U.S. Department of Agriculture

Office of Inspector General
Great Plains Region

Audit Report

Animal and Plant Health Inspection Service
Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase II
and
Food Safety and Inspection Service
Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Products - Phase III

Report No. 50601-10-KC
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UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington, D.C. 20250

January 25, 2006

REPLY TO
ATTN OF: 50601-10-KC

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William C. Smith
Assistant Administrator
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FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Animal and Plant Health Inspection Service - Bovine Spongiform Encephalopathy (BSE) Surveillance Program - Phase II and Food Safety and Inspection Service - Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Products - Phase III

This report presents the results of our audit of the enhanced BSE surveillance program and controls over specified risk materials and advanced meat recovery products. Your written response to the official draft report, dated January 20, 2006, is included as exhibit G with excerpts of the response and the Office of Inspector General's (OIG) position incorporated into the Findings and Recommendations section of the report, where applicable.

We accept the management decisions for all recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer (OCFO). We are providing a separate memorandum to the agencies and OCFO that provides specific information on the actions to be completed to achieve final action.

We appreciate your timely response and the cooperation and assistance provided to our staff during the audit

Executive Summary

Animal and Plant Health Inspection Service - Bovine Spongiform Encephalopathy (BSE) Surveillance Program - Phase II and Food Safety and Inspection Service - Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Products - Phase III

Results in Brief

This report evaluates elements of the interlocking safeguards in place to protect United States (U.S.) beef from Bovine Spongiform Encephalopathy, widely known as BSE or "mad cow disease." Since 1990, the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), has led a multi-agency effort to monitor and prevent BSE from entering the food supply. After discovering a BSE-positive cow in December 2003, APHIS expanded its BSE surveillance program. To further protect the food supply, USDA banned materials identified as being at risk of carrying BSE (specified risk materials (SRM)), such as central nervous system tissue. As part of this effort, USDA's Food Safety and Inspection Service (FSIS) required beef slaughter and processing facilities to incorporate controls for handling such materials into their operational plans. Onsite FSIS inspectors also inspect cattle for clinical signs in order to prevent diseased animals from being slaughtered for human consumption. To evaluate the effectiveness of the safeguards, we assessed APHIS' implementation of the expanded surveillance program, as well as FSIS' controls to prevent banned SRMs from entering the food supply.

In June 2004, APHIS implemented its expanded surveillance program; participation by industry in this surveillance program is voluntary. As of May 2005, over 350,000 animals were sampled and tested for BSE. To date, two animals tested positive for BSE; one tested positive after implementation of the expanded surveillance program.

USDA made significant efforts to implement the expanded BSE surveillance program. Much needed to be done in a short period of time to establish the necessary processes, controls, infrastructure, and networks to assist in this effort. In addition, extensive outreach and coordination was undertaken with other Federal, State, and local entities, private industry, and laboratory and veterinary networks. This report provides an assessment as to the progress USDA made in expanding its surveillance effort and the effectiveness of its controls and processes. This report also discusses the limitations of its program and data in assessing the prevalence of BSE in the U.S. herd.

Surveillance Goals and Objectives

In March 2004, USDA published its plan to expand the BSE surveillance program. The plan's goal was to collect samples from as many adult[1] cattle from the high-risk population as possible in 12-18 months while ensuring that there was statistically appropriate geographical representation of the adult cattle population in the United States. Overall, USDA designed the program to define whether BSE was actually present in the U.S. cattle population and if so, to what level.

When USDA published its plan, Office of Inspector General (OIG) was examining the pre-expansion program. In anticipation of the coming changes, we reviewed the plan in order to determine if its design would allow the Department to reach statistically valid conclusions about the presence and level of BSE. Since the implementation plan had not been finalized, we provided recommendations for USDA to consider as they moved forward with implementing an expanded surveillance program. In August 2004, we released our report, Animal and Plant Health Inspection Service and Food Safety and Inspection Service, Bovine Spongiform Encephalopathy (BSE) Surveillance Program – Phase I (Report No. 50601-9-KC), which discussed our observations of the challenges USDA faced in meeting its stated goals and made 19 recommendations for USDA to consider as it moved forward with implementation. Our prior report primarily focused on (1) the potential for unwarranted statistical conclusions to be drawn from the data USDA planned to collect, and (2) the challenges in identifying and testing high-risk cattle. In response to our report, APHIS agreed to disclose the limitations of the data and the assumptions made and its impact on any statistical representations regarding the prevalence of BSE in order to obviate misinterpretation.

We reviewed the specific corrective actions APHIS and FSIS agreed to take in response to prior audit recommendations during this audit. In this report, we discuss the specific areas where corrective actions were not fully effective in addressing our concerns in the following areas: obtaining representative samples, identifying and obtaining samples from the high-risk surveillance streams, and completeness and accuracy of program data.

APHIS has provided OIG unpublished drafts of its preliminary analysis, which included various statistical approaches to determining the prevalence of BSE. In general, each approach mitigates some, but not all of the limitations associated with its data and underlying assumptions in the design and implementation of its surveillance program. Some of the approaches also

[1] FSIS considers bulls and cows to be mature cattle with cows ordinarily having given birth to one or more calves. FSIS defines SRMs to be present in cattle 30 months of age or older, while APHIS defines its target population for BSE sampling to be over 30 months of age. Dentition is used to estimate the age ranges of cattle. Dentition is the development of teeth and their arrangement in the mouth.

introduce new challenges because any conclusions are extremely sensitive to the accuracy of the underlying data. The accuracy of the underlying data is also critical to the development of a future maintenance surveillance program. We cannot fully assess any of the approaches being considered by APHIS since it has not finalized its analysis. In Finding 1, however, we do offer several observations for APHIS to consider as it develops its conclusions about the prevalence of BSE in the U.S. cattle population.

Inherent Limitations in Identifying and Testing High-Risk Cattle

APHIS obtained significantly more samples for testing than they originally anticipated would be needed to achieve its stated level of confidence in estimating the prevalence of BSE in the U.S. herd. Because of the voluntary nature of its program, however, we could not determine how successful APHIS was in obtaining a representative proportion of high-risk cattle for testing. Our prior report recognized the significant challenges for APHIS to obtain samples from the high-risk population because of the inherent problems with obtaining voluntary compliance and transporting carcasses for testing. APHIS took steps to obtain facilitated pathways, by entering into over 100 agreements, to collect and test brain samples for BSE. However, using USDA published data that estimates the distribution of the cattle population, as well as those that died or became nonambulatory, we could not determine whether APHIS achieved either geographical representation or representation of the desired surveillance stream (clinical suspects, fallen stock, casualty slaughter fallen stock, and routine slaughter). Findings 1 and 2 present the conditions noted that impact this evaluation.

USDA Testing Protocols and Quality Assurance Procedures

In November 2004, USDA announced that its rapid screening test produced an inconclusive BSE test result. A contract laboratory ran its rapid screening test on a brain sample collected for testing and produced three high positive reactive results. As required, the contract laboratory forwarded the inconclusive sample to APHIS' National Veterinary Services Laboratories (NVSL) for confirmation. NVSL repeated the rapid screening test, which again produced three high positive reactive results. Following established protocol, NVSL ran its confirmatory test, an immunohistochemistry (IHC) test, which was interpreted as negative for BSE.

Faced with conflicting results between the rapid screening and IHC tests, NVSL scientists recommended additional testing to resolve the discrepancy but APHIS headquarters officials concluded that no further testing was necessary since testing protocols were followed and the confirmatory test was negative. In our discussions with APHIS officials, they justified their decision to not do additional testing because the IHC test is internationally recognized as the "gold standard" of testing. Also, they believed that

conducting additional tests would undermine confidence in USDA's testing protocols.

OIG obtained evidence that indicated additional testing was prudent. We came to this conclusion because the rapid screening tests produced six high positive reactive results, the IHC tests conflicted, and various standard operating procedures were not followed. Also, our review of the relevant scientific literature, other countries' protocols, and discussions with experts led us to conclude that additional confirmatory testing should be considered in the event of conflicting test results.

To maintain objectivity and independence, we requested that USDA's Agricultural Research Service (ARS) perform the Office International des Epizooties (OIE) Scrapie-Associated Fibrils (SAF) immunoblot test. The additional testing produced positive results. To confirm, the Secretary of Agriculture requested that an internationally recognized BSE laboratory in Weybridge, England (Weybridge) perform additional testing. Weybridge conducted various tests, including their own IHC tests and three Western blot tests. The tests confirmed that the cow was infected with BSE. The Secretary immediately directed USDA scientists to work with international experts to develop new protocols that include performing dual confirmatory tests in the event of an inconclusive BSE screening test.

We attribute the failure to identify the BSE positive sample to rigid protocols, as well as the lack of adequate quality assurance controls over its testing program. Details of our concerns are discussed in Findings 3 and 4.

Controls (Firewalls) to Prevent BSE in the Food Supply

USDA instituted proactive procedures to prevent tissues and products that could possibly contain the infective agent for BSE from entering the food supply. FSIS performs inspections on cattle before slaughter (ante mortem) to observe clinical signs that may indicate a central nervous system disorder or other signs that may be associated with BSE. Such animals are condemned and prohibited from slaughter for human consumption. FSIS also identified high-risk beef tissue and products as SRMs, and banned them from the food supply. FSIS inspects slaughter processes to verify that slaughterhouses have incorporated controls for handling SRMs into their operational plans; adequate procedures must be in place for removing, segregating, and disposing of SRMs.

OIG reviewed the SRM plans of several establishments, observed FSIS inspection procedures, and evaluated the effectiveness of controls during the slaughter process. We did not identify SRMs entering the food supply. However, due to the lack of adequate records, we could not determine whether SRM procedures were followed and/or were adequate in 9 of

12 establishments visited during the audit. There is no requirement in the United States for the age of animals to be recorded, therefore, APHIS and FSIS rely on meat establishments to determine the age of cattle slaughtered using documentation or dentition. SRM restrictions apply predominantly to cattle 30 months of age or older. FSIS periodically checks the accuracy of age determinations through dentition; however, we could not determine how often these checks are made. We found that improvements can be made in the following areas.

- FSIS approved an alternate ante mortem inspection procedure that limited the number of cattle subject to inspection. FSIS discontinued this procedure during the audit.
- FSIS does not have an information system capable of readily identifying the scope of, and trends in, noncompliance violations relating to SRMs.
- Most of the establishments reviewed did not have adequate SRM plans, and FSIS did not always identify these deficiencies.
- Several of the establishments did not comply with their SRM plans and/or maintain records to support that they follow their plans.

FSIS has addressed the specific cases of noncompliance identified during the audit. Findings 5 through 9 discuss our assessment of the effectiveness of USDA's firewalls.

Other Program Administration Issues

FSIS and APHIS did not maintain current and comprehensive listings of renderers[2] and related businesses. These entities are required to register with FSIS as a condition of engaging in business.[3] As a result, should serious animal diseases be detected in the United States, USDA's ability to quickly determine and trace the source of infections to prevent the spread of the disease could be impaired. Also, APHIS could not use the registrations to identify potential sources to mitigate geographical gaps in BSE testing. We discuss the details of this issue in Finding 11.

We also determined that an APHIS area office paid costs for sampling and carcass transportation, storage, and disposal that exceeded national cost recovery guidelines and/or that were ineligible for reimbursement. The area office entered into 10 reimbursable agreements before national office cost recovery guidelines had been issued but did not adjust the agreements afterwards although instructed to do so by the national office. Instead, the area office included the questionable costs in amounts proposed (by

[2] For purposes of this report, the term renderers also includes pet food manufacturers and plants that handle dead, dying, disabled, or diseased livestock.
[3] 9 CFR 320.5, states that every person that engages in business in or for commerce, as a meat broker, renderer, or animal food manufacturer … shall register with the Administrator [of FSIS].

third parties) in other allowable cost categories. The area office official stated he changed supporting records because he believed he should honor the prior negotiated costs. As a result, at least $1.2 million of about $11.2 million paid were unsupported program costs. Finding 12 more fully examines the unsupported costs and why they went undiscovered.

The expanded stage of USDA's BSE surveillance program is nearing its end. Accordingly, it is vital that the conditions summarized above be considered as USDA uses the data gathered to design an effective BSE surveillance maintenance program and to report its assessment of the prevalence of BSE in the U.S. herd. In particular, APHIS must develop testing protocols which are grounded in science and flexible enough to adapt to changing circumstances. For its part, FSIS must ensure that it effectively monitors SRM handling practices to ensure they comply with Federal regulations. Implemented, these management controls will help USDA continue to effectively safeguard the U.S. beef supply for consumers.

Recommendations In Brief

We are recommending that APHIS:

- Ensure the transparency of published information so that stakeholders are fully advised of the assumptions and procedures used, limitations of data, and the basis of conclusions reached as a result of the BSE surveillance program;
- Continually re-evaluate and adjust testing protocols based on emerging science; and
- Perform additional outreach to emphasize the age of the target animals and to ensure laboratory personnel understand procedures for submitting the desired samples; and followup with laboratories that appear to be providing an insufficient number of samples.

We are also recommending that FSIS:

- Implement a review and evaluation program to be conducted by FSIS' Office of Program Evaluation, Enforcement, and Review to verify the adequacy of SRM control programs at all beef slaughter and processing establishments; and
- Verify compliance with its SRM control procedures through its Performance Based Inspection System, which should also be modified to allow for timely analysis of violation trends and tracking corrective action.

Last, we are recommending that USDA:

- Determine whether FSIS and/or APHIS need additional authorities to perform inspection and BSE sampling activities in pre-screening areas immediately adjacent, or contiguous to, official slaughter establishments.

Agency Response

In their January 20, 2006, written response to the official draft report, APHIS and FSIS were in general agreement with the findings and recommendations presented therein. The response provided specific actions the agencies have taken, or plan to take as well as timeframes for implementing proposed actions. The APHIS and FSIS joint response is included in its entirety as exhibit G.

OIG Position

We concur with APHIS' and FSIS' proposed corrective actions and have accepted management decisions for all recommendations. We have incorporated applicable portions of the written response to the draft report along with our position in the Findings and Recommendations section of this report.

