments are complying with 9 CFR 310.22. These FSA tools already are in use and related training continues.

Over 300 EIAOs, EIAO-trained PHVs, case specialists, deputy district managers, and district managers were trained during the summer of 2008 in the use of these tools as part of the Advanced EIAO training course. The tools have been incorporated into the basic EIAO training course, and FSIS plans to conduct 3 more Advanced EIAO training courses starting in January 2009 for the remaining EIAO-trained PHVs and district office personnel. Training is expected to be completed by May 2009.

OIG Position

We accept FSIS' management decision.

Recommendation 23

Implement procedures to require that, as part of their supervisory visits, FLSs provide ongoing oversight to FSIS inspectors in their SRM-related inspection duties.

Agency Response

As noted earlier, FSIS has made improvements to the IPPS Supervisory Guidelines that will result in better accountability for carrying out SRM-related and other inspection activities. The new guidelines will contain explicit instructions for conducting IPPS assessments and testing the knowledge of in-plant inspection personnel on the policies and procedures for

which they are responsible, as well as how to observe their performance of inspection and verification procedures. The guideline provides a “work method” to ensure that the supervisors ask the right questions and observe the performance of the inspection personnel on every aspect of their jobs, including whether inspection personnel perform verification of an establishment’s SRM controls correctly. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken, i.e., correlation, re-training, and to perform a follow-up IPPS within 60 days and document their observations during that follow-up session. FSIS plans to issue the revised guideline in December 2008.

OIG Position

We accept FSIS’ management decision.

Recommendation 24

Strengthen guidance to clarify when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment pre-requisite plans.

Agency Response

FSIS will issue a new notice by March 2009 that clarifies when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment pre-requisite plans.

OIG Position

We accept FSIS’ management decision.

Recommendation 25

Assess the level of training needed by both FLSs and in-plant inspectors on SRM verification responsibilities, and develop controls to ensure that such training is provided in a timely manner.

Agency Response

FSIS will ensure that all FLSs, as well as in-plant inspectors and PHVs performing SRM verification, complete the updated SRM training course in AgLearn. To ensure appropriate inspection personnel receive needed training, OFDER/DAIG will conduct quarterly analyses of the training data and

provide a report to the Office of Outreach, Employee Education, and Training and the districts so that they can follow up with those inspection personnel that have not received needed training. FSIS estimates that all appropriate inspection personnel will receive this training by April 2009.

OIG Position

We accept FSIS' management decision.

Scope and Methodology

We performed our audit at FSIS Headquarters in Washington, D.C., 6 FSIS district offices, and 10 cull cattle slaughter establishments between March and June 2008. To accomplish our objectives, we interviewed responsible FSIS personnel and establishment employees who worked at Hallmark-Westland Meat Packing Company (Hallmark) in Chino, California, as well as reviewed pertinent establishment and FSIS records gathered for OIG's criminal investigation into potential violations of the Federal Meat Inspection Act. The investigation is ongoing and OIG Investigations is working cooperatively with FSIS OPEER and other law enforcement agencies, as well as coordinating their efforts with the U.S. Department of Justice. The purpose of our involvement in selected aspects of the investigation was to determine what inspection controls or processes may have broken down at Hallmark that allowed the egregious humane handling violations to occur.

Hallmark slaughtered cull cows. We concluded that establishments that slaughter cull cows are a higher risk for potential humane handling concerns because of the condition, age, and health of the animals slaughtered. Therefore, we limited the scope of this audit to FSIS pre-slaughter activities at cull slaughter operations to determine whether the conditions or abuses that occurred at Hallmark were isolated or systemic. Because this is an ongoing investigation, the audit is limited by the information we have to date.

During the audit, we interviewed appropriate FSIS officials, reviewed files, procedures, and operations related to FSIS' performance of and oversight over, pre-slaughter activities. We observed ante-mortem inspections, as well as FSIS' oversight over the accountability of animals moving from ante-mortem inspection to slaughter. We examined post-mortem controls over the monitoring and removal of SRMs and evaluated compliance with inspector-generated residue sampling and testing procedures. Our review covered current slaughter operations and we examined prior inspection and slaughter records (calendar years 2006 and 2007), as necessary.

FSIS Headquarters and Field Offices

At FSIS Headquarters, we determined the responsibilities of the following offices as they relate to pre-slaughter activities, SRMs, and residue sampling and testing:

- Program Evaluation, Enforcement and Review—assesses FSIS program functions and operations;

- Field Operations—manages the national program of inspection and enforcement activities;
- Policy and Program Development—develops and makes recommendations concerning all domestic policy;
- Public Health Science—provides scientific analysis, advice, data, and recommendations regarding matters involving public health and science;
- Office of Outreach, Employee Education and Training—provides education resources and technical support; and
- Office of Management—provides a full range of administrative and support services.

We obtained and analyzed data covering the period January 2006 through April 2008 from FSIS' automated data and reporting systems (PBIS), Electronic Animal Disposition Reporting System (eADRS), Residue Violation Information System (RVIS), related to ante-mortem inspection, control of SRMs, and residue sampling and testing, and HATS. We also evaluated management use of PBIS, eADRS and/or HATS to monitor inspection operations and evaluated whether FSIS used these data to effectively monitor and supervise inspection activities.

We performed audit work at the following six FSIS district offices. They were selected because they provide management oversight of the 10 slaughter establishments included in this audit.

- Alameda, California
- Des Moines, Iowa
- Lawrence, Kansas
- Philadelphia, Pennsylvania
- Dallas, Texas
- Madison, Wisconsin

We visited the FSIS Financial Processing Center in Urbandale, Iowa, to gain familiarity and understanding of time and attendance reporting requirements for inspection personnel, and policies and procedures for entering FAST test screening results into the automated system for recording these results.

During our audit field work, we also visited the Midwestern and Western FSIS laboratories in St. Louis, Missouri, and Alameda, California, respectively, to evaluate their roles and responsibilities regarding the residue sampling and testing program. At the laboratories, we interviewed laboratory

officials and staff regarding residue testing policies and laboratory procedures, and observed sample processing at the laboratories.

Slaughter Establishments

We selected 10 of the top 49 establishments that slaughter cull cows. We considered such factors as 2007 slaughter statistics, geographic representation, relative establishment size, and participation in Government feeding programs. These animals would generally be over 30-months old and be subject to full compliance with SRM requirements. Four of the establishments reviewed supplied product to five processors who provided 59.7 percent of processed beef used in the National School Lunch Program.

We made unannounced visits to these establishments, observed pre-slaughter inspection operations, and held discussions with establishment officials, FSIS PHVs, front-line supervisors, and inspectors to obtain an understanding of their responsibilities and to become familiar with the establishments' operations. We observed FSIS' ante-mortem inspections and post-mortem inspection practices relating to SRM removal and residue testing. We interviewed in-plant inspectors and PHVs, obtained records/documentation to support the procedures for the identification, handling, removal, segregation, and disposal of SRMs. We interviewed FSIS personnel, and obtained and reviewed documentation used in support of the inspection operations reviewed, including tracking the identification of suspected residue animals through the FAST test screening process and residue sample collection at the establishments.

We also reviewed the establishments' NRs to identify SRM violations, and food safety assessments and reports of humane handling verification visits to determine whether any of the conditions identified during the audit were previously identified by FSIS.

To accomplish our audit objectives, we:

- Identified and reviewed laws, regulations, policies, and procedures related to humane handling, residue testing, SRMs, and pre-slaughter and post-mortem inspection requirements;
- Obtained and reviewed performance reports prepared by the establishment or 3rd parties for its monitoring or supervision activities of pre-slaughter/humane handling operations where available;
- Evaluated FSIS controls/processes that are to provide oversight and monitoring of inspection operations;

- Evaluated the effectiveness of management controls FSIS put into place in response to our prior audit recommendations. Specifically, how FSIS management verifies inspectors are in compliance with SRM control procedures and identifies trends in NRs through the use of PBIS enhancements, IPPS, and AssuranceNet reviews;
- Obtained FSIS' procedures (staffing models/standards) used to assign inspection resources and supervisory levels for oversight at slaughter establishments;
- Evaluated FSIS' organization control over the development and training of its inspection resources; and
- Contacted various international experts, academia, and other knowledgeable industry individuals, as necessary.

We conducted this performance audit in accordance with 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.

Exhibit A – Pre-Slaughter Inspection Issues

ISSUES	ESTABLISHMENTS										
	H	1	2	3	4	5	6	7	8	9	10
No documentation of suspect animals at ante-mortem inspection.	X		X	X	X						X
Ante-mortem inspections were performed by non-veterinarians outside the immediate supervision of a PHV.	X		X	X		X	X	X	X		X
Food inspectors performing ante-mortem inspection did not have required formal training.						X	X				
Animals were not observed both in motion and at rest during ante-mortem inspection.	¹¹¹								X	X	X
Animals were viewed in groups rather than individually during ante-mortem.	¹¹¹	X				X			X	X	
Animals were not viewed from both sides during ante-mortem.	¹¹¹	X								X	X
Ear tags were not used to identify suspect animals.	X	X	X	X		X				X	X
Ear tags were not used to identify condemned animals.	X	X									
No reconciliation of animal counts per pen cards to establishment slaughter records.	¹¹¹	X	X			X			X		
Accuracy of pen cards not verified through actual counts of animals in pens.	¹¹¹	X							X		X
PHV pre-signed pen cards before performing ante-mortem inspection.	¹¹¹					X					
Suspect animals were not slaughtered separately from other animals.	X	X	X								
Disposition of animals that become non-ambulatory after ante-mortem inspection not adequately documented.	¹¹¹									X	X
Downer doors, winches, and additional knock-sites not under FSIS lock.	¹¹¹	X			X	X	X	X	X		X

¹¹¹ For Hallmark, we have no information in this area.