Abbreviations Used in This Report

AMR	Advanced Meat Recovery
AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
AVIC	Area Veterinarian-in-Charge
BSE	Bovine Spongiform Encephalopathy
CFR	Code of Federal Regulations
CNS	Central Nervous System
CVB	Center for Veterinary Biologics
DRG	Dorsal Root Ganglia
EED	Evaluation and Enforcement Division
ELISA	Enzyme Linked Immunosorbent Assay
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FY	Fiscal Year
GAO	Government Accountability Office
HACCP	Hazard Analysis and Critical Control Point
IEC	International Electrotechnical Commission
IHC	Immunohistochemistry
IPPS	In-Plant Performance System
ISO	International Organization for Standardization
NASS	National Agricultural Statistics Service
NR	Noncompliance Record
NVSL	National Veterinary Services Laboratories
OCFO	Office of the Chief Financial Officer
OD	Optical Density
OFO	Office of Field Operations
OIE	Office International des Epizooties
OIG	Office of Inspector General
OPEER	Office of Program Evaluation, Enforcement, and Review
OPPED	Office of Policy, Program and Employee Development
PBIS	Performance Based Inspection System
PHV	Public Health Veterinarian
PR	Pathogen Reduction
RAMS	Registration Activity Management System
SAF	Scrapie-Associated Fibrils
SOP	Standard Operating Procedure
SSOP	Sanitation Standard Operating Procedure
SRM	Specified Risk Materials
TAHC	Terrestrial Animal Health Code
TSE	Transmissible Spongiform Encephalopathy
U.K.	United Kingdom
U.S.	United States
USDA	U.S. Department of Agriculture
VMO	Veterinary Medical Officer
Weybridge	International Reference Laboratory, Weybridge, England

Table of Contents

Background and Objectives

Background

Bovine Spongiform Encephalopathy (BSE), widely known as "mad cow disease," is a chronic, degenerative disease affecting the central nervous system (CNS) of cattle. Worldwide there have been more than 180,000 cases in cattle since the disease was first diagnosed in 1986 in Great Britain; however, over 90 percent of these cases were found before 1998. BSE belongs to the family of diseases known as transmissible spongiform encephalopathy (TSE), the causes of which are not fully known. TSE diseases have a prolonged incubation period of months or years and result in a progressive, debilitating neurological illness, which is always fatal. BSE affected animals may display changes in temperament, such as nervousness or aggression, abnormal posture, decreased milk production, or loss of body weight despite continued appetite. There is no approved test to detect BSE in a live animal.

The Animal and Plant Health Inspection Service (APHIS) leads an interagency effort to monitor BSE and has had an active surveillance program for BSE in place since May 1990. There are two other agencies involved in the surveillance program: the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA).[4]

As a result of the discovery of a BSE positive cow in Washington State in December 2003, the U.S. Department of Agriculture (USDA) expanded its surveillance effort for BSE in the United States. The primary focus of the enhanced surveillance effort was to test as many cattle as possible in the target population[5] over a period of 12 to 18 months beginning June 1, 2004. APHIS defined high-risk cattle at its web site as follows:[6]

- *Nonambulatory cattle;*
- *Cattle exhibiting signs of a central nervous system disorder;*
- *Cattle exhibiting other signs that may be associated with BSE, such as emaciation or injury; and*
- *Dead cattle*.

USDA personnel will also sample all cattle condemned on ante mortem inspection by USDA's Food Safety and Inspection Service.

[4] The Food and Drug Administration of the Department of Health and Human Services, is primarily responsible for preventing BSE's introduction and spread through animal feed.

[5] Unless otherwise designated, samples were to be obtained from animals over 30 months as evidenced by the eruption of at least one of the second set of permanent incisors. APHIS defined high-risk animals as downer/nonambulatory cattle; cattle with CNS signs and/or rabies negative; cattle exhibiting other signs that may be associated with BSE; cattle that were condemned or euthanized or that died as a result of a moribund condition, tetanus, emaciation, injuries, or nonambulatory conditions; and dead cattle with clinical signs prior to death, if known, that do not preclude it from the target population.

[6] http://www.aphis.usda.gov/lpa/issues/bse_testing/faq.html#highrisk.

APHIS also planned to sample about 20,000 apparently normal, healthy animals from 40 federally inspected plants that handle about 86 percent of the 6.2 million[7] adult cattle slaughtered each year. APHIS completed testing of the additional sample of 21,216 cattle on November 21, 2005.

USDA implemented a number of regulatory changes to reduce the likelihood that high-risk tissues would enter the human food supply. FSIS declared certain beef tissues and products to be specified risk materials (SRM) and banned these products from the human food supply.[8] Prior to the Federal Register notice, the banned materials had been permitted in certain products and processes, such as meat from advanced meat recovery (AMR) systems[9] and tripe. 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 (DRG) of cattle 30 months of age and older were listed as SRMs. In addition, the tonsils and distal ileum of the small intestine of all cattle, regardless of age, were declared SRMs.[10]

Since most of the materials FSIS banned come from cattle 30 months of age or older, FSIS prescribed the method inspectors were to use to verify the age of slaughtered cattle. The guidance[11] provided that inspectors would accept documentation of the age of cattle provided the records appeared reliable. In the absence of acceptable documentation of the cattle's age, inspectors were required to perform a dental examination. In establishments that only process carcasses or parts of carcasses, the establishments were required to present acceptable documentation of the age of the cattle from which the carcasses or parts were derived. If the establishment cannot prove the cattle's age through documentation, the carcasses and parts must be treated as if they were derived from cattle 30 months of age or older.

[7] In the BSE Surveillance Plan, dated March 15, 2004, APHIS approximates this 6.2 million based on National Agricultural Statistics Service (NASS) data. It is consistent with the 6,256,000 slaughtered under Federal inspection in 2002 per Table 7-17 of NASS publication Agricultural Statistics 2003 (equals 2,607,000 dairy cows plus 3,051,000 other cows plus 598,000 bulls and stags).

[8] 9 Code of Federal Regulations (CFR) 310.22 and FSIS Notices: 4-04, dated January 9, 2004, 7-04, dated January 14, 2004, and 9-04, dated January 23, 2004.

[9] AMR systems are designed to remove attached skeletal muscle tissue from livestock bones by separating meat by scraping, shaving, or pulling muscle from the bones. Unlike traditional mechanical separation, this machinery cannot break, grind, or pulverize bones to recover muscle tissue.

[10] The distal ileum was declared to be an SRM; however, FSIS initially determined that the entire small intestine should be banned from the human food supply. Federal Register, Vol. 70, No. 172, (Docket No. 03-0251FA), dated September 7, 2005, provides that FSIS is amending the SRM interim final rule to permit for use as human food beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments or in certified foreign establishments in countries listed by FSIS in 9 CFR 327.2(b) as eligible to export meat products to the United States.

[11] FSIS Notice 5-04, IV and Attachment, dated January 12, 2004, and Docket Number 03-025IF (Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Nonambulatory Disabled Cattle), Interim final rule and request for comments, Verification of the Age of Cattle, dated January 12, 2004.

Establishments are also required to control or prevent SRMs from entering the slaughter process. Plants that process both cattle under 30 months of age and cattle 30 months of age or older must segregate banned materials derived from animals 30 months old or older from acceptable materials from younger cattle. The banned materials must be controlled and prevented from being processed on the slaughter line. The banned materials may be processed as inedible rendering or otherwise destroyed. The plants must also ensure that the slaughter line is properly cleaned after animals 30 months old or older are processed.

Some products containing SRMs can be processed and shipped provided that proper controls are established to ensure SRMs are removed by downstream processors. These products, generally carcasses and carcass parts that still contain the vertebral column and DRG, may be shipped to processors provided they are labeled to show they contain SRMs and the plant ensures that the processor removes the banned materials prior to sale at the retail level. The processors generally use the carcasses and carcass parts to fabricate products, such as steaks (T-bone steaks and porterhouse steaks cannot be made from cattle 30 months old or older).

Under the new rules, skulls and vertebrae from cattle 30 months old or older are not allowed to be processed in AMR systems although these materials from younger animals can be used in AMR. AMR is a technology that uses special equipment to remove muscle tissue from bones in a manner that is considered similar to hand trimming in that the bones remain basically intact. AMR product is considered meat and is labeled as meat. That is, it is to be comparable in texture and composition to meat trimmings so it does not require special labeling. However, the product is not allowed to contain spinal cord or other CNS tissue because these tissues fall outside the definition of meat. Since the use of skulls and spinal column bones in AMR systems carries the risk of incorporating CNS tissue with the AMR meat, FSIS has established a monitoring program to sample and test AMR meat. Any AMR product containing CNS tissue will be recalled because it is considered misbranded, i.e., CNS tissue is not considered "meat."

In addition to the restrictions on SRMs and AMR products, effective June 1, 2004, FSIS began to collect brain tissue samples for BSE testing from all cattle condemned on ante mortem inspection at slaughter plants. Alternatively, slaughter plants could elect to have the samples collected offsite at a rendering facility, pet food manufacturer, 3D/4D processor (dead, dying, disabled, and diseased), etc. The offsite sampling facilities, while not federally inspected plants, should be registered with FSIS as meat and poultry program handlers under new regulations[12] adopted as a BSE control measure.

[12] 9 CFR 320.1 and 320.5 and FSIS Notices: 28-04, dated May 20, 2004, 29-04, dated May 27, 2004, and 33-04, dated June 14, 2004.

In the case of offsite sampling, the ante mortem condemned cattle must be euthanized at the slaughter plant under FSIS supervision. The carcasses of the condemned cattle must also be denatured[13] prior to shipment to the offsite sample collection facility. Proper controls are supposed to be in place to ensure the condemned cattle arrive at the offsite facility and SRMs are properly controlled and disposed of at the remote location.

BSE testing is conducted at USDA's laboratory, the National Veterinary Services Laboratories (NVSL), in Ames, Iowa, and a network of seven contract laboratories[14] around the country. Samples are collected and submitted to the laboratories by authorized State and Federal animal health or public health personnel, accredited veterinarians, and trained contractors.

In August 2004, the USDA Office of Inspector General (OIG) issued a report on its evaluation of USDA's BSE surveillance program.[15] This evaluation included the program in place prior to the discovery of the BSE positive cow in December 2003, as well as USDA's plan for an expanded surveillance effort. The report identified several limitations inherent in APHIS' proposed surveillance plan and made numerous proactive recommendations for APHIS to consider as it moved forward in implementation. Most critical was the need for APHIS to establish and implement a strong management control structure to provide assurance that the BSE surveillance program was effectively implemented and operated as represented to the public, industry, and United States (U.S.) trading partners.

There are about 3,400 establishments that slaughter and/or process beef with SRMs; 2,500 are federally inspected.[16] About 60 plants are considered large plants that slaughter and/or process over 24.7 million cattle annually.[17] In 2003, 30 establishments processed beef vertebrae in AMR systems; in 2004, there were 19 plants operating AMR systems. This number declined to about 14 by the conclusion of our fieldwork. In fiscal year (FY) 2003, FSIS condemned approximately 43,000 cattle; in FY 2004, about 27,720 cattle were condemned.

[13] 9 CFR 314.3 provides that condemned carcasses or carcass parts that are not destroyed by incineration or processed into inedible rendering must be denatured. Denaturing is accomplished by the use of crude carbolic acid, or cresylic disinfectant, specified formula, or any other proprietary material approved by the Administrator.
[14] The seven laboratories are in California, Colorado, Georgia, New York, Texas, Washington, and Wisconsin. An additional five laboratories are approved, but have not participated in the BSE surveillance program.
[15] Audit Report No. 50601-9-KC, APHIS and FSIS BSE Surveillance Program – Phase I.
[16] About 870 federally inspected plants slaughter over 32 million cattle; 280 slaughter older cattle (approximately 5.8 million head of cows and bulls) and about 590 slaughter fat cattle.
[17] FSIS considers large establishments to have 500 or more employees, small plants to have 10 or more employees but less than 500, and very small plants to have fewer than 10 employees.

Objectives

Our overall objective was to evaluate whether the newly expanded BSE surveillance program was accomplishing its intended objectives and had been effectively implemented and administered. An additional objective was to evaluate whether the USDA enforcement of the ban on SRMs in meat products and administration of its testing program and controls to prevent CNS tissue in AMR meat had been effectively implemented.

Findings and Recommendations

Section 1. From Surveillance to Maintenance

In August 2004, the USDA OIG issued a report on our evaluation of USDA's BSE surveillance activities, which USDA expanded because of the discovery of a BSE positive cow in December 2003. USDA published an enhanced surveillance plan on March 15, 2004, to "help to define whether BSE is actually present in the population and if so, at what level." The plan's primary objective was "to collect samples from as many adult cattle from the high-risk population as possible in 12-18 months while ensuring that there is statistically appropriate geographical representation of the adult cattle population in the United States." Also, the plan discusses "the incorporation of random sampling of clinically normal aged animals at slaughter in addition to the defined targeted surveillance goal."

We reviewed USDA's March 2004 plan to determine if it was designed to enable USDA to achieve the statistical conclusions stated as its desired goals. Because implementation plans had not yet been finalized, we offered observations based on its current surveillance efforts at that time. We recognized that there were many challenges that the Department needed to address in implementing an effective and supportable BSE surveillance program. Some of the challenges were inherent to industry practice, as well as current legal authorities. Therefore, our August 2004 report provided an assessment of USDA's proposed surveillance program and our observations of the challenges USDA faced in meeting its stated goals. The report made 19 recommendations for USDA to consider as it moved forward with implementation.

USDA made significant efforts to implement this expanded surveillance effort. Much needed to be done in a short period to establish the processes, controls, infrastructure, and networks to assist in this effort. In addition, extensive outreach and coordination was required with other Federal, State, and local entities, private industry, and laboratory and veterinary networks. A description of those efforts is provided, where appropriate, throughout this report, as well as in exhibit C to this report.

Finding 1 BSE Surveillance Efforts – Stated Versus Achieved Objectives

In our prior audit report, we expressed concerns regarding the statistical inferences that could be made due to unstated limitations associated with critical assumptions in the March 2004 BSE surveillance plan. We recommended, and APHIS agreed, to fully disclose the impact of these assumptions on any statistical representations regarding the prevalence of BSE in U.S. cattle so that these representations will not be misinterpreted by the public, industry, or U.S. trading partners. The validity of those statistical statements depended on the following assumptions, some disclosed, but others only implied in the March 15, 2004, plan.

1. All BSE positive cattle are in the target subpopulation; i.e., no BSE positive cattle are in the apparently healthy subpopulation.
2. Confidence levels apply only to **detectable** BSE, not total BSE (i.e., there are no false negative BSE test results).
3. There are 446,000 cattle in the target subpopulation.
4. Cattle are selected randomly from their corresponding subpopulations and thus, the cattle tested for BSE are representative of their subpopulation.[18]

On September 9, 2004, APHIS published a clarification of its surveillance goals and objectives on its web site; this publication discusses related limitations and factors that might mitigate them. APHIS also disclosed the possibility of using alternative statistical evaluation methods, including approaches recommended by Cohen and Grey of the Harvard Center for Risk Analysis, and the much more sophisticated method incorporated into *BSurvE,*[19] a tool specifically designed for the complexities associated with interpreting aggregated BSE test results. *BSurvE*, as well as the less complex, but related system recently incorporated by the Office International des Epizooties (OIE) into the *Terrestrial Animal Health Code* (*TAHC*),[20] assign "point values" to each sample based on the animal's age and its surveillance stream (clinical suspects, casualty slaughter, fallen stock, and routine slaughter); points are assigned based on the likelihood of testing positive for the disease. Points may be accumulated over a period of a

[18] To understand how the March 15, 2004, plan's statistical statements depend on these conditions, assume five of 446,000 in a target (higher-risk) population are diseased and the rest are not. If 268,500 are randomly selected from the 446,000, there is a 99 percent chance that at least one of the 268,500 will be one of the five diseased, per the hypergeometric distribution. Assuming further that none of the 268,500 tests on target cattle produce false negative results, and that no apparently healthy (lower-risk) adult cattle are diseased, this implies a 99 percent chance of detecting at least one of the five diseased animals in an adult cattle population of about 45 million; i.e., the prevalence rate is five in 45 million, or less than one in 10 million.