Exhibit B – Residue Testing Issues

ISSUES	ESTABLISHMENTS										
	Hallmark	1	2	3	4	5	6	7	8	9	10
Inspector-generated residue testing were not based on herd history.	X	X		X	X	X	X	X	X		X
Establishment personnel delegated responsibility for collecting test samples.	X			X	X		X		X		
Test samples were not adequately secured while at establishments.			X		X			X			
FSIS depended upon establishment personnel for notification when animals were received from known violators.						X		X			

Exhibit C – Specified Risk Material Issues

ISSUES	ESTABLISHMENTS									
	1	2	3	4	5	6	7	8	9	10
FSIS did not ensure that establishments adequately reassessed their HACCP System for SRM control.			X	X						
Establishments did not follow pre-requisite plans for shipping to downstream processors.		X								
Establishments did not properly carry out SRM removal.										X
Establishments did not use dedicated or properly cleaned equipment when cutting products that contained SRMs.	X									X
FSIS did not take enforcement actions on SRM violations.	X ¹¹²	X ¹¹³	X	X ¹¹⁴						X ¹¹⁵

¹¹² FSIS Headquarters officials stated that an NR was unnecessary because they believed the sanitizer spray was sufficient to address the problem.

¹¹³ In-plant inspection personnel did issue an NR when we notified them as to what we found. However, we were subsequently notified by the district office that the NR had been rescinded. An FSIS Headquarters official stated that the establishment was generally following their written procedure and the OIG finding represented only a “minor variation.”

¹¹⁴ In-plant inspection personnel disagreed with the deficiency. However, the district office agreed and directed the in-plant personnel to write an NR.

¹¹⁵ In-plant inspection personnel did not write an NR because they concluded the cited deficiency did not represent a violation of a critical control point.

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 1 of 16



United States
Department of
Agriculture

Food Safety
and Inspection
Service

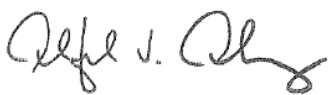
Washington, D.C.
20250

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: Alfred V. Almanza
Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Evaluation of
FSIS Management Controls Over Pre-Slaughter Activities (Audit 24601-
7-KC)

NOV 20 2008



We appreciate the opportunity to review and comment on this official draft report. The Food Safety and Inspection Service (FSIS) has carefully reviewed the official draft report and has provided responses to OIG's recommendations.

Responses to Recommendations

Recommendation 1:

Require that DVMS reviews evaluate the effectiveness of in-plant FSIS personnel in overseeing slaughter establishments' humane handling activities. Also, establish controls to ensure that DVMS review results are correlated with prior reported violations to determine whether inspection processes need to be reassessed or other administrative actions taken.

FSIS Response:

FSIS will issue a new Directive providing District Veterinary Medical Specialists (DVMSs) with additional guidance related to their reviews. DVMSs will be instructed to review data for the past six months, to include any noncompliance records (NRs), Memoranda of Information, and suspensions and to also review the previous Humane Handling Verification visit results prior to conducting their Humane Handling Verification visit. While at the plant the DVMS will engage all in-plant inspection program personnel in a discussion regarding any issues of concern noted by the in-plant inspection program personnel and any discussions that took place with establishment management regarding issues that did not rise to the level of a noncompliance, but that may be of concern. Based on the observations and the assessment any appropriate administrative action could be taken.

During the Humane Handling Verification visits the DVMSs will engage the in-plant inspection program personnel in a discussion to ascertain their knowledge base. This information will then be provided in a written document to the District Manager and Deputy District Managers who in turn will share it with the appropriate Frontline

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 2 of 16

Supervisor (FLS) to address performance issues. While at the plant, if the DVMS determines in-plant inspection personnel have a knowledge deficiency, the DVMS will provide the appropriate information. In addition, if there are indications that in-plant inspection program personnel are not adequately monitoring conditions based on the observations, the District Manager and Deputy District Managers will also be apprised of the issue in order to facilitate performance correction by the appropriate supervisor. The FSIS Directive containing the additional DVMS guidance will be published by February 2009.

Estimated Completion Date:
February 2009

Recommendation 2:
Reassess the humane handling risks associated with cull slaughter establishments, and determine whether DVMS reviews should be conducted on a more frequent basis at those establishments.

FSIS Response:
The Office of Food Defense and Emergency Response's Data Analysis and Integration Group (OFDER/DAIG) will complete an analysis of noncompliance rates for humane handling procedures at dairy cow establishments as compared to rates at establishments that slaughter other market classes of adult cattle. The analysis will be completed by August 2009, and provided to the Office of Field Operations (OFO) for final determination.

Also, the DVMSs will be given additional guidance in the form of an FSIS Directive to monitor all humane handling noncompliance, establishment corrective actions and other findings as brought forward by inspection personnel, which could result in more frequent Humane Handling Verification visits.

Estimated Completion Date:
August 2009

Recommendation 3:
Establish a process to analyze PBIS data for anomalies or variances in both slaughter establishment and inspector performance that could require additional followup by district management.

FSIS Response:
OFDER/DAIG will develop a quarterly humane handling alert based on a review of establishment noncompliance data. The quarterly alert 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. The process will be established by January 2009 and the first alert will be distributed in March 2009.

2

Exhibit D – Agency Response to the Draft Report

Estimated Completion Date:
March 2009

Recommendation 4:
Determine whether FSIS-controlled in-plant video monitoring would be beneficial in preventing and detecting animal abuses at cull cow slaughter establishments.

FSIS Response:
FSIS has determined that FSIS-controlled video cameras would not provide the definitive data needed to support enforcement of humane handling requirements, as compared to the direct, ongoing and random verification of establishment handling and slaughter practices that FSIS uses. For example, video footage would not likely provide definitive evidence of whether an animal was conscious at a certain point during the slaughter process. And, reliance by inspection program personnel on video for verification or enforcement could lead unscrupulous establishments or establishment employees to regularly mishandle livestock outside of the camera's view.

That being said, industry use of video cameras to monitor humane handling compliance, such as monitoring of employee humane handling actions in holding pens, can be useful to the establishments themselves in deterring and detecting animal abuses. This is especially true if the establishment has implemented a systematic approach to meeting the humane handling and slaughter requirements, as FSIS recommended in a 2004 *Federal Register* Notice (69 FR 54625). FSIS has authority to access establishments' video records under the Federal Meat Inspection Act, specifically 21 U.S.C. 642. FSIS has enforced access to video records when the video was used to meet certain aspects of HACCP and SSOP requirements.

FSIS will issue Compliance Guidelines for Using Video Records to industry for designing, maintaining and validating their video system so that the video records are trustworthy, accurate and a true representation of the process. An accompanying FSIS Directive will clarify FSIS inspection personnel access to and verification of establishment video records. Both documents will be issued by March 2009.

Estimated Completion Date:
March 2009

Recommendation 5:
Develop a documented, supportable methodology for assigning in-plant inspection staff for offline inspection activities, including a basis for assignment at different types of plants.

FSIS Response:
The Agency is currently developing the Public Health Information System (PHIS), an effort to strengthen its public health data infrastructure as part of the ongoing effort to improve food safety and food defense. Concurrently, the Agency is planning changes to off-line inspection personnel work. Models are being designed to estimate time,

procedures, and frequency of tasks required by establishment shift. These models are inclusive off-line work assignments that include ante-mortem and post-mortem inspection responsibilities. The testing of the new method of providing off-line inspection is scheduled for the spring of 2009. The work assignment assumptions used to develop the models also will be available at this time. As FSIS moves forward with the implementation of the new off-line inspection procedures, the use of personnel resources will be better utilized through enhanced use of data.

Estimated Completion Date:
June 2009

Recommendation 6:
Reassess and support the methodology used to establish the supervisory span of control for frontline supervisors.

FSIS Response:
The FLS positions have primary oversight of inspection and enforcement activities at the in-plant level. The primary focus of the FLS position is to protect the public health through coordination and supervision of Consumer Safety Inspectors or subordinate in-plant supervisory personnel. The subordinate supervisory personnel provide technical and administrative supervision of in-plant inspection employees who conduct inspections and enforcement activities at slaughter and processing establishments.

The FLS position was not designed to provide daily supervision to each subordinate assigned within the circuit boundaries; instead, the FLS develops goals, explains policies, and delegates daily supervisory tasks to in-plant supervisors. The FLS independently plans, develops, and carries out their supervisory and technical responsibilities.

In 2005, the Program Evaluation and Improvement Staff of the Office of Program Evaluation, Enforcement and Review conducted a study of the FLS position on behalf of OFO. The study recommended increasing the number of FLS positions to enable a greater leadership role in its food safety and food defense mission. An OFO task group comprised of FLSs, District Managers, and Program Analysts reviewed the study and selected key recommendations from the study for future implementation under FSIS Directive 1010.2, Revision 2, Circuit Maintenance Guidelines.

The primary objective of revising the Circuit Maintenance Guidelines was to provide Agency managers with key parameters to use to determine the optimum number of FLS positions based on the number of plants, employees, and travel within a district. The Directive was not an attempt to develop a work measurement instrument for the FLS position, nor can it determine the absolute span of control of the FLS position due, in part, to the highly variable nature of their work. Revising the Circuit Maintenance Directive created seventeen new circuits bringing the total number of circuits to 175. Additional impact of the revised Circuit Maintenance Guidelines includes:

Exhibit D – Agency Response to the Draft Report

- Fewer establishments per circuit: on average the number of plants per circuit decreased from 37 to 34 – each circuit will have fewer than 45 establishments.
- Fewer direct reporting lines to the FLS: on average the number of direct reports decreased from 20 to 15 – each FLS will have fewer than 16 direct reports.
- Fewer indirect reporting lines: on average the number of indirect reports will decrease from 33 to 32 – each FLS will have fewer than 55 indirect reports.
- Reduce the amount of travel for FLS: on average the FLS travel reduced from 1.8 travel days to 1.6 travel days

Implementing the new Circuit Maintenance Guidelines will increase the total number of FLS positions, thereby reducing the span of control of FLS positions. Increasing the number of FLS positions will provide management with the opportunity to strengthen management controls over in-plant inspection activities including the application of HACCP programs. More FLS positions allow for more routine on-site reviews of in-plant operations and ongoing assessments of inspection data generated at the in-plant level. The new Circuit Maintenance Guidelines Directive was completed in September 2008. FSIS will fully implement the Directive during the second quarter of FY 2009. Further, FSIS will perform an assessment of these new guidelines by the end of the first quarter, 2010, to determine, among other things, the impact of the reduction of the FLS span of control.

Estimated Completion Date:
March 2010

Recommendation 7:

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.