[19] *Development of a Method for Evaluation of National Surveillance Data and Optimization of National Surveillance Strategies for Bovine Spongiform Encephalopathy.* A Project Conducted by the European Union TSE Community Reference Laboratory, Veterinary Laboratories Agency Weybridge, U.K., by Wilesmith, John, Roger Morris, Mark Stevenson, Rob Cannon, Deb Prattley and Helen Benard (March 12, 2004), hereafter referred to as Wilesmith et al. (2004).

[20] *2005 OIE Terrestrial Animal Health Code* (*TAHC*), Appendix 3.8.4.

maximum of 7 years per the *2005 OIE TAHC* system (Article 3.8.4.4.2).[21] These accumulated points can then be used to estimate a maximum BSE prevalence rate at a desired confidence level and help determine the extent of surveillance needed in the future to maintain that confidence level.

At the time of this report, APHIS had not decided which statistical evaluation method it will use. During August 2005, APHIS provided OIG unpublished drafts of its preliminary analysis, which included several statistical approaches to estimating the BSE prevalence in U.S. adult cattle, including the *2005 OIE TAHC* system and several based on *BSurvE*. All approaches used in this preliminary analysis mitigate some, but not all of the limitations associated with the four previously mentioned assumptions; each method's reliability depends on how well the cattle tested represent their corresponding surveillance stream. Also, most of these evaluation approaches introduce new challenges because of the sensitivity of the underlying logic to the accuracy of the data (see exhibit D) used to:

a. stratify U.S. cattle tested by age,
b. classify U.S. cattle tested by surveillance stream,
c. estimate the herd's age distribution, which also estimates the probability that non-infected cattle annually leave the herd at each age, and
d. for each age group in (c), estimate the probability of leaving the herd via each surveillance stream.

Significant aspects of these evaluation methods depend on European data and experience.[22] USDA needs to determine its validity and comparability in estimating conditions in the United States. The European Union has had a mandatory surveillance program since 2001. The U.S. program is voluntary and sampling is not random. The success of the program depends on the cooperation of industry and a variety of other conditions, including some that differ across geographical areas and other demographic attributes of the U.S. herd. Therefore, compared to the Europeans, USDA exerts less control over which animals can be tested for BSE, and is generally less able to assure that those tested represent the herd, their surveillance stream, or their age group within each surveillance stream.

Each evaluation method has its own merits and limitations. However, in any assessments made, APHIS must fully disclose the critical limitations inherent

[21] In contrast, the authors of *BSurvE* (Wilesmith et al. 2004, p.15) state that accumulated "surveillance points" gradually become out of date and propose that they expire at an annual rate that steadily reduces them during "the maximum time over which a cow is likely to live…if there are concerns about the exposure history of a particular country then points would be made to expire somewhat faster."

[22] For example, the authors of *BSurvE* state, "The distribution for age at which BSE becomes detectable would generally be country-specific, but is based on research data concerning incubation periods in the British cattle population." Also, the authors of *BSurvE* state that the "probabilities of culling of non-infected animals would be country-specific" (Wilesmith et al., 2004, p. 25).

in its data and analysis of its surveillance program. This analysis is critical to the effectiveness of any future maintenance surveillance program.

OIG has provided comments to APHIS on its draft preliminary analysis. Until APHIS finalizes this document, we cannot issue our final conclusions. However, OIG has identified the following issues that APHIS needs to consider before publishing its final assessment of the effectiveness of its surveillance program and its estimation of the level (prevalence) of BSE in the U.S. herd.

2003 BSE Positive Cow Excluded From Surveillance Data

In its preliminary analysis, APHIS excluded the BSE positive cow detected in December 2003 in Washington State because it was imported from Canada. That is, instead of assuming two cases of BSE had been detected, APHIS assumed there was only one case, the November 2004 BSE positive cow in Texas. By excluding the Canadian cow from its statistical analysis, APHIS lowered the number of *BSurvE* points needed to achieve its desired 95 percent confidence level by about 33 percent. For example, the minimum *BSurvE* points required for 95 percent confidence that there are no more than one in a million adult cattle with BSE when two positive cases are detected is 6,295,800 compared to the 4,743,870 points required when only one positive case is detected.

APHIS officials believe its approach is supportable because Canadian cattle were prohibited from importation since May 20, 2003; they believe that there are an extremely low proportion of cattle from Canada in the current U.S. cattle inventory. APHIS concluded that this would result in an overly conservative estimate of the prevalence of BSE in the current U.S. herd.

One of the goals of the program, however, is to estimate the BSE prevalence in the population, and some of this population includes adult cattle imported from other countries. OIG has concluded that the BSE-positive cow detected in December of 2003 should be included when statistically projecting BSE prevalence for a variety of reasons, including the following.

- USDA considers imported cattle raised in U.S. feed lots, slaughtered, and/or prepared in the United States as domestic livestock; imported cattle were not identified and excluded from the population tested.
- Many *2005 OIE Terrestrial Animal Health Code (TAHC)* and *BSurvE* surveillance points are based on the results of tests conducted prior to May 20, 2003. (For example, at least half of the *2005 OIE TAHC* points estimated through June 30, 2005, were accumulated from October 1, 1998, through May 20, 2003.)
- The average estimated time between infection and detection of BSE appears to exceed 5 years; any surviving imported cattle infected before May 20, 2003, may not yet be detectable, even though they currently

have the disease and may live long enough to eventually manifest its clinical signs.

Estimate of the Target Population

The effective target population is significantly larger than that estimated by APHIS in its March 2004 enhanced surveillance plan. APHIS accepted for testing any and all cattle from the subpopulation of fallen stock (dead) – regardless of the cause of death, or if unknown, regardless of whether the sample collector attempted to determine the cause of death. This resulted in an effective target population of about one million per year (1.5 million over an 18-month period),[23] rather than the original target of 446,000.[24] OIG does not question the merit of testing all fallen stock; this is consistent with the definition used in the point-based surveillance evaluation models. However, care should be exercised by APHIS in discussing the success of its surveillance effort in relation to its original population estimate of 446,000, and the related minimum sample size of 268,500. This is important to avoid the conclusion that virtually all of the original target population has been tested for BSE (see discussion on geographical representation). Also, underestimating the size of a population can distort statistical projections.

Clinical Signs Necessary for BSE Analysis Not Obtained

Because of the voluntary nature of the program, APHIS did not successfully determine the clinical signs or history of the cattle sampled. Of the 356,195 targeted animals sampled through May 2005, 308,237 (87 percent) had "dead-unknown cause" recorded as the only clinical sign and 100 samples had no clinical signs recorded. This occurred because more than half of the samples tested were collected at renderers; sampling agreements did not require sample collectors to make a determination of the cause of death. APHIS made no effort to determine the clinical history of the animals due to the resources that would be necessary to trace back the animal to its owner. Therefore, any conclusion regarding those animals most likely to have BSE and, ultimately, those to be targeted in a reduced (maintenance) surveillance effort may not be reliable. The December 2003 BSE positive cow had reported clinical signs of downer. The November 2004 BSE positive cow was reported in APHIS' data as dead-unknown cause; although various sources have reported this animal as a downer. The importance of obtaining representative samples within each surveillance stream is emphasized by the OIE and the authors of *BSurvE.* OIE emphasizes that to

[23] APHIS estimated 4.8 percent of dairy cows and 1.5 percent of adult beef breeding cattle annually die on farms, per *'97 Beef & Dairy 2002*, respectively. National Agricultural Statistics Service (NASS) January 1, 2005, inventory of about 9.005 million dairy cows, 33.055 million beef cows, and 2.219 million bulls, suggests the number of adult cattle that would die during the 12 months ended May 31, 2005, would be about 961,350 (= .048 × 9,005,000 + .015 × [33,055,000 + 2,219,000]). About 1 million cattle over a year period would project to 1.5 million over an 18-month period.

[24] APHIS originally estimated 446,000 by summing its estimate of the following three target subpopulations of primarily adult cattle:

Foreign animal disease investigations	129
FSIS slaughter with condemnation codes consistent with BSE	194,225
Dead on farms with clinical signs that are unknown or consistent with BSE	251,532
	445,886

efficiently implement a maintenance surveillance program, good quality data are needed. Also, according to Wilesmith et al. (2004, p. 10), data must be genuinely representative of the particular surveillance stream from which it is drawn, and if this is not true, then findings will be biased by such errors.

Geographical Representation

In our prior report, we raised concerns as to whether APHIS could achieve its stated objective of collecting as many samples as possible from the high-risk population in 12-18 months "…while ensuring there is a statistically appropriate geographical representation of the adult cattle population in the United States." Originally, APHIS established goals for each State based on the cattle population derived from the USDA National Agricultural Statistics Service (NASS) data and weighted for some assumed differences in death losses between dairy and beef cattle populations. We recommended, and APHIS agreed, to work with industry and State personnel to obtain samples necessary to obtain adequate representation from all parts of the country. APHIS also agreed to monitor the data throughout the program and where the data fell short, additional outreach would be performed.

For the first 12 months of the enhanced surveillance program—June 1, 2004, through May 31, 2005,—APHIS had already tested significantly more cattle than originally anticipated would be necessary to meet its overall sample goals. Specifically, during this period APHIS tested the obex[25] of about 356,200 target cattle. Although sampling goals had originally been established for each State based on an estimate of its cattle population, APHIS began reporting the distribution of samples by six regional boundaries. According to APHIS officials, State goals were established primarily for administrative purposes and APHIS was not trying to meet particular levels in particular States.[26]

Statistical projections based on the "adjusted target population" method described in the APHIS (2005) preliminary analysis, like those stated in the March 15, 2004, enhanced surveillance plan, require all items in the target population subject to sampling to have equal selection probabilities. Even statistical projections using point-based systems like *BSurvE* require sample selections to be representative of their respective surveillance subpopulations. By reporting the samples obtained by regional boundaries, it is not readily apparent that adequate testing may not have been achieved in some large geographical areas of the country (see exhibit E). Achieving proportional goals is important if APHIS intends to use the total number of tests in statistical projections. This should include adjusting geographic goals when the number of actual tests substantially exceeds the number of tests originally planned (i.e., the goal for the northwest region would be revised from 36,319 to 48,181 based on an increase in the national sampling to 356,000).

[25] Research has shown that BSE prion proteins accumulate primarily in the brainstem of cattle, and the obex is the specific area of the brainstem where they begin to accumulate first.
[26] As of December 1, 2005, information on State goal allocations was published on the APHIS web site.

In our prior report, we pointed out the challenges in obtaining a geographical distribution of cattle from States that frequently ship across regional boundaries for slaughter or rendering in other States; as an example, States in the Northwest Region. This challenge was not fully addressed in the expanded program; however, this conclusion is based on incomplete data since the origin (owner) of cattle had not always been identified in APHIS' sample data. We identified 102,600 samples (27 percent)[27] in the database where the owner field was blank and 8,231 where the owner was identified as a slaughter facility, collection site, or sale barn.

According to APHIS officials, their focus has been on achieving meaningful traceback capability; they are not concerned with incomplete data if it will not be used for scientific analysis. Collection sites are required to adequately identify the origin[28] of all cattle sampled for BSE and to maintain information necessary to trace sampled animals and to make that information available to APHIS upon request. We would argue, however, that the origin of the animal is necessary for analysis since any assessment of the surveillance effort would need to consider geographical representation of the U.S. herd. We also question whether timely and efficient traceback can be achieved if APHIS must visit each collector to review additional records for traceback.

The accuracy of projections based on the *2005 OIE TAHC* evaluation method and those based on *BSurvE* depend on how well the cattle tested represent their respective surveillance streams. Therefore, we attempted to determine whether a representative sample was obtained from nonambulatory cattle, since these comprise a large portion of the "casualty slaughter" surveillance subpopulation. Further, APHIS suggested in September 2004 that data on the "distribution of portions of the target population … could be used to assess the potential for bias in the target population surveillance,"[29] and as an example, referred to a NASS study, *Nonambulatory Cattle and Calves*, published on May 5, 2005. In its report, NASS estimates how many cattle became nonambulatory during 2003 and 2004, what proportion of these eventually died, and how these annual totals are distributed across three geographic regions. Specifically, NASS estimates that 270,000 cattle weighing over 500 pounds "became unable to stand or walk" during 2004 (155,000 from dairy operations, 85,000 from beef operations, and 30,000 others). Of these 270,000, only 59,700 were culled or recovered, while the rest died, as shown by region in Table 1.

[27] The percentage is based on 381,120 total samples in the BSE database, including non-targeted samples, from June 1, 2004, – May 31, 2005.
[28] Appendix G of the *Procedure Manual for BSE Surveillance*, dated October 2004, contains instructions for completing the submission forms. The instructions state, "Enter the National Premises identification for the premises on which the sampled animal was last held or resided, if available. Otherwise, enter as much of the requested information as is known."
[29] *USDA BSE Surveillance Plan: Background on Assumptions and Statistical Inferences*, (September 9, 2004, p. 9).

TABLE 1 NONAMBULATORY CATTLE DURING 2004 (at least 500 pounds) Source: "Nonambulatory Cattle and Calves," NASS, May 5, 2005			
NASS Region	Total	Culled or recovered	Died
Mountain & Western	95,000	15,200	79,800
Midwestern	90,000	20,700	69,300
Southern & Eastern	85,000	23,800	61,200
Total	270,000	59,700	210,300

To compare these estimates of the population of nonambulatory cattle and their geographic distribution to those tested by APHIS, Table 2 displays the number of nonambulatory cattle sampled for BSE for the 12 months ended May 31, 2005, categorized consistent with how APHIS reports them, and for tests of obex, partitioned into the geographic regions defined in the NASS report summarized above.

TABLE 2 NONAMBULATORY CATTLE SAMPLED FOR BSE (with collection dates June 1, 2004, - May 31, 2005)			
Cattle sampled:	On farms	Condemned Ante Mortem at FSIS slaughter	Total
Targeted	26,354	4,151	30,505
Other	573	464	1,037
Total tests of obex	26,927	4,615	31,542
Tested but not obex	241	83	324
Not tested	44	49	93
Total sampled	27,212	4,747	31,959
Total tests of obex by region:			
Mountain & Western	4,912	1,979	6,891
Midwestern	14,868	1,267	16,135
Southern & Eastern	7,147	1,369	8,516
	26,927	4,615	31,542

Since the NASS data in Table 1 represents all cattle weighing at least 500 pounds, it may not be exactly comparable to the nonambulatory cattle tested for BSE reported in Table 2. In particular, while all cattle weighing at least 400 pounds condemned at FSIS slaughter facilities were tested for BSE, generally only **adult** cattle that became nonambulatory **on farms** were targeted (unless they exhibited signs of CNS or were rabies negative). However, given these caveats, the proportions of tested cattle condemned at FSIS slaughter across these three geographic regions appears roughly similar to the NASS estimates, while the geographic proportions of those sampled on farms do not. Specifically, Table 2 suggests that adult cattle that became nonambulatory on farms in the Midwestern region were tested for BSE in greater numbers than those that became nonambulatory on farms in the other two regions.

As exhibit E indicates, proximity to percent allocation sample goals vary greatly by region. The multi-State regional comparisons in the exhibit indicate that differences between the actual and goal in some States are often offset by opposing differences in other States of the same region. This suggests that the greater the size of the region, the more likely State-level deviations from goals will not be obvious.

OIG recognizes that APHIS tested far more cattle for BSE than it originally estimated were necessary to meet its surveillance objectives. However, if APHIS chooses to compare a demographic (e.g., geographic) distribution of the cattle tested to that of its original sample goals, APHIS needs to enhance the comparability of these distributions. The comparability can be enhanced by adjusting the original sample goals upward to reflect the actual total that exceeds the original goal.

Age of Cattle Tested Was Incomplete or Estimated

For BSE surveillance purposes, accurate determination of the specific age of the cattle tested is critical to its assessment of the prevalence of BSE. The age of cattle tested was not recorded for about half of the samples collected prior to June 1, 2004. APHIS estimated the distribution of all unknown ages by setting them equal to the distribution of ages that were known; this assumption is valid only to the degree of the similarity of these distributions. Improvements were made, however, throughout the expanded surveillance program. Between June and October 2004, missing ages in the database decreased to about 14 percent of the samples collected; and to less than 1 percent after October 2004.

Prior to October 25, 2004, sample collectors were to record the age of the cattle tested in ranges, instead of years or months. APHIS then converted the age ranges as follows:

- From "less than 20 months" to 19 months;
- From "20-30 months" to 20 months;
- From "31-36 months" to 31 months;
- From "4 years" to 4 years; and[30]
- From "5 years or more" to 5 years.

The conversion of range "5 years or more" to 5 years, resulted in all cattle 6 years or older to be classified as 5 years old. Since surveillance points per animal are highest for those that are 5 years old, surveillance points will be overstated. We determined that for the clinical suspect surveillance stream, the net effect of these conversion issues would overestimate surveillance points by over 300,000. The points are used to estimate the prevalence of BSE – in other words, this incorrect aging would underestimate the prevalence rate at the 95 percent confidence level.

The dentition field was blank for over 31,000 samples recorded as 2 or 3 year olds out of 352,842 samples tested for reasons other than CNS, rabies, or ante mortem condemned. These 31,000 samples would be considered part of the target population if the dentition field indicated the second incisor had erupted. This field was added to the database after October 2004 to validate that targeted animals were tested.

Integrity of Surveillance Data

In our prior report, we concluded that APHIS needed to establish and implement a strong management control structure to ensure the accuracy and integrity of its BSE test data. APHIS took action to develop an information system to track and report its test results. Also, APHIS established sample collection and data review procedures to ensure the accuracy, consistency, and reliability of its data. Among the controls put in place were periodic reviews and reconciliations of data forms to the BSE database, as well as quality assurance compliance reviews conducted by the Agricultural Marketing Service (AMS).

As discussed in this finding, APHIS was not always successful in using these reviews to ensure the completeness and accuracy of its data. Standard Operating Procedures (SOP)[31] called for weekly data quality assurance reviews, but only three such reviews were done because they were resource intensive. Over 1,000 deficiencies were noted during the three reviews. AMS conducted two reviews; one in August 2004 and one in March 2005. The March 2005 report noted "…data entry deviations continue to cause

[30] Also, prior to October 25, 2004, the aging of cattle 37 to 47 months old may have been distorted by early sample forms offering the following two adjacent options: "31-36 months" next to "4 years." That is, all cattle 37 to 47 months old would needed to be classified as "4 years," whereas the software program classifies as 4 years old all with recorded ages of 4 years or 48-59 months.

[31] BSE Submission Data Reconciliation SOP, dated August 4, 2004, states that routine quality assurance processes will be put in place to assure that information which is collected, is being entered, reported, and properly maintained. Reconciliation is to be conducted weekly to review data integrity and analytical evaluations.

concern among personnel that have to match up sample analysis to the animals sampled." AMS reported that owner information was missing and that data were not always input in the same format. APHIS attempted to address these deficiencies by sending data management reports to field units and reissuing instructions on how to complete sample forms.

Also, during its recent analysis of its data, APHIS attempted to make mass corrections of incomplete and inconsistent information. While some of the assumptions they made for these mass corrections appeared reasonable, the accuracy of the data was not confirmed.

Apparently Healthy Cattle Not Selected Randomly and Focus is Not on Older Adults

APHIS circulated its *Plan for Sampling 20,000 Apparently Healthy Adult Cattle at Slaughter* on September 12, 2005, indicating, "sampling will not be randomized. The distribution of the number of samples collected will be based on plants rather than regions." This differs from the March 15, 2004, plan, which discusses the "random sampling of clinically normal aged animals at slaughter." These 20,000 tests represent one of the four "surveillance streams" or subpopulations in point-based systems like the *2005 OIE TAHC* and *BSurvE*, and thus, these 20,000 tests will contribute, albeit in only a very small way, to the total "surveillance points" used for statistical projections regarding the prevalence of BSE.

European experience clearly indicates that BSE is rarely detected in cattle that are 3 years old or younger, and that the average age of cattle with detectable BSE in Europe exceeds 5 years. However, APHIS intends to measure the minimum age eligible for testing of these 20,000 by noting the eruption of one of the second incisors, which occurs in the 24-30 month age range.

Conclusion

In conclusion, the various evaluation models under consideration by APHIS provide supportable analytic tools to estimate the prevalence of BSE and provide a basis for the establishment of a future maintenance surveillance program. However, APHIS must ensure accuracy and completeness of its data and clearly discuss the limitations of its program and data in any published assessment of its surveillance effort. This would minimize the potential that stakeholders misinterpret its conclusions.

Recommendation 1

Ensure transparency of published information so that stakeholders are fully advised of the assumptions and procedures used, limitations of data, and the basis of conclusions reached as a result of the BSE surveillance program.

Agency Response.

APHIS concurs with this recommendation. We will complete the final analysis on the BSE enhanced surveillance effort by February 28, 2006, and will ensure transparency of the published information as recommended. The initial assignment of regional goals was based on the pre-determined sample estimate of 268,500, which was primarily done to facilitate management of enhanced surveillance program resources. APHIS' intent is to report the actual number of samples tested in each of the six regions alongside the pre-determined goals in the final report. We agree that it is important to clarify the target population estimates used for surveillance planning prior to implementation of the enhanced surveillance program (and the concomitant statistical inferences to be made from those estimates) and how the expansion of the target population occurred resulting in a larger effective target population. This clarification will be supplied in the final analysis document.

A detailed discussion of the potential biases incurred with over sampling in one region as compared to another and the effects these biases may have on the overall enhanced surveillance program will also be included in the final analysis report.

APHIS also expressed concern with OIG's presentation on State goal allocations; it implies that APHIS had State goal allocations, which were subsequently not met, and that those State goals were posted on APHIS' website. APHIS believes its website is clear that evaluation of its data will be done at a national level. APHIS had regional collection goals, which have been exceeded. There was never an attempt to meet specific State goal numbers. Therefore, APHIS feels that page one of exhibit E is misleading, as there were no specific State targets set by APHIS (see exhibit G for APHIS' response in its entirety).

OIG Position.

APHIS agreed to ensure transparency of published information presented in their final analysis of the BSE enhanced surveillance effort. They also agreed that it is important to clarify the target population estimates and provide a detailed discussion of the potential biases incurred from over sampling in geographical regions. Therefore, we accept management decision.

However, APHIS was concerned that our presentation on samples collected by State was misleading since no specific State targets were set by APHIS. OIG agrees that the published *Examples of Geographic Distributions of Sample Collections* clarify that APHIS did not intend for the data to be evaluated individually at the State or regional level. Our concern is whether the data evaluated at a national level will reflect the U.S. cattle population. More specifically, OIG questions how APHIS intends to determine whether it

met the following objective stated in its March 15, 2004 plan: "to collect samples from as many adult cattle from the high-risk population as possible in 12-18 months while ensuring that there is *statistically* appropriate geographical representation of the adult cattle population in the United States" (emphasis added).

The importance of obtaining samples that represent the national herd is emphasized in the *2005 OIE TAHC* (Article 3.8.4.3.1): "A country should design its surveillance strategy to ensure that samples are representative of the herd of the country, zone, or compartment, and include consideration of demographic factors such as production type and geographic location …"

More specifically, the importance of obtaining representative samples *within each surveillance stream* is emphasized by the authors of *BSurvE*[32] who state that their "analytical approach relies on the surveillance data reported being genuinely representative of the particular surveillance stream from which it is drawn, and if this is not true then the findings will be biased by such errors." As examples of potential problems, they include "low and geographically variable success in sampling fallen stock."

APHIS has agreed to provide a detailed discussion of the potential biases and limitations of the data in its final analysis of its surveillance effort, therefore, OIG's concerns should be addressed.

Recommendation 2

In future surveillance programs, enforce management controls over the integrity of surveillance testing data.

Agency Response.

APHIS concurs with the need to maintain the integrity of surveillance testing data. The National Surveillance Unit is currently developing data standards to be used in all surveillance programs. The projected time period for the completion of the initial data standards is March 31, 2006. Future surveillance programs will utilize those data standards, and will have safeguards to prevent data errors.

OIG Position.

We accept management decision.

[32]Wilesmith, John, Roger Morris, Mark Stevenson, Rob Cannon, Deb Prattley, and Helen Benard. *Development of a Method for Evaluation of National Surveillance Data and Optimization of National Surveillance Strategies for Bovine Spongiform Encephalopathy*; page 10 (March 12, 2004).

Finding 2 — Inherent Challenges in Identifying and Testing High-Risk Cattle Still Remain

Our prior report identified a number of inherent problems in identifying and testing high-risk cattle. We reported that the challenges in identifying the universe of high-risk cattle, as well as the need to design procedures to obtain an appropriate representation of samples, was critical to the success of the BSE surveillance program. The surveillance program was designed to target nonambulatory cattle, cattle showing signs of CNS disease (including cattle testing negative for rabies), cattle showing signs not inconsistent with BSE, and dead cattle. Although APHIS designed procedures to ensure FSIS condemned cattle were sampled and made a concerted effort for outreach to obtain targeted samples, industry practices not considered in the design of the surveillance program reduced assurance that targeted animals were tested for BSE.

Rabies Negative Samples

In our prior report, we recommended that APHIS work with public health and State diagnostic laboratories to develop and test rabies-negative samples for BSE. This target group is important for determining the prevalence of BSE in the United States because rabies cases exhibit clinical signs not inconsistent with BSE; a negative rabies test means the cause of the clinical signs has not been diagnosed.

APHIS agreed with our recommendation and initiated an outreach program with the American Association of Veterinary Laboratory Diagnosticians, as well as State laboratories. APHIS also agreed to do ongoing monitoring to ensure samples were obtained from this target population.

Although APHIS increased the samples tested from this target group as compared to prior years, we found that conflicting APHIS instructions on the ages of cattle to test resulted in inconsistencies in what samples were submitted for BSE testing. Therefore, some laboratories did not refer their rabies negative samples to APHIS in order to maximize the number tested for this critical target population. In addition, APHIS did not monitor the number of submissions of rabies negative samples for BSE testing from specific laboratories.

According to the Procedure Manual for BSE Surveillance, dated October 2004, the target population includes:

> Central nervous system (CNS) signs and/or rabies negative - **sample animals of any age** (emphasis added):
> a. Diagnostic laboratories –samples submitted due to evidence of CNS clinical signs.

b. Public health laboratories – rabies negative cases.
c. Slaughter facilities – CNS ante mortem condemned at slaughter, sampled by FSIS.
d. On-the-farm – CNS cattle that do not meet the criteria for a foreign animal disease investigation.

For FYs 2002, 2003, and 2004 (through February 2004), NVSL received 170, 133, and 45 rabies-negative samples, respectively. Between June 1, 2004, and May 29, 2005, the number of samples received for testing increased to 226 rabies suspect samples. The collection sites submitting these samples follow.

Collection Site	Number of Rabies Suspect Submissions *
Slaughter Plant	0
Renderer	2
On-Farm	11
Public Health Lab	94
Diagnostic Lab	81
3D-4D	8
Other	4
Total	200

* 26 were tested but not counted by APHIS towards meeting the target goals because the obex was not submitted.

We obtained a copy of a memorandum, dated July 13, 2004, that APHIS sent to diagnostic and public health laboratories providing them instructions on submitting samples for cattle showing signs of CNS diseases, but testing negative for rabies. The letter was sent to about 170 State veterinary diagnostic and public health laboratories and discussed the need to submit specimens to NVSL of **all adult cattle** (emphasis added) that showed signs of CNS diseases, but tested negative for rabies. This directive did not specify the age of the cattle. The Procedure Manual for BSE Surveillance, dated October 2004, specified samples of cattle of any age should be submitted.

We contacted laboratories in six States to determine if it was standard procedure to submit all negative rabies samples to NVSL. We found that, because of the lack of specificity in the APHIS letter and inadequate followup by APHIS, there were inconsistencies in the age of cattle samples submitted for BSE testing. For those States contacted, the following samples were submitted versus tested as negative for rabies.

Rabies Negative Tests Not Sent for BSE Testing Since June 1, 2004

State	Negative Rabies Tests	Sent for BSE Testing	Not Sent for BSE Testing
Pennsylvania a/	33	15	18
Kansas b/	85	69	16
Wisconsin c/	12	1	11
South Dakota d/	7	0	7
Arizona e/	5	5	0
Mississippi e/	4	4	0
Total	146	94	52

a/ A Pennsylvania laboratory official said only rabies negative cattle over 20 months of age were submitted for BSE testing. The laboratory did not submit 18 samples for BSE testing because the animals were less than 20 months of age.

b/ Kansas laboratory officials said early in the expanded surveillance program, there was confusion as to the cattle ages that should be submitted for BSE testing. They did not know if cattle should be submitted that were above 20 months or 30 months of age. Of the 16 animals not submitted for BSE testing, 14 were under 20 months of age from early in the expanded surveillance program. The other two animals were not tested due to internal laboratory issues. The Kansas and Nebraska area office officials contacted the laboratory and told the officials to submit rabies negative cattle of any age for BSE testing. The laboratory now submits all rabies negative cattle for BSE testing.

c/ A Wisconsin laboratory official said only rabies negative cattle samples 30 months of age or older are submitted for BSE testing. Of the 11 animals not submitted for BSE testing, 8 were less than 30 months of age. Wisconsin laboratory officials were not certain why the other three samples were not submitted.

d/ Laboratory officials from South Dakota said they did not receive notification from APHIS regarding the submission of rabies negative cases for BSE testing. The section supervisor and laboratory director were not aware of any letter sent to the laboratory. The section supervisor said most bovine rabies tests at the laboratory are performed on calves. We confirmed the laboratory's address matched the address on APHIS' letter distribution list. However, there was no evidence that the South Dakota area office contacted the laboratory. The laboratory was not listed on the documentation from the APHIS regional office detailing the area office contacts with laboratory personnel. We contacted the South Dakota area office and were advised that while some contact had been made with the laboratory, the contact may have involved Brucellosis rather than BSE. On May 4, 2005, the area office

advised us they recently contacted the laboratory regarding the submission of rabies negative samples for BSE testing.

e/ Arizona and Mississippi laboratory officials said they submitted all rabies negative samples for BSE testing regardless of the age of the animal.