FSIS Response:

FSIS will establish policies and procedures to ensure that all mission critical occupational groups (Food Inspector, Consumer Safety Inspector, Public Health Veterinarian, Frontline Supervisor, Program Investigator, Import Inspector) receive formal, entry level on the job, or classroom training based on their job description, performance standards, and Agency policies and procedures within one year of coming on board in the position, and sooner when possible (e.g., within the first 3-6 months). Further, FSIS will require that inspection program personnel recertify this training annually. These policies and procedures will be implemented and described in an FSIS Directive or Notice to be issued by September 2009.

In the interim before the implementation of the new policies and procedures, to ensure inspection program personnel demonstrate the appropriate level of competency, the In-Plant Performance System (IPPS) Supervisory Guideline has been modified to include

Exhibit D – Agency Response to the Draft Report

explicit instructions for how to conduct an IPPS assessment to evaluate 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 provides a “work method” to ensure that the supervisors ask the right questions and observe the performance of the inspection personnel on every aspect of their jobs. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken, e.g., correlation, re-training, and to perform a follow-up IPPS within 60 days and document their observations during that follow-up session. The Draft IPPS Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. FSIS plans to issue the revised Guideline by December 2008.

Estimated Completion Date:
September 2009

Recommendation 8:

Strengthen management controls to ensure that district management teams are performing on-site 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:

During this past IPPS cycle, four of the fifteen Districts fell below the 10% requirement for reviewing IPPS assessments documented by FLSs and in-plant supervisors- these Districts ranged from 5% to 7% IPPS assessments reviewed. All but one of the fifteen Districts met or exceeded the 1% performance standard for conducting on-site evaluations of the IPPS assessments reviewed by the District management team. However, the District that did not meet the 1% requirement did conduct onsite evaluations of IPPS in three of its eight circuits.

A few recent developments will assist the Districts to better monitor their own progress in meeting these requirements in the future. This last summer, the District Analysts were trained to more effectively use the custom reports in AssuranceNet. These reports allow the Districts to see what percentage of reviews they have performed overall, as well as broken down by circuit so that they can better monitor and target their efforts more efficiently throughout the rating cycle. This reporting allows them to monitor the performance of their FLS personnel in reviewing subordinate supervisors’ performance of IPPS assessments, as well. In addition, the AssuranceNet system was also enhanced during the summer to allow District management teams to see which IPPS assessments have generated follow-up due to deficiencies identified by the supervisor performing the IPPS assessment. This enhances the ability of the District to focus on IPPS assessments on which weaknesses have been identified and to ensure that effective follow-up is accomplished by subordinate supervisory levels. Following the next IPPS cycle, an assessment will be performed on these improvements to determine whether they resulted in the Districts meeting the required IPPS frequencies. A report will be prepared of the results of this assessment.

Exhibit D – Agency Response to the Draft Report

Estimated Completion Date:

November 2009

Recommendation 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.

FSIS Response:

FSIS is writing a new FSIS Notice pertaining to verification of an establishment's identification records and reconciling livestock numbers between ante-mortem and slaughter. This Notice is expected to be issued in December 2008. The Notice will clarify that the establishment is responsible for providing livestock data (that identify livestock) to inspection program personnel when requesting ante-mortem inspection. It also will explain that inspection program personnel are to verify the establishment's data when performing ante-mortem inspection as well as the verification method to be used. After livestock have passed this verification process during ante-mortem inspection, they may be moved to slaughter. In April 2009, FSIS will revise and reissue FSIS Directive 6100.1 ("Ante-Mortem Livestock Inspection") to permanently capture the content of the December 2008 FSIS Notice. This Directive will also provide clarified tagging instructions for livestock that have been determined to be a US Suspect or US Condemned animal.

Estimated Completion Date:

April 2009

Recommendation 10:

Require inspectors to verify the accuracy of the animal counts on pen cards and drive sheets, and reconcile these to establishment slaughter records.

FSIS Response:

FSIS is writing a new FSIS Notice pertaining to verification of an establishment's identification records and reconciling livestock numbers between ante-mortem and slaughter. This Notice will clarify that the establishment is responsible for providing livestock data (that identify livestock) to inspection program personnel when requesting ante-mortem inspection. This Notice will explain that inspection program personnel are to verify the establishment's data when performing ante-mortem inspection as well as the verification method to be used. After livestock have passed this verification process during ante-mortem inspection, they may be moved to slaughter. This Notice is expected to be issued in December 2008.

Estimated Completion Date:

December 2008

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 8 of 16

Recommendation 11:

Strengthen existing guidance for inspectors to observe animals both at rest and in motion during ante-mortem inspection.

FSIS Response:

FSIS will revise and reissue FSIS Directive 6100.1 (“Ante-Mortem Livestock Inspection”) to clarify that inspection program personnel are to observe animals both at rest and in motion during ante-mortem inspection. The revised Directive is expected to issue in April 2009.

Estimated Completion Date:

April 2009

Recommendation 12:

Implement controls to ensure that each non-veterinary inspector has received necessary training, both formal and informal, before performing ante-mortem inspection.