An NVSL official stated that APHIS is not concerned with rabies negatives samples from cattle less than 30 months of age. This position, however, is contrary to APHIS' published target population.

Downers and Cattle that Died on the Farm

Our prior audit recognized the significant challenge for APHIS to obtain samples from some high-risk populations because of the inherent problems with obtaining voluntary compliance and transporting the carcasses for testing. USDA issued rules to prohibit nonambulatory animals (downers) from entering the food supply at inspected slaughterhouses. OIG recommended, and the International Review Subcommittee[33] emphasized, that USDA should take additional steps to assure that facilitated pathways exist for dead and nonambulatory cattle to allow for the collection of samples and proper disposal of carcasses. Between June 1, 2004, and May 31, 2005, the APHIS database documents 27,617 samples were collected showing a reason for submission of nonambulatory and 325,225 samples were collected with reason of submission showing "dead."

APHIS made extensive outreach efforts to notify producers and private veterinarians of the need to submit and have tested animals from these target groups. They also entered into financial arrangements with 123 renderers and other collection sites to reimburse them for costs associated with storing, transporting, and collecting samples. However, as shown in exhibit F, APHIS was not always successful in establishing agreements with non-slaughter collection sites in some States. APHIS stated that agreements do not necessarily reflect the entire universe of collection sites and that the presentation in exhibit F was incomplete because there were many collection sites without a payment involved or without a formal agreement. We note that over 90 percent of the samples collected were obtained from the 123 collection sites with agreements and; therefore, we believe agreements offer the best source to increase targeted samples in underrepresented areas.

We found that APHIS did not consider industry practices in the design of its surveillance effort to provide reasonable assurance that cattle exhibiting possible clinical signs consistent with BSE were tested. Slaughter facilities do not always accept all cattle arriving for slaughter because of their business requirements. We found that, in one State visited, slaughter facilities pre-screened and rejected cattle (sick/down/dead/others not meeting business

[33] Report from the Secretary's Advisory Committee on Foreign Animal and Poultry Diseases, February 13, 2004.

standards) before presentation for slaughter in areas immediately adjacent or contiguous to the official slaughter establishment. These animals were not inspected and/or observed by either FSIS or APHIS officials located at the slaughter facilities.

FSIS procedures state that they have no authority to inspect cattle not presented for slaughter. Further, APHIS officials stated they did not believe that they had the authority to go into these sorting and/or screening areas and require that the rejected animals be provided to APHIS for BSE sampling. Neither APHIS nor FSIS had any process to assure that animals left on transport vehicles and/or rejected for slaughter arrived at a collection site for BSE testing. FSIS allows slaughter facilities to designate the area of their establishment where federal inspection is performed; this is designated as the official slaughter establishment.[34]

We observed animals that were down or dead in pens outside the official premises that were to be picked up by renderers. Animals that were rejected by plant personnel were transported off the premises on the same vehicles that brought them to the plant.[35]

A policy statement[36] regarding BSE sampling of condemned cattle at slaughter plants provided that effective June 1, 2004, FSIS would collect BSE samples for testing: 1) from all cattle regardless of age condemned by FSIS upon ante mortem inspection for CNS impairment, and 2) from all cattle, with the exception of veal calves, condemned by FSIS upon ante mortem inspection for any other reason.

FSIS Notice 28-04, dated May 20, 2004, informed FSIS personnel that, "FSIS will be collecting brain samples from cattle at federally-inspected establishments for the purpose of BSE testing." The notice further states that, "Cattle off-loaded from the transport vehicle onto the premises of the ***federally-inspected establishment*** (emphasis added), whether dead or alive, will be sampled by the FSIS Public Health Veterinarian (PHV) for BSE after the cattle have been condemned during ante mortem inspection. In addition, cattle passing ante mortem inspection but later found dead prior to slaughter will be condemned and be sampled by the FSIS PHV."

[34] FSIS regulations do not specifically address the designation of an establishment's "official" boundaries; however, FSIS Notices 29-04 (dated May 27, 2004) and 40-04 (dated July 29, 2004) make it clear that FSIS inspection staff are not responsible for sampling dead cattle that are not part of the "official" premises.

[35] APHIS' area office personnel stated that it was their understanding that some establishments in the State were not presenting cattle that died or were down on the transport vehicle to FSIS for ante mortem inspection. The dead and down cattle were left in the vehicle, if possible. In rare circumstances, dead cattle may be removed from the trailer by plant personnel to facilitate the unloading of other animals.

[36] A May 20, 2004, Memorandum between the Administrators of APHIS and FSIS.

APHIS has the responsibility for sampling dead cattle off-loaded onto plant-owned property that is adjoining to, but not considered part of, the "official premises.[37] FSIS procedures[38] provide that "Dead cattle that are off-loaded to facilitate the off-loading of live animals, but that will be re-loaded onto the transport vehicle, are not subject to sampling by FSIS.

While performing our review in one State, we reviewed the circumstances at two slaughter facilities in the State that inspected and rejected unsuitable cattle before the animals entered the official receiving areas of the plants. This pre-screening activity was conducted in areas not designated by the facility as official premises of the establishment and not under the review or supervision of FSIS inspectors. The plant rejected all nonambulatory and dead/dying/sick animals delivered to the establishment. Plant personnel refused to offload any dead or downer animals to facilitate the offloading of ambulatory animals. Plant personnel said that the driver was responsible for ensuring nonambulatory animals were humanely euthanized and disposing of the carcasses of the dead animals. Plant personnel informed us that they did not want to jeopardize contracts with business partners by allowing unsuitable animals on their slaughter premises.

In the second case, one family member owned a slaughter facility while another operated a livestock sale barn adjacent to the slaughter facility. The slaughter facility was under FSIS' supervision while the sale barn was not. Cattle sometimes arrived at the sale barn that were sick/down/dead or would die or go down while at the sale barn. According to personnel at the sale barn, these animals were left for the renderer to collect. The healthy ambulatory animals that remained were marketed to many buyers including the adjacent slaughter facility. When the slaughter facility was ready to accept the ambulatory animals for processing, the cattle would be moved from the sale barn to the slaughter facility where they were subject to FSIS' inspection.

We requested the slaughter facilities to estimate the number of cattle rejected on a daily basis (there were no records to confirm the estimates). We visited a renderer in the area and found that the renderer had a contract with APHIS to collect samples for BSE testing. In this case, although we could not obtain assurance that all rejected cattle were sampled, the renderer processed a significant number of animals, as compared to the slaughter plants' estimates of those rejected. Due to the close proximity (less than 5 miles) of the renderer to the slaughter facilities, and the premium it paid for dead cattle that were in good condition, there was a financial incentive for transport drivers to dispose of their dead animals at this renderer.

[37] FSIS Notice 40-04, dated July 29, 2004.
[38] FSIS Notice 29-04, dated May 27, 2004.

In our discussions with APHIS officials in Wisconsin and Iowa, they confirmed that there were plants in their States that also used pre-screening practices. On May 27, 2005, we requested APHIS and FSIS to provide a list of all slaughter facilities that pre-screened cattle for slaughter in locations away from the area designated as the official slaughter facility. Along with this request, we asked for information to demonstrate that either APHIS or FSIS confirmed there was a high likelihood that high-risk animals were sampled at other collection sites.

In response to our request, the APHIS BSE Program Manager stated that APHIS did not have information on slaughter plants that pre-screen or screen their animals for slaughter suitability off their official plant premises. To their knowledge, every company or producer that submits animals for slaughter pre-sorts or screens them for suitability at various locations away from the slaughter facility. For this reason, USDA focused its BSE sample collection efforts at other types of facilities such as renderers, pet food companies, landfills, and dead stock haulers. Further, in a letter to OIG on June 14, 2005, the administrators of APHIS and FSIS noted the following:

> *"…we believe that no specific actions are necessary or appropriate to obtain reasonable assurance that animals not presented for slaughter are being tested for BSE. There are several reasons for our position. First, we do not believe that the practice is in fact causing us to not test a significant enough number of animals in our enhanced surveillance program to invalidate the overall results. Second, OIG has concluded that because of the geographical proximity and business relationships of the various entities involved in the case investigated, there is reasonable assurance that a majority of the rejected cattle had been sampled. Third, it is also important to remember that the goal of the enhanced surveillance program is to test a sufficient number of animals to allow us to draw conclusions about the level of BSE (if any) in the American herd…We believe that the number we may be not testing because of the "pre-sorting" practice does not rise to a significant level. The number of animals tested to date has far exceeded expectations, so it is reasonable to infer that there are few of the animals in question, or that we are testing them at some other point in the process…APHIS estimated…there were approximately 446,000 high risk cattle…[and APHIS has]…tested over 375,000 animals in less than 1 year. This indicated that we are missing few animals in the high-risk population, including those that might be pre-sorted before entering a slaughter facility's property."*

We obtained 123 APHIS sampling agreements and contracts with firms and plotted their locations within the United States (see exhibit F). We also analyzed the samples tested to the BSE sampling goals allocated to each State under the prior surveillance program. This analysis showed that there are

sampling gaps in two large areas of the United States where APHIS did not have contracts with collection sites. These two areas are shown in the following chart (Montana, South Dakota, North Dakota and Wyoming – Group 1 and Louisiana, Oklahoma, Arkansas, and Tennessee – Group 2):

State	Original Sampling Goal Based on (268,500 sampling goal)	Samples collected as of May 31, 2005	Deficit	No. of BSE Sampling Agreements/ Contracts[39]
MT	5,076	182	4,894	2
SD	6,938	2,792	4,146	1
ND	3,616	174	3,442	0
WY	2,513	61	2,452	0
AREA TOTAL			**14,934**	
OK	7,792	2,407	5,385	1
AR	3,672	353	3,319	0
TN	4,938	3,050	1,888	1
LA	2,312	452	1,860	1
AREA TOTAL			**12,452**	

APHIS notes that for the current surveillance program, it had established regional goals and APHIS was not trying to meet particular sampling levels in particular States. However, we believe that it would be advantageous for APHIS to monitor collection data and increase outreach when large geographical areas such as the above States do not provide samples in proportion to the numbers and types of cattle in the population.

We also disagree with APHIS/FSIS' contention that because they have tested over 375,000 of their 446,000 estimate of high risk cattle, few in the high-risk population are being missed, including those that might be pre-screened before entering a slaughter facility's property. In our prior audit, we reported that APHIS underestimated the high-risk population; we found that this estimate should have been closer to 1 million animals (see Finding 1). We recognize that BSE samples are provided on a voluntary basis; however, APHIS should consider industry practice in any further maintenance surveillance effort. Animals unsuitable for slaughter exhibiting symptoms not inconsistent with BSE should be sampled and their clinical signs recorded. However, this cited industry practice results in rejected animals not being made available to either APHIS or FSIS veterinarians for their observation and identification of clinical signs exhibited ante mortem. Although these animals may be sampled later at other collection sites, the animals are provided post mortem without information as to relevant clinical signs exhibited ante mortem. For these reasons, we believe APHIS needs to

[39]APHIS noted that sites with agreements do not necessarily reflect the entire universe of collection sites and at some sites APHIS collects samples with no payment involved and no agreement in place. OIG agrees that not all collection sites are reflected in our presentation of the 123 sites with reimbursable agreements. OIG believes obtaining sampling agreements is one of the primary methods available to increase sample numbers in areas with sampling gaps.

observe these animals ante mortem when possible to assure the animals from the target population are ultimately sampled and the clinical signs evaluated.

Recommendation 3

Determine whether FSIS and/or APHIS need additional authorities to perform inspection and BSE sampling activities in pre-screening areas immediately adjacent, or contiguous to, official slaughter establishments.

Agency Response.

The question as to whether FSIS has jurisdiction is not determinable merely on the basis of proximity of where certain activities take place. FSIS' ability to conduct activities in pre-screening areas is related to the relationship between the activities the establishment performs in the pre-screening areas and the slaughter process. The closer and more exclusively those activities are related to the slaughter process, the more likely it is that FSIS would be able to exercise jurisdiction in the pre-screening area. The available information, however, does not allow a judgment on the concern raised by OIG. FSIS will, however, remain open to learning more about the situations raised by OIG and pursue any leads that indicate that such activities directly relate to slaughter and are under the control of the establishment.

APHIS does not believe that additional authorities are needed to perform inspection and BSE sampling in pre-screening areas immediately adjacent, or contiguous to, official slaughter establishments. As stated in the report, OIG observed animals that were down or dead in those areas that were to be picked up by renderers. OIG also states that they observed that animals that arrived at a sale barn that were sick/down/dead or would die or go down while at the sale barn were also left for the renderer to collect. APHIS utilized the knowledge of industry practices regarding the disposition of animals presented at these facilities and then rerouted, and designed the surveillance system to collect at renderers where these animals were ultimately destined. OIG visited a renderer in the area of a slaughter facility and found the renderer had a contract with APHIS to collect samples for BSE testing. OIG also states that "...there was a financial incentive for transport drivers to dispose of their dead animals at this renderer." The goal of the enhanced surveillance program is to test a sufficient number of animals to draw conclusions about the level of BSE in the American herd, not to test every animal in the target population. APHIS does not think it would be a prudent use of taxpayer dollars to seek and use new authorities to seize and test these few animals. Credible, scientifically valid conclusions can be drawn without spending the taxpayers' money to comply with this recommendation.

APHIS is also concerned with OIG's analysis and presentation of sampling gaps in two large areas of the United States where APHIS did not have contracts with collection sites, and the chart referencing that point. The commentary and the chart purport to make the case that APHIS failed to meet State by State surveillance goals. APHIS believes that this is inaccurate and unnecessarily and unfairly questions the overall validity of the program. Again, APHIS was not trying to meet particular levels in particular States. APHIS worked to meet regional goals, and those are the goals that should be evaluated.

In addition, agreements do not necessarily reflect the entire universe of collection sites we work with. For a collection site where there is no payment involved, there is no agreement in place. Attempting to determine distribution of sampling by plotting only collection sites with agreements is misleading, since it is an incomplete list of collection sites. In fact, the random tool used to develop allocations for maintenance surveillance planning drew from approximately 165 large sites and more than 260 small ones, far more than the 123 with which we had reimbursement agreements.

Further, exhibit F is an inaccurate representation of collection sites. In summary, based on our knowledge of the industry, APHIS focused collection efforts at animal disposal facilities such as rendering facilities, and salvage and slaughter facilities. In many areas of the country, such facilities do not exist. APHIS worked with existing facilities and entered into agreements with those facilities. Those States without agreements are States without animal disposal facilities of the sort that are crucial in the BSE surveillance program. In those cases, samples were collected through other mechanisms, which resulted in approximately 5,000 collection sites without agreements referenced above (see exhibit G for APHIS' response in its entirety).

OIG Position.

Both APHIS and FSIS do not believe they need additional authorities to perform inspection and BSE sampling activities in pre-screening areas immediately adjacent, or contiguous to, those areas at slaughter plants designated as the official slaughter establishment. We accept the management decision that such authorities are not needed.

However, we remain concerned that the FSIS and APHIS personnel interviewed during the audit were not aware such authorities exist. FSIS, in their response, states that the information provided by OIG does not allow a judgment on the concerns raised; FSIS' ability to conduct activities in pre-screening areas depends on whether such activities are directly related to slaughter. As the report discusses, the animals pre-screened by the establishments were not accepted for slaughter. FSIS directives clearly discuss their, and APHIS' authorities, for sampling cattle off-loaded onto

plant-owned property that is not considered part of the "official premises." The directive states that animals offloaded in those areas are not subject to sampling by FSIS.

We did not recommend that APHIS seek additional authority to "seize" animals for testing in the pre-screening areas. In our view, the pre-screening areas are points of concentration that would likely already fall under APHIS' existing authority for sample collection. Also, APHIS stated they utilized the knowledge of industry practices regarding the disposition of animals presented at these facilities (and then re-routed) and designed the surveillance system to collect at renderers where these animals were ultimately destined. However, during the audit, we requested that both APHIS and FSIS provide us those slaughter locations where these pre-screening activities occur and information to demonstrate that the agencies confirmed there was a high likelihood that high-risk animals were tested at other collection sites. In a June 14, 2005, letter, the Administrators of APHIS and FSIS informed us that they did not believe specific actions were necessary or appropriate to obtain reasonable assurance that animals not presented for slaughter are being tested for BSE. We disagree since those animals that were not allowed in those areas designated as the official slaughter establishment are the target animals at highest risk for BSE.

As discussed in the report, 90 percent of the samples collected were obtained from the 123 collection sites with agreements. In those two large areas with sampling gaps, there were about 930 of the 5,000 collection sites referenced by APHIS that did not have sampling agreements. OIG continues to believe formal agreements offer the best source to increase targeted samples in underrepresented areas.

Recommendation 4

Consult with technical experts and determine what ages of animals of rabies negative cattle should be tested for BSE. Perform additional outreach and personal contacts to emphasize the age of the target animals and to ensure laboratory personnel understand procedures for submitting the desired samples. Provide periodic monitoring of laboratory submissions and followup with laboratories that appear to be providing an insufficient number of samples.

Agency Response.

APHIS concurs with the recommendation. Once the final analysis of the BSE surveillance effort is completed, APHIS will make a final determination on the ages of rabies negative animals that should be tested for BSE, and will notify laboratories within 30 days of that determination, no later than April 15, 2006. Veterinary Services personnel at NVSL and in the field will

personally contact all involved laboratories by June 1, 2006, to ensure that the laboratories have received and understood the procedures for submitting samples. By April 30, 2006, APHIS will establish a monitoring process that includes a threshold on the number of samples expected from laboratories based on those laboratories' particular situation. That process will include an action step to contact any laboratory not meeting reasonable expectations given their circumstances.

OIG Position.

We accept management decision.

In November 2004, USDA announced that its rapid screening test, Bio-Rad Enzyme Linked Immunosorbent Assay (ELISA), produced an inconclusive BSE test result as part of its enhanced BSE surveillance program. The ELISA rapid screening test performed at a BSE contract laboratory produced three high positive reactive results.[40] As required,[41] the contract laboratory forwarded the inconclusive sample to the APHIS National Veterinary Services Laboratories (NVSL) for confirmatory testing. NVSL repeated the ELISA testing and again produced three high positive reactive results.[42] In accordance with its established protocol, NVSL ran its confirmatory test, an immunohistochemistry (IHC) test, which was interpreted as negative for BSE. In addition, NVSL performed a histological[43] examination of the tissue and did not detect lesions[44] consistent with BSE.

Faced with conflicting results, NVSL scientists recommended additional testing to resolve the discrepancy but APHIS headquarters officials concluded no further testing was necessary because testing protocols were followed. In our discussions with APHIS officials, they justified their decision not to do additional testing because the IHC is internationally recognized as the "gold standard." Also, they believed that conducting additional tests would undermine confidence in USDA's established testing protocols.

However, OIG obtained evidence that indicated additional testing was prudent to ensure that USDA's testing protocols were effective in detecting BSE and that confidence in USDA's testing procedures was maintained. OIG came to this conclusion because the rapid tests produced six high positive reactive results, confirmatory testing conflicted with the rapid test results, and various standard operating procedures were not followed. Also, our review of scientific literature, other country protocols, as well as discussions with internationally recognized experts led us to conclude that confirmatory testing should not be limited when conflicting test results are obtained. To maintain objectivity and independence in our assessment, we requested the USDA Agricultural Research Service (ARS) perform the Office International des Epizooties (OIE) Scrapie-Associated Fibrils (SAF)

[40] ELISA test procedures require two additional (duplicate) tests if the initial test is reactive, before final interpretation. If either of the duplicate tests is reactive, the test is deemed inconclusive.
[41] Protocol for BSE Contract Laboratories to Receive and Test Bovine Brain Samples and Report Results for BSE Surveillance Standard Operating Procedure (SOP), dated October 26, 2004.
[42] The NVSL conducted an ELISA test on the original material tested at the contract laboratory and on two new cuts from the sample tissue.
[43] A visual examination of brain tissue by a microscope.
[44] A localized pathological change in a bodily organ or tissue.

immunoblot.[45] ARS performed the test at the National Animal Disease Center because NVSL did not have the necessary equipment[46] (ultracentrifuge) to do the test. APHIS scientists observed and participated, as appropriate, in this effort.

The additional tests conducted by ARS produced positive results. To confirm this finding, the Secretary requested the internationally recognized BSE reference laboratory in Weybridge, England, (Weybridge) to perform additional confirmatory testing. Weybridge conducted various tests, including their own IHC methods, as well as three Western blot methods. The tests confirmed that the suspect cow was infected with BSE. Also, Weybridge confirmed this case as an unequivocal positive case of BSE on the basis of IHC. As a result of this finding, the Secretary immediately directed USDA scientists to work with international experts to develop a new protocol that includes performing dual confirmatory tests in the event of another inconclusive BSE screening test.

Finding 3 Rigid Protocols Reduced the Likelihood BSE Could be Detected

APHIS Declares BSE Sample Negative Despite Conflicting Results

APHIS relied on a single test method, as well as a histological examination of tissue for lesions consistent with BSE, to confirm the presence of BSE even though discrepant test results indicated further testing may be prudent. When IHC test results were interpreted as negative, APHIS concluded the sample tested negative for BSE. Subsequent independent tests initiated by OIG using a different testing method, as well as confirmatory testing by Weybridge, determined that the suspect sample was a positive case of BSE.

When the tissue sample originally arrived at NVSL in November 2004 from the contract lab, NVSL scientists repeated the ELISA screening test and again produced three high positive reactive results. NVSL scientists cut out two sections of the brain sample for IHC testing. One section was used for an experimental procedure that was not part of the confirmatory testing protocol, and the other cut was for normal IHC testing using scrapie for a positive control.[47] According to NVSL scientists, the experimental test results were inconclusive but the IHC test was interpreted as negative. The NVSL scientists were concerned with the inconsistencies and conducted

[45] The OIE SAF immunoblot is an internationally recognized confirmatory test, often referred to as a Western blot test. There are different types of Western blots; the OIE SAF immunoblot includes enrichment steps taken with the sample prior to the standard Western blot steps.

[46] APHIS has now ordered the necessary equipment for NVSL.

[47] A positive control is a sample that is known to contain a given disease or react in the test. The sample then can be used to make sure that the test for that disease works properly. In the case of BSE, tissue infected with either scrapie or BSE can serve as a positive control for an IHC test for BSE since both are different forms of the same disease (transmissible spongiform encephalopathy or TSE).

another IHC test using BSE as a positive control.[48] The test result was also interpreted as negative. Also, according to the NVSL scientists, the histological examination of the tissue did not detect lesions consistent with BSE.

After the second negative IHC test, NVSL scientists supported doing additional testing. They prepared a plan for additional tests; if those tests had been conducted, BSE may have been detected in the sample. The additional tests recommended by NVSL scientists, but not approved by APHIS Headquarters officials, were the IHC using other antibodies (IHC testing using different antibodies ultimately produced positive results); IHC testing of additional regions of the brain (the cerebellum tested positive); regular and enriched (OIE-like) Western blots (the obex and cerebellum tested positive); and variable rapid tests (the obex and cerebellum tested positive with two different rapid tests). NVSL officials also recommended that the sample be sent to Weybridge for confirmatory testing (to conduct IHC and OIE Western blot tests). In June 2005, Weybridge conducted IHC testing with three different antibodies, including the antibody used in the United States (tested positive), the OIE Western blot (tested positive), a modified commercial kit Western blot (negative) and the NaPTA[49] Western blot (tested positive).

Evidence Indicated Additional Testing Would Be Prudent

We obtained information as to the differing protocols used by other countries. We found that while APHIS determined that additional testing was unnecessary after the IHC test, other countries have used multiple tests to confirm positives. In Japan, for example, all reactive screening test samples are examined by both IHC and a Western blot (different from the OIE SAF immunoblot). In the United Kingdom (U.K.), IHC and Western blot (different from the OIE SAF immunoblot) tests are used for all animals that test positive with a screening test. When IHC and the Western blot fail to confirm a positive rapid test, the U.K. resorts to a third test, the OIE SAF immunoblot. With these procedures in place, both Japan and the U.K. have found BSE cases that were rapid test reactive, IHC negative, and finally confirmed positive with a Western blot.

We also spoke with an internationally recognized BSE expert regarding the advisability of limiting confirmatory testing when conflicting results are obtained. This official expressed concern about limiting confirmatory tests to the IHC despite its status as one of the "gold standard" tests. He advised that the IHC is not one test; it is a test method that can vary significantly in sensitivity from laboratory to laboratory. New antibodies can improve or

[48] The NVSL uses scrapie as the positive control as part of its normal IHC testing procedures. Due to the conflicting results between the ELISA and IHC tests, the NVSL conducted another IHC test with BSE as the positive control. Subsequently, the NVSL modified the Confirming Inconclusive Results from BSE Testing Laboratories at the NVSL SOP to show that all IHC tested BSE inconclusive samples from contract laboratories will use BSE as the positive control.
[49] Sodium phosphotungstic acid.

reduce sensitivity, as can variations in many of the reagents[50] used. He explained that his laboratory had experienced cases where an initial confirmatory IHC test was challenged by either a more extensive IHC test or "…applying a more sensitive immunoblot." He emphasized the importance of having additional confirmatory testing to resolve discrepant results since there are many variables, and most of the variability appears to be due to test performance of the laboratory.

OIG became concerned that APHIS relied on its confirmatory test methods when rapid screening tests produced high positive reactive results six times.[51] Also, we found that APHIS did not pursue and/or investigate why the ELISA produced high reactive positives. An official from the manufacturer of the ELISA test kit told us that they requested, but did not receive, information on the inconclusive reported by USDA in November 2004. These officials requested this information in order to understand the reasons for the discrepant results. The Bio-Rad ELISA rapid screening test is internationally recognized as a highly reliable test and is the rapid screening test used for USDA's surveillance effort. According to APHIS officials, they felt it would be inappropriate to collaborate on the one sample because Bio-Rad is a USDA-APHIS regulated biologics company and only one of several competing manufacturers. To maintain confidence in USDA's test protocols, it would have been a prudent course of action for USDA to determine why such significant differing results were obtained. The fact that they did not pursue this matter caused concerns relating to testing quality assurance procedures. In this regard, we found lack of compliance with SOPs relating to laboratory proficiency and quality assurance (see Finding 4), and, in this case, the storage of sampled material and reporting of test results.

We found that the NVSL did not prepare a report to document its confirmatory testing of the November 2004 sample. The SOP[52] states that the BSE network laboratory initiating the inconclusive will receive a report of the case. NVSL officials could not explain why a final report had not been prepared. We also found that the inconclusive sample was frozen prior to IHC confirmatory testing. APHIS protocols state that samples are not to be frozen prior to laboratory submission. The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals states that the tissues for histological or IHC examination are not to be frozen as this will provide artefactual[53] lesions that may compromise the identification of vacuolation,[54] and/or target site location. Although the sample was frozen, APHIS did not conduct a Western

[50] A substance used in a chemical reaction to detect, measure, examine, or produce other substances.
[51] The six high positive reactive results were from three tests of the submitted sample (multiple runs of the same test).
[52] Confirming Inconclusive Results from Bovine Spongiform Encephalopathy Testing Laboratories at the NVSL SOP, dated August 13, 2004.
[53] A structure or feature not normally present but visible as a result of an external agent or action, such as one seen in a microscopic specimen after fixation.
[54] A small space or cavity in a tissue.

blot test on the sample. An NVSL official said freezing the sample does not make it unsuitable for IHC. APHIS determined that the sample was suitable for IHC and therefore, in accordance with its SOP, did not conduct a Western blot test.

APHIS also handled the December 2003 BSE positive differently than the November 2004 sample. For the December 2003 BSE positive sample, APHIS conducted several confirmatory tests in addition to the IHC testing and histological examination (unlike the November 2004 sample tests, both of these were interpreted as positive). ARS performed two Western blots (Prionics Check Western blot and an ARS developed Western blot). When we questioned why the samples were handled differently, APHIS officials stated that the Western blots were done because the IHC in December 2003 was positive. The additional testing was done to further characterize the case, because it was the first U.S. case; the additional testing was not done to decide whether the case was positive or negative.

We discussed our concerns with limiting confirmatory testing, particularly given conflicting results, with the APHIS Administrator and staff in May 2005. He explained that international standards recognized more than one "gold standard" test. In setting up its testing protocols, USDA had chosen one as the confirming test, the IHC test, and stayed with it. APHIS protocols only allow a Western blot in cases where the sample has become unsuitable for IHC tests (e.g., in cases where the brainstem architecture is not evident).

International standards, he continued, accept a tissue sample as negative for BSE if its IHC test is negative. Once the test is run in accordance with protocols, additional tests undermine the USDA testing protocol and the surveillance program. He concluded that since APHIS' protocols accepted the IHC test as confirming the presence or absence of BSE, no further testing was necessary. According to protocol, the tissue sample was determined to have tested negative for BSE.

On June 24, 2005, USDA announced that the additional testing by the BSE reference laboratory in England confirmed the presence of BSE in the tissue sample. To obviate the possibility that a future sample would be declared negative and then found positive, the Secretary of Agriculture announced a change to APHIS' testing protocols that same day. He called for "dual confirmatory tests in the event of another 'inconclusive' [reactive] BSE screening test." He also indicated that he would reinforce proper procedures so that samples will not be frozen, and to spot-check the laboratories to see that they complete reports as required. APHIS issued a SOP on the new confirmatory testing protocols on November 30, 2005.