FSIS Response:

FSIS has implemented and will continue a structured on-the-job (OJT) training program for all Food Inspectors (FIs) and other non-veterinary inspectors performing ante-mortem inspection. The structured OJT training, which was implemented on September 10, 2008, is one of six modules contained in the 2008 Interim Employee Development Guide (IEDG) which provides resources to supervisors and trainers to aid in their training efforts in the first phase of a new inspector’s career. The structured OJT module contains several topics for which new inspectors must demonstrate basic proficiency. These topics include the following: Sanitation and SSOPs, Ante-mortem and Post-mortem inspection, Good Commercial Practices, HACCP overview, Food Safety Standard (Fecal) Overview, Condemned/Inedible, and Food Defense Overview. The structured OJT module includes forms that both the new inspector and supervisor/trainer must initial when the inspector has attained basic proficiency on each subject. The supervisor/trainer must then add written comments on each of the forms reflecting both the inspector’s strengths and weaknesses in the particular core competency or subject matter. The comments must also include their plan to improve on deficiencies in both knowledge and/or execution for that competency. When all of the subjects in the structured OJT module have been completed, the signed forms must be submitted to the District Office so that the District can track each new inspector through the training and to ensure the completion of the structured OJT module is recorded in the inspector’s learning history. Once the forms are submitted to the District, generally within two to four weeks of starting OJT, the inspector is ready for the Center for Learning’s Formal Classroom Training. Newly hired inspector’s will be required to complete the formal classroom training course in a timely manner, typically within one year of entering on duty. Further, FSIS will require that these inspection program personnel recertify this training annually. To ensure that appropriate inspection personnel have received the necessary training, OFDER/DAIG will conduct quarterly analysis of this training data for inspection program personnel and provide a report to the Office of Outreach, Education and Employee Training (OOEET) and the Districts so that they can follow-up with those

8

inspection personnel who have not received the required training. The first report that will include a status of inspection program personnel who have received the structured OJT will be completed by September 2009.

Estimated Completion Date:

September 2009

Recommendation 13:

Develop procedures to require PHVs 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:

This verification is already part of the IPPS system. However, FSIS has made some improvements to the IPPS Supervisory Guideline that will result in better accountability for carrying out the ante-mortem and other inspection activities. The Agency has revised the Guideline to change it from a document that largely outlined regulatory requirements and the contents of Directives and Notices to a document with explicit instructions for how to conduct an IPPS assessment to test the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible, as well as how to observe their performance of inspection and verification procedures. The Guideline provides a “work method” to ensure that the supervisors ask the right questions and observe the performance of the inspection personnel on every aspect of their jobs, including whether inspection personnel perform ante-mortem procedures correctly. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken, i.e., correlation, re-training, and to perform a follow-up IPPS within 60 days and document their observations during that follow-up session. The draft IPPS Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. FSIS plans to issue the revised Guideline in December 2008.

Estimated Completion Date:

December 2008

Recommendation 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.

FSIS Response:

FSIS does not have statutory or regulatory authority to require that secondary entrances and equipment be placed under FSIS control in general. However, FSIS does recognize the need to ensure that these entrances and pieces of equipment are not used in violation of the statutes or regulations. By May 2009, FSIS will either issue a new FSIS Notice or revise FSIS Directive 6900.1 Revision 1, “Humane Handling of Disabled Livestock,” to clarify that inspection program personnel, through ongoing verification activities, are to

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 10 of 16

ensure that secondary entrances and equipment are not used by official establishments to adulterate product, create insanitary conditions, handle livestock inhumanely, or to violate the statutes or regulations in any other way. The issuance will instruct inspection program personnel to take regulatory control or other actions if official establishments misuse secondary entrances or equipment in such a manner.

Estimated Completion Date:

May 2009

Recommendation 15:

Develop specific guidance and procedures for in-plant FSIS personnel to use herd history as a basis for performing residue tests.

FSIS Response:

FSIS receives a weekly report on residue violators from USDA's National Information Technology Center. This report identifies establishments that have purchased, on more than one occasion, animals with violative residues, as confirmed by FSIS laboratories, and from the same supplier. Upon receipt of the report, FSIS headquarters currently notifies the District Offices about these establishments through the shared "Outlook residue mailbox files."

By December 2008, the Agency will issue an FSIS Notice to instruct District Offices to inform all IICs (and their FLSs) at establishments known to have purchased livestock from repeat residue violators about new violations involving the violating firms. The Notice will advise inspection program personnel at these establishments about their responsibilities when they are informed that an establishment repeatedly (more than once) has purchased from the same supplier animals with violative levels of residues. Among other things, the Notice will give instructions to PHVs regarding additional residue sampling if an establishment continues to purchase livestock from a supplier with repeat residue violations.

Estimated Completion Date:

December 2008

Recommendation 16:

Develop a process that provides on-going monitoring and analysis of inspector-generated residue sampling. Initiate follow-up actions when there are variances in inspector performance and/or residue test results.

FSIS Response:

FSIS will implement the eSample system by June 2009. Among other things, this system will be used to collect Fast Antimicrobial Screen Test (FAST) results or other rapid test results used in inspector generated sampling. The eSample database will eliminate any duties Office of Management currently has related to the collection of these test results at the Federal Processing Center in Urbandale, IA.