Recommendation 5

Continuously re-evaluate, and adjust, testing protocols based on emerging science.

Agency Response.

APHIS concurs with the recommendation. The NVSL has in the past re-evaluated and adjusted its testing protocols based on emerging science, and will continue to do so. For example, NVSL has revised laboratory standard operating procedures (SOPs) to include the use of the OIE scrapie associated fibril (SAF) immunoblot procedure as a mandatory confirmatory test (in addition to IHC already required) for confirmation testing with inconclusive results. Additionally, based on the recommendations of OIG, NVSL scientists, and other internationally recognized experts, NVSL will incorporate additional language into the IHC SOP so that NVSL scientists may incorporate the flexibility of adding additional antibodies, chromagens, and variations in specific tissue treatments (including fixation methods) as needed to further clarify interpretation of the IHC results. These changes will be considered normal variations of the SOP and not considered research procedures. Additional tests and flexibility will be utilized when conflicting or unexplained anomalies in test results occur, and will only be performed after consultation with appropriate Agency and Department officials. If such further testing is requested and approved, NVSL will provide the Deputy Administrator with a specific testing protocol together with a written explanation of that protocol. APHIS will implement the new SOP when we move from the enhanced surveillance program level of testing to a level commensurate with the OIE guidelines. APHIS estimates that will occur during the spring of 2006.

OIG Position.

We accept management decision.

Recommendation 6

Strengthen controls over contract laboratories to ensure that the samples are not frozen and that laboratory testing results are properly documented and reported by NVSL.

Agency Response.

APHIS agrees with the recommendation and has issued NVSL standard operating procedure GPPISOP0032.06, which contains the following instructions to the BSE contract laboratory personnel: "Do not freeze the obex or place it in formalin. The obex will be shipped refrigerated." An

additional footnote states: "Note: If it is not possible to ship the obex in order for it to be received at NVSL within 48 hours, the entire sample should be frozen. Every effort should be made, however, to insure that **refrigerated** obex will arrive at NVSL within 48 hours." APHIS added this language in late June 2005, after the initial OIG inquiry on this matter. APHIS also emphasized the instructions in an e-mail to and a conference call with the BSE network laboratory Directors. By March 15, 2006, APHIS will establish further procedures for ensuring test results are properly documented and reported by NVSL.

OIG Position.

We accept management decision.

Finding 4 — Laboratory Proficiency and Quality Assurance Procedures Should be Reviewed and Strengthened

The NVSL had not established and/or implemented adequate controls and procedures to ensure the quality or capability of its BSE testing program. We found noncompliance with established quality assurance SOPs designed to ensure the accuracy and reliability of results. Also, NVSL had not implemented an adequate quality assurance program for its own laboratory testing procedures, nor had they obtained internationally recognized accreditation for its BSE testing program. While the NVSL considered OIG, Government Accountability Office (GAO), and Agricultural Marketing Service (AMS)[55] audits to fulfill the need for management reviews of the NVSL, these audits and/or reviews are not technical reviews that evaluate the testing procedures and proficiency of the laboratory. We attribute the failure to identify the BSE positive sample to be caused, in part, by the lack of adequate quality assurance controls over its testing program. As a result, there is reduced confidence in the reliability of reported test results.

Laboratory Proficiency Testing Was Not in Place at NVSL

Although APHIS established an ELISA proficiency-testing program for the seven contract laboratories that participated in the BSE surveillance program, they did not establish such controls for NVSL's IHC testing procedure. Confirmatory testing of the November 2004 sample as BSE positive by ARS, as well as the BSE reference laboratory in Weybridge, demonstrates the need for a formal and regular laboratory proficiency-testing program at the NVSL.

[55] In response to OIG's prior audit recommendations to establish management controls over its sampling and testing program, APHIS requested AMS to perform compliance reviews. As part of its assessment, AMS reviewed the processing of BSE samples and observed and interviewed NVSL personnel relative to how packaging, materials, shipping, and/or records are handled at the laboratory.

OIE guidelines[56] emphasize the need for proficiency testing. Proficiency testing is an interlaboratory test comparison conducted for the express purpose of determining a laboratory's capability to conduct specific diagnostic tests. Optimally, OIE recommends that proficiency testing be done on a twice-yearly basis. Twice yearly provides sufficient time between proficiency tests to undertake any corrective actions which might prevent a participating laboratory from losing its recognition status. The laboratory shall have policy and procedures that ensure that nonconforming testing (conditions that exist that have or could adversely affect the reliability of test results) is detected and promptly corrected.

According to APHIS officials and information provided by the Secretary of Agriculture on June 24, 2005, there is no single commercially available off-the-shelf IHC test at the moment, and laboratories do not use identical methods. Attempts have been made to do so, but even variations in quality of reagents, such as water, can make a difference in the performance of the tests.

In June 2005, Weybridge conducted confirmatory testing of the November 2004 sample. Weybridge noted that there was a marked difference in the sensitivity of the immunostaining (for IHC testing) when the sections prepared at Weybridge are compared with the NVSL submitted sections indicating that the NVSL's immunostaining protocol may be suboptimal, and should be critically reviewed. Weybridge, therefore, encouraged the USDA to enable the NVSL to participate in interlaboratory proficiency testing.

NVSL officials have discussed the possibility of interlaboratory proficiency testing with Canada but, to date, this process has not been put in place due to other priorities. Between the period June 1, 2004, and May 31, 2005, NVSL conducted about 18,000 BSE tests. Over 8,000 samples were fixed in formalin, for which only an IHC test could be performed.[57] APHIS needs to expedite establishing a program of interlaboratory proficiency testing for the NVSL so that confidence in its IHC tests is assured.

NVSL Accreditation Should be Actively Pursued

International standards for laboratory accreditation establish a formal process for the review and recognition of any organization that wants to assure its customers of the precision, accuracy, and repeatability of results. To attain and maintain laboratory accreditation, internal reviews are necessary to ensure quality standards are in place. Although APHIS has recognized the need to obtain accreditation for international recognition as a leader in animal disease testing programs, it has not established and/or implemented adequate quality assurance processes to demonstrate it can meet internationally recognized standards.

[56] OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases.
[57] The rapid screening test cannot be conducted on a sample that has been preserved in formalin.

The USDA Quality Assurance and Laboratory Accreditation Action Plan states that in order to be internationally recognized as a leader in animal health, NVSL needs to achieve International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 accreditation.[58] Also, the Action Plan recognizes that NVSL needs to assume a leadership role in supporting appropriate quality assurance improvement programs consistent with the ISO/IEC Standard 17025 for laboratories. The plan includes a recommendation to develop and implement a quality assurance and control system for both federal and State laboratories that meets or exceeds international standards and to maintain and disseminate an active database of laboratories meeting these standards. The plan states that NVSL does not have any external accreditation status, even though this has been a longstanding goal for over 5 years.

According to APHIS' Strategic Plan, dated February 2001, the NVSL is striving towards ISO 17025 accreditation. Although the Transmissible Spongiform Encephalopathy (TSE)[59] testing program was reviewed in 1998 by external parties, there have been no further external assessments made. The strategic plan calls for repeat reviews over the next 5 years to determine what, if any, improvements have been made and to target areas that may still need work. The NVSL Director advised that the NVSL hired a contractor to begin the ISO accreditation process starting June 2005, with a target completion date of FY 2006 or 2007.

In contrast, all four FSIS laboratories are accredited under ISO Standard 17025. Also, all seven BSE contract laboratories (as well as four of five additional laboratories approved for BSE testing) are accredited by the American Association of Veterinary Laboratory Diagnosticians. The additional laboratory approved for BSE testing that has not been accredited is the APHIS Federal Diagnostic Laboratory in Frankfort, Kentucky.

[58] The International Organization for Standardization (ISO) has issued standards that apply to any organization that wants to assure its customers of precision, accuracy, and repeatability of results. An accreditation program is a formal process for recognition of laboratory quality and capability by an independent authority. It requires that laboratories successfully participate in such a program on an ongoing basis in order to maintain their recognition status. The independent authority awards or denies recognition based on stipulated requirements for quality and capability. However, it is recognized that in some laboratories, this level of compliance may be difficult to achieve for a variety of reasons. Lack of formal accreditation should not necessarily preclude participation in proficiency testing schemes.

[59] BSE is a TSE along with scrapie and chronic wasting disease.

External Peer Review Not Conducted

In our Phase I report, we discussed our concerns that the last external peer review of the TSE section of the NVSL was conducted in 1998.[60] The 1998 peer review was conducted 6 years prior to the expanded BSE surveillance program. We did not identify any internal NVSL procedures specifying how frequently a peer review should be performed. An NVSL official stated a peer review has been delayed because of animal health emergencies and other priorities. The review of the TSE section is now scheduled for 2006.

We noted a 2000 procedure[61] covering NVSL that provided some guidance on establishing a peer review process for validation of laboratory services against international standards for high-impact foreign animal disease threats and endemic diseases. However, neither the 2000 document nor a 1998 SOP specified timeframes for conducting peer reviews.

Periodic Quality Assurance Reviews Have Not Been Conducted

APHIS has not conducted an internal review of the NVSL BSE laboratory since 2002. The 2002 review found that 1) current laboratory documents did not reflect the current process or procedure the laboratory was following, 2) critical processes performed in the laboratory were not formally documented, and 3) data corrections were not made according to the process approved in the SOP. NVSL could not provide documentation to demonstrate these issues were corrected. To attain and maintain laboratory accreditation, internal reviews are necessary to ensure quality standards are in place. According to NVSL officials, management reviews had not been performed because the NVSL did not have a quality assurance manager. Also, the priorities have been placed on emergency program operations.

OIE[62] guidelines provide that the laboratory shall periodically conduct internal audits of its activities to verify that its operations continue to comply with the requirements of its quality system and this Standard. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The quality system and test related activities shall be reviewed by management at least once per year.

An NVSL official stated that the NVSL recently hired five quality assurance managers.

[60] The review document we were provided was dated 1995 but NVSL later informed us that the review was actually conducted in 1998.
[61] Validation of Laboratory Activities through Peer Review SOP, dated October 16, 2000.
[62] OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases.

Contract Laboratory Monitoring Could Be Improved

The SOP for oversight of contract laboratories states that peer reviews/inspections of the contract laboratories would be conducted. However, the SOP does not mention the frequency of inspections. NVSL and APHIS headquarters officials stated that the inspections would be conducted annually. In comparison, the U.K. reviews its testing laboratories as they come online, after they have been testing for a few months, and thereafter, on an annual basis. The NVSL conducted the first round of contract laboratory peer reviews in August – October 2004.

The NVSL did not have a followup process in place to ensure that problems found during the inspections were corrected. An NVSL official stated that the original plan was for the reviewers to ensure corrective actions were taken on any deficiencies during the following review (1 year later). However, the plan has been revised, starting with the second round of reviews, to send the contract laboratories a letter 2 weeks after the review to request evidence of corrective actions on any deficiencies. He also stated that there were no major deficiencies identified during the first reviews. On August 24, 2005, NVSL officials said they were in the process of scheduling the second round of contract laboratory reviews.

Written procedures[63] are in place for APHIS personnel to use during the review of the compliance of contract laboratories. We obtained the testing checklist (laboratory inspection worksheet) [64] for seven laboratories. Issues noted by the review teams included confidentiality statements not signed by all TSE laboratory staff, no record of BSE laboratory temperature and humidity, the need for SOP changes, and the lack of seals for inconclusive samples to be submitted to NVSL.[65]

Contract Laboratory Proficiency Testing

NVSL conducted proficiency testing at the contract laboratories prior to the expanded surveillance effort. The NVSL did not conduct any further proficiency testing at the contract laboratories until 9 months into the expanded surveillance program. AMS, in its compliance reviews dated September 2004 and March 2005, questioned the lack of proficiency testing at BSE contract laboratories.

The Quality Assurance: Proficiency Testing of BSE Testing Laboratories by NVSL SOP, dated August 13, 2004, states that APHIS will use two major

[63] Audit of NVSL Contract Laboratories Conducting BSE ELISA Tests Standard Operating Procedure (SOP), dated August 11, 2004.

[64] The testing checklist covers such areas as receipt and login, sample tracking and handling, cut-in, ELISA test procedure, sample storage, laboratory equipment and environment, quality assurance, test records, reporting results, and understanding of USDA expectations and procedures. Upon completion of the review, the APHIS reviewer is to discuss findings with the laboratory contact person and leave a copy of the laboratory inspection worksheet with the laboratory. If there are noncompliant issues, followup correspondence in the form of a report will be sent back to the laboratory after discussion has been held and agreements made with the laboratory regarding compliance.

[65] One laboratory we visited in February 2005 still did not have seals for inconclusive samples.

methods to evaluate the quality of the testing at the contract laboratories: 1) evaluation of an initial proficiency test and continued passing performance on the proficiency test every 6 months and 2) weekly monitoring of test performance and comparison of this performance to other laboratories in the network and to previous performance of the contract laboratory (see discussion on sample controls).

The contract laboratories were given 20 samples (check tests) from the NVSL before the laboratories began BSE testing in June 2004. The NVSL did not conduct any subsequent proficiency testing at the contract laboratories until March 2005 (9 months later). An NVSL official stated that the NVSL originally intended to provide the contract laboratories with a sample of 20 check tests annually. However, the NVSL reevaluated the frequency of check tests and determined check tests should be performed more frequently. NVSL officials explained that the proficiency tests would be performed twice a year at the contract laboratories, not necessarily every 6 months. On August 24, 2005, NVSL officials said they were in the process of conducting the next round of contract laboratory proficiency testing.

In the U.K., proficiency testing panels consisting of 10 homogenized samples are issued to rapid testing laboratories three or four times a year. USDA needs to consider more frequent proficiency testing so that confidence in its testing program is assured.

Sample Controls for ELISA Tests Were Discontinued

The NVSL discontinued its requirement for contract laboratories to submit sample optical density (OD) values (raw test data) to NVSL after December 2004. The OD value is used to define the sample as positive or negative relative to a cutoff value predetermined by the manufacturer. AMS reported noncompliance with this NVSL SOP in their March 2005 compliance report. Contrary to the SOP,[66] NVSL officials determined it was unnecessary to continue reviewing OD values, because they concluded that the data through December 2004 was "very strong." As a result, there was reduced assurance that contract laboratory performance problems and equipment failures could be identified in a timely fashion.