10

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 11 of 16

The Office of Public Health Science (OPHS), Residue Branch, will analyze data from eSample and the Electronic Animal Disposition Reporting System (eADRS) to include production volumes (number of head slaughtered), number of in-plant screening tests conducted and test results, both positive and negative, for each establishment on a quarterly basis. OPHS has identified and will implement the following parameters as part of this process: 1) select and monitor in-plant screening tests with acceptable sensitivity and low specificity (close to tolerance and low numbers of “false” positives), 2) improve inspector generated sampling criteria, and 3) establish uniform in-plant sampling between establishments. The estimated completion date for the first analysis is August 2009. Once the data are analyzed, OPHS will provide OFO and other FSIS program managers with a report indicating any discrepancies in in-plant screening testing procedures so that appropriate action can be taken.

Estimated Completion Date:

August 2009

Recommendation 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.

FSIS Response:

FSIS has selected a new in-plant residue test screening method to be used by inspectors in all slaughter establishments. By April 2009, FSIS will draft an FSIS Directive to provide instructions to field personnel regarding comprehensive criteria for performing in-plant residue screen tests (herd history, current health of animal presented for inspection, etc.). The Directive also will provide directions on how to collect and submit samples to ensure sample integrity and, specifically in response to OIG concerns, how to secure samples onsite prior to submission to FSIS labs. To further ensure that inspectors are fully aware of the protocol for shipping samples, FSIS will link the new Directive (once it is posted to the FSIS Web site) to the current FSIS Directive 7355.1, Revision 2, “Use of Sample Seals for Laboratory Samples and Other Applications.”

Estimated Completion Date:

April 2009

Recommendation 18:

Develop processes, as part of the new PHIS system, to verify that inspectors are regularly performing SRM-related tasks as part of their inspection duties. Incorporate features in PHIS that will allow managers to track and evaluate the extent to which such tasks are being performed at the establishment, circuit, and district levels.

FSIS Response:

The PHIS, currently being developed, will have features that require inspection personnel to record which specific regulatory requirements are verified each time they are performed, even if noncompliance is not found. For example, when inspection personnel

11

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 12 of 16

perform HACCP verifications at beef plants and verify that establishments handle specified risk material (SRM) in accordance with their plans and regulatory requirements, the regulatory requirements that inspection personnel verified will be recorded in the PHIS database. The data will be available to OFO supervisory personnel for them to track to 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 the PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track that tasks are performed and that the appropriate regulatory requirements are verified as required. This feature will apply to all regulatory requirements, not only those related to SRMs. The PHIS will be in full production readiness by March 2010.

Estimated Completion Date:
March 2010

Recommendation 19:

Implement procedures for district offices to monitor and analyze SRM-related NRs as part of the agency's overall management control process. Provide district-level users access to all information, including OFDER's monthly exception reports.

FSIS Response:

FSIS will modify PBIS by adding a drop down menu that will provide the Districts with a tool to sort and search all NRs by regulatory citations. This will enable them to monitor and analyze specific SRM-related NRs (i.e., those not in compliance with 9 CFR 310.22). This proposed PBIS modification is an interim measure pending PHIS implementation. In addition, OFDER/DAIG prepares quarterly exception reports that are distributed to OPPD and OFO. These reports will be shared by the Executive Associates for Regulatory Operations (EAROs) with each corresponding district. Information contained in these reports will provide each District with data for correlation purposes. Districts may further use such information and data to follow-up on particular issues of concern. FSIS will provide the Districts with guidance in the form of an FSIS Directive or Notice that will explain how and what to do with both the PBIS data and OFDER's report to monitor and analyze SRM-related NRs as part of the Agency's overall management control process. The modifications to PBIS will be made and the FSIS Directive or Notice will publish by March 2009.

Estimated Completion Date:
March 2009

Recommendation 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.

12

FSIS Response:

FSIS has determined that general performance elements and measures are the most effective approach to ensure that inspection personnel understand the broad concepts and thought processes they are to use in performing their verification activities, regardless of the pathogen or adulterant in question. However, the Agency agrees that it should provide specific guidance to supervisors on how to assess knowledge and performance of those verification activities, with reference to specific hazards, like SRMs or *E. coli* O157:H7, as they apply to the inspector's assignment.

The revised IPPS Supervisory Guideline provides specific instructions to supervisors for determining the knowledge and proficiency of their inspection personnel on various aspects of their jobs. The sections dealing with HACCP verifications, SSOP verifications and prerequisite program verifications specifically direct the supervisor on how to assess the employee's knowledge and proficiency in carrying out verification of SRM control activities. The instructions are set up in this manner because establishments may incorporate their SRM controls into the HACCP plan, SSOP or prerequisite program. For example, if the supervisor is assessing the performance of an inspector conducting HACCP verification activities and the SRM controls are in the establishment HACCP plan, the supervisor evaluates the employee's knowledge and execution of verifications concerning SRM regulatory requirements when evaluating the HACCP verification activity. The Draft IPPS Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. The revised Guideline should issue in December 2008.