Other countries, however, require the submission of, and evaluate raw test data from each laboratory in their network. The U.K. periodically requires the submission of raw test data from each laboratory so that evidence of variability in test performance can be detected. In Canada, part of the National BSE Reference Laboratory's Quality Assurance responsibility is to

[66] The Quality Assurance: Proficiency Testing of BSE Testing Laboratories by NVSL SOP, dated August 13, 2004, states that each laboratory will provide NVSL with the Excel spreadsheet output from all runs to cover testing for the previous 7 days. All laboratories will provide the output on the same day. NVSL will collate the data and provide mean OD values from each laboratory to all of the network laboratories. This data will allow both NVSL and the partner laboratories to observe the ODs on control and surveillance samples, which can indicate technical proficiency and allow problems to be identified before they affect program integrity. It will also allow validation of numbers of samples run in the network.

monitor, monthly, the median OD values of the screening laboratories. Canadian officials advised that this process provides a good understanding of how the individual laboratories perform and how to interpret higher negative OD values, if they occur.

According to the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, interlaboratory test comparisons may be undertaken for a variety of reasons, which may include:

1. Determining a laboratory's capability to conduct specific diagnostic tests.
2. Checking or certifying the performance of individual operators.
3. Checking or certifying the calibration of instrumentation.
4. Harmonizing existing test methods.
5. Evaluating new test methods.
6. Assigning values and ranges to standard materials.
7. Resolving interlaboratory differences.

The OIE guidelines also provide that the laboratory shall have policy and procedures that ensure that nonconforming testing (conditions that exist that have or could adversely affect the reliability of test results) is detected and promptly corrected.

After December 2004 data were submitted, the NVSL instructed the contract laboratories to no longer forward the OD values to the NVSL for their review because the NVSL concluded that it was not necessary to continue the analysis of the OD data. However, NVSL decided that it would be prudent for all laboratories to continue to collect and save the OD data should analysis be required in the future. We concluded that NVSL should continue to obtain and evaluate OD test values on an ongoing basis to evaluate laboratory performance and identify possible equipment problems.[67] This review should also include NVSL's own test data.

We obtained the OD summary report prepared by NVSL based on BSE OD data from the weeks of September 21 - December 18, 2004. The report stated:

> Overall findings indicate that OD values are very consistent and have very low Standard Deviations. Higher mean ODs and Standard Deviations trend towards having negative samples outside the expected population range of the negative ODs. Previous data from Europe

[67] Three laboratories had problems with the New Sample Pr(p)eparator machine, such as plugged tips and the robotic arm sticking. According to the manufacturer's web site, the new Sample Pr(p)eparator is a robotic system that automates the purification portion of the manufacturer's second-generation test. In addition, one laboratory had problems with the plate washers. From October 13, 2004, to January 31, 2005, this laboratory had seven positives on the first rapid test that were negative on the two repeat rapid tests. In response to those seven occurrences, the laboratory cleaned the deep plate washer and flush washer, and called the manufacturer for washer service.

> indicated an association of higher ODs and larger Standard Deviations with an increased number of false positives (initial reactors), but this does not appear to be the case with our data.

When asked about this information, an NVSL official said:

> There did appear to be a trend towards laboratories with higher ODs resulting in more ODs outside the expected range, but these OD warnings are just an indicator that the OD is higher than would normally be expected in a statistical population, but there did not seem to be any significant correlation to this finding and incidence of initial reactors.

The report also noted "…A few interesting trends...in some laboratories and these findings will be pursued on an individual laboratory basis." We questioned NVSL officials about the trends found with the raw test data. An NVSL official said one laboratory consistently had higher OD values, but this did not result in any initial reactors. NVSL discussed this finding with the laboratory including several possible explanations; NVSL suggested that the laboratory discuss this with the kit manufacturer.

We contacted the manufacturer and learned that some contract laboratories contacted them because they were getting low OD value for positive controls. The manufacturer determined it was caused by various problems, depending on the situation in the laboratories. In one laboratory, it was due to hot and humid conditions in the laboratory (air conditioning was installed); another laboratory was not letting their controls warm up to room temperature. Another laboratory was experiencing higher OD values for samples; the manufacturer determined their plate washer was not being cleaned well; they visited the laboratory, replaced the manifold and tubing on the washer, and showed them how to clean it to give maximum efficiency.

Because NVSL discontinued obtaining and analyzing OD data shortly after they determined the November 2004 sample to be negative, we determined it was necessary to confirm that there were no further positive reactive samples. We requested APHIS obtain the OD values for the BSE tests conducted by laboratories through June 2005. We reviewed this data to determine if there were any samples above the positive cutoff. We found 28 instances at the 7 contract laboratories where BSE sample OD values were above the positive cutoff. We contacted the laboratories and obtained documentation that showed, in each of the 28 cases, the 2 required repeat tests were conducted and produced negative results. APHIS should continuously review and analyze this data to identify any trends needing followup or corrective actions.

Our interviews with BSE contract laboratory officials disclosed that they found the OD value report from the NVSL helpful because they could

compare their OD values to those at the other laboratories; it provided an indication of how well their laboratory was performing compared to other laboratories.

Recommendation 7

Expedite the process for the NVSL, and other APHIS laboratories, to become ISO 17025 accredited. Establish the necessary management control review processes, including external peer reviews, to achieve and maintain accreditation.

Agency Response.

NVSL is implementing its 2003 Plan for Quality Assurance. The plan includes full-time quality managers in each laboratory (and one for common services) and a contract consultant, which are all in place. The laboratory system and a variety of high-consequence tests across all laboratories and multiple technologies, including BSE testing, will be accredited to the ISO/IEC 17025 standard by December 31, 2006. Internal audits of the high-consequence testing areas have been accomplished, corrective actions are being formulated, and management reviews are scheduled. In the case of the transmissible spongiform encephalopathy (TSE) testing internal audit, the results of the 2003 internal audit were incorporated and corrective actions for all findings written. NVSL plans to assist other APHIS (e.g., State-Federal) and network laboratories in improving their quality assurance systems using established international guidelines as it progresses in its accreditation.

To ensure the most appropriate technical methods are being followed within the quality system, the external, international peer review process will continue, with reviews of high-impact program areas being reviewed approximately annually, on a 5-year cycle. Its findings will be incorporated into the NVSL corrective action and management review system. NVSL scientists will continue to participate in international conferences and collaborations to stay abreast of the latest techniques.

OIG Position.

We accept management decision.

Recommendation 8

Develop and implement a formal and regular laboratory proficiency testing program at the NVSL and any APHIS laboratory that will participate in future animal disease surveillance and/or testing programs.

Agency Response.

APHIS concurs with this recommendation and will review all current proficiency testing programs and revise them as appropriate by December 31, 2006. NVSL will ensure that formal and regular laboratory proficiency testing programs are in place for all future animal disease surveillance and/or testing programs.

OIG Position.

We accept management decision.

Recommendation 9

Develop controls to ensure that all established laboratory quality assurance processes are followed and any conditions noted are reviewed for followup and action, as appropriate.

Agency Response.

APHIS concurs with this recommendation. By December 31, 2006, APHIS will develop controls to ensure that all current laboratory quality assurance processes are followed and to ensure that any necessary follow-up action is taken.

OIG Position.

We accept management decision.

Recommendation 10

Review and analyze continuously, OD values for contract laboratories and resolve any trends that warrant further evaluation or corrective actions.

Agency Response.

APHIS concurs with this recommendation. NVSL has an SOP in place that describes how it will review and analyze OD values. The SOP "Quality Assurance: Proficiency Testing of BSE Testing Laboratories by NVSL," (GPPISOP0033.03) states that weekly monitoring will be performed by NVSL until no longer deemed necessary by the Chief of the Pathobiology Laboratory, NVSL. Each laboratory will provide NVSL with the Excel spreadsheet output from all runs to cover testing for the previous 7 days. NVSL will collate the data and provide mean OD values from each laboratory to all of the network laboratories. This will be coded so as not to reveal laboratory identity of other laboratories. This data will allow both

NVSL and the partner laboratories to observe the ODs on control and surveillance samples, which can indicate technical proficiency and allow problems to be identified before they affect program integrity. It will also allow validation of numbers of samples run in the network. NVSL will also review data as deemed scientifically justified such as on special request, upon inspection, and during the review of proficiency data. It should be noted that there are no methods recognized by the test manufacturer or by international standards to determine how BSE ELISA OD data should be analyzed. Accordingly, NVSL will, by March 1, 2006, begin to analyze the weekly OD values by laboratory to determine what seems to be a normal range of values. After looking at this data for two months, NVSL will establish an acceptable range of OD values that do not of themselves raise concerns. After establishing that range, NVSL will contact any laboratory which submits samples for a week which do not fall within the range to determine if there are important concerns.

OIG Position.

We accept management decision.

Section 3. Controls (Firewalls) to Prevent BSE in the Food Supply

On January 12, 2004, FSIS promulgated a series of regulations designed to protect the human food supply from contamination by BSE.[68] These regulations identified certain beef tissues and products that could possibly contain the infective agent for BSE and established controls[69] to require segregation and destruction of such materials so they do not enter the food supply; FSIS declared these beef tissues and products to be specified risk materials (SRM). Also, FSIS' ongoing inspection processes at slaughter and processing establishments are a critical control to ensure proper sanitation procedures, and prevents high-risk animals, nonambulatory cattle and cattle with clinical signs consistent with BSE, from being slaughtered and entering the food supply.

FSIS conducts ante mortem inspection of cattle prior to slaughter. Ante mortem inspection involves the observance of cattle at rest and in motion from both sides to identify any abnormal or diseased cattle. This process is critical to identify any cattle exhibiting clinical signs consistent with BSE. Such cattle must be condemned.

Beef slaughter and processing establishments are required to incorporate controls and procedures for handling SRMs into one of three types of preexisting operational plans: Hazard Analysis and Critical Control Point (HACCP),[70] Sanitation Standard Operating Procedures (SSOP),[71] or prerequisite programs.[72] Establishments are required to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. FSIS inspectors verify that the plant's procedures for handling SRMs are adequately described in its operating plans and that the establishment has complied with Federal requirements for handling SRMs.[73]

We reviewed the SRM plans of 12 establishments visited, observed FSIS inspection procedures designed to evaluate, monitor, and ensure compliance with the firewalls, and observed controls in operation. We found that improvements can be made in the following areas:

[68] Federal Register, Vol. 69, No. 7 (Docket No. 03-025IF), 9 CFR Parts 309, 310, 311, 318, and 319.
[69] USDA has used the term "firewall" to describe the controls put in place to prevent BSE from entering the food supply.
[70] HACCP is a systematic preventative approach to food safety that addresses physical, chemical, and biological hazards as a means of prevention rather than finished product inspection. To address food safety hazards, key actions, known as Critical Control Points, can be taken to reduce or eliminate the risk of the hazards being realized.
[71] SSOPs are to describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
[72] Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food.
[73] FSIS Notice 4-04, dated January 9, 2004, and FSIS Notice 9-04, dated January 23, 2004.

- FSIS approved an alternate ante mortem inspection procedure that limited the process and the number of cattle subject to an ante mortem inspection. During the audit, FSIS took action to discontinue this procedure.
- FSIS does not have a management information system capable of readily identifying the scope and trends of noncompliance violations relating to SRMs.
- Nine of 12 establishments reviewed, did not prepare adequate SRM plans and/or records documenting establishment compliance and FSIS process validation.
- Six establishments reviewed did not comply with their SRM plans and/or maintain records to support the process followed.
- FSIS does not maintain documentation of their reviews of establishment compliance with its SRM procedures.
- FSIS did not always follow pre-operational sanitation inspection procedures.

We also identified, in 2 of 12 establishments reviewed, that FSIS did not follow consistent policy in condemning nonambulatory cattle.

FSIS has already taken action to strengthen its ante mortem inspection procedures and has addressed the specific cases identified during the audit.

Finding 5 — FSIS' Alternative Ante Mortem Inspection Procedures Reduced the Likelihood of Detecting Targeted Animals

Alternative ante mortem inspection procedures followed at some slaughter and processing establishments reduced assurance that abnormal and diseased animals, including cattle exhibiting CNS symptoms, were identified and condemned. The alternative ante mortem inspection procedure had been in place for over 10 years and its effectiveness and risks had not been reassessed. During this period, there have been significant changes to FSIS inspection processes, its organizational structure, as well as the emergence of international animal diseases, such as BSE. During the audit, FSIS took action to discontinue the alternative ante mortem inspection process.

International guidelines[74] recommend that all cattle slaughtered for food be subject to ante mortem inspection. APHIS posted information on its web site that did not fully disclose the ante mortem procedures used. The information posted on the web site states:

[74] Office International des Epizooties (OIE) Animal Health Code Chapter 2.3.13 recommends that all slaughtered cattle and meat offered for export should be from cattle that were subjected to ante mortem examination.

All cattle slaughtered in federally inspected establishments in the United States are subject to inspection by USDA's FSIS inspectors. Cattle are carefully examined to identify any symptoms of disease, including signs of CNS impairment. Cattle that are suspect for any reason are then reexamined by an FSIS veterinarian to determine whether the animal is eligible for slaughter. No animal that shows signs of systemic illness and disease is allowed into the human food supply.

Under alternative inspection procedures, only 5-10 percent of the cattle were subject to the traditional ante mortem examination, which involves observing the cattle at rest and in motion from both sides. The remaining 90-95 percent was observed only at rest in holding pens.[75] This procedure was generally to be used only at establishments that slaughtered young animals coming from feedlots or other sources considered unlikely to supply older or diseased cattle. However, our review disclosed that establishments following the alternative procedure did receive cattle 30 months old and older; these cattle now fall under SRMs restrictions.

At the time of our fieldwork, the most recent procedure[76] for the alternative ante mortem inspection program became effective in June 1995, and it had not been reassessed since its implementation. The Notice provided that establishments that have a good history of regulatory compliance, have suitable facilities and volume of operations, have condemnation rates within the national average for fat cattle, apply the alternative ante mortem inspection procedures only to domestic livestock (animals fed out in the United States[77]), and segregate abnormal animals, and hold animals (normal and abnormal) for examination by FSIS personnel may obtain approval for alternative ante mortem inspection procedures. The notice also required that the approval to use the alternative ante mortem inspection procedure was to be re-evaluated and approved by FSIS every 5 years.

FSIS could not provide us with a list of establishments approved for the alternative inspection procedure without doing a special data call to each FSIS district office. At our request, FSIS identified 33 establishments using the alternative ante mortem inspection procedure. During FY 2004, these establishments slaughtered 23.5 million head; approximately 650,000 were identified in inspection records as bulls and cows (most likely 30 months of age or older). FSIS stated they expected that older animals would be presented in separate lots so that the traditional inspection could be provided for these animals while the remainder of the younger cattle could receive the alternative procedure. During the data call, FSIS inspectors at 3 of the 33 establishments reported they used the alternative ante mortem inspection

[75] We observed holding pens with 50-100 cattle at the establishments visited.
[76] FSIS Notice 37-95, dated June 2, 1995, Alternative Ante Mortem Inspection Procedures.
[77] Before the ban on imported live cattle from Canada, this applied to imported Canadian cattle fed out in the United States. FSIS Notice 37-95 states that animals fed out in the United States are considered to be domestic livestock.

procedure on all cattle presented for slaughter, including bulls and cows. These three slaughter plants reported slaughtering over 93,000 bulls and cows during FY 2004. FSIS instructed the inspection staff