Also, the PHIS currently being developed will have features that require inspection personnel to record which specific regulatory requirements are verified each time they are performed, even if noncompliance is not found. For example, when inspection personnel perform HACCP verifications at beef plants and verify that establishments handle SRM in accordance with their plans and regulatory requirements, the regulatory requirements that inspection personnel verified will be recorded in the PHIS database. The data will be available to OFO supervisory personnel for them to track to 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 the PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track that tasks are performed and that the appropriate regulatory requirements are verified as required. In line with the Agency's preference for general performance elements and because its management controls are not designed to track performance of individual inspection program personnel, this feature will apply to all regulatory requirements, not only those related to SRMs. That is, while the new system of management controls will reflect PHIS features, it likely will not contain a management control specific to SRM verification. The PHIS will be in full production readiness by March 2010.

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 14 of 16

Estimated Completion Date:

March 2010

Recommendation 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 (IIC) at each establishment to certify completion of this review to the district offices.

FSIS Response:

FSIS will issue an FSIS Notice or revise Directives 6100.2, "Post-Mortem Livestock Inspection," and 6100.4, "Verification Instructions Related to Specified Risk Materials," to require the IIC at each slaughter establishment to verify that his or her staff has reviewed the regulatory requirements and verification instructions in the directives relative to SRM controls and the establishment's HACCP, Sanitation SOP and prerequisite programs. These issuances will contain a reporting or notification process that captures whether the IIC at the establishment completes the review. The new instructions will be issued by April 2009.

Estimated Completion Date:

April 2009

Recommendation 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.

FSIS Response:

FSIS agrees that it is necessary to incorporate mechanisms into the FSA process to ensure compliance with SRM requirements and has modified the FSA documentation to include these requirements. As part of the PHIS data infrastructure enhancement initiative, the FSA documentation process has been improved to a question and answer format and includes an SRM section within the 03J meat slaughter FSA tool. These pointed questions lead the EIAO to verify that slaughter establishments are complying with 9 CFR 310.22. These FSA tools already are in use and related training continues.

Over 300 EIAOs, EIAO-trained PHVs, case specialists, Deputy District Managers, and District Managers were trained during the summer of 2008 in the use of these tools as part of the Advanced EIAO training course. The tools have been incorporated into the basic EIAO training course also and the FSIS plans to conduct 3 more Advanced EIAO training courses starting in January 2009 for the remaining EIAO trained PHVs and district office personnel. Training is expected to be completed by May 2009.

Estimated Completion Date:

May 2009

14

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 15 of 16

Recommendation 23:

Implement procedures to require that, as part of their supervisory visits, FLSs provide ongoing oversight to FSIS inspectors in their SRM-related inspection duties.

FSIS Response:

FSIS has made some improvements to the IPPS Supervisory Guideline that will result in better accountability for carrying out the SRM-related and other inspection activities. The Agency has revised the Guideline to change it from a document that largely outlined regulatory requirements and the contents of Directives and Notices to a document with explicit instructions for how to conduct an IPPS assessment to test the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible, as well as how to observe their performance of inspection and verification procedures. The Guideline provides a “work method” to ensure that the supervisors ask the right questions and observe the performance of the inspection personnel on every aspect of their jobs, including whether inspection personnel perform verification of an establishments SRM controls correctly. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken, i.e., correlation, re-training, and to perform a follow-up IPPS within 60 days and document their observations during that follow-up session.

FLSs do not provide daily supervision to each subordinate assigned within the circuit boundaries; instead, the FLS develops goals, explains policies, and delegates daily supervisory tasks to in-plant supervisors. FLSs do however, conduct some IPPS assessments, e.g. for non-supervisory inspection program personnel assigned to processing establishments within a circuit. To the extent they conduct IPPS assessments, FLSs would use the revised IPPS Supervisory Guide which provides specific instructions to supervisors for determining the knowledge and proficiency of their inspection personnel on various aspects of their jobs, including verification of SRM controls. The draft IPPS Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. FSIS plans to issue the revised Guideline in December 2008.

Estimated Completion Date:

December 2008

Recommendation 24:

Strengthen guidance to clarify when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment pre-requisite plans.

FSIS Response:

FSIS will issue a new FSIS Notice that clarifies when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment pre-requisite plans. This new Notice is expected to be issued by March 2009.

15

Exhibit D – Agency Response to the Draft Report

Exhibit D – Page 16 of 16

Estimated Completion Date:

March 2009

Recommendation 25:

Assess the level of training needed by both FLSs and in-plant inspectors on SRM verification responsibilities, and develop controls to ensure that such training is provided in a timely manner.

FSIS Response:

FSIS will ensure that all FLSs and in-plant inspectors and PHVs performing SRM verification complete the updated SRM training course in AgLearn. To ensure appropriate inspection personnel receive needed training, OFDER/DAIG will conduct quarterly analysis of the training data and provide a report to OOEET and the Districts so that they can follow-up with those inspection personnel that have not received needed training. The Agency estimates that all appropriate inspection personnel will receive this training by April 2009.

Estimated Completion Date:

April 2009

Informational copies of this draft report have been distributed to:

Administrator, FSIS	(20)
Attn: Agency Liaison Officer	
Government Accountability Office	(1)
Office of Management and Budget	(1)
Office of the Chief Financial Officer	
Director, Planning and Accountability Division	(1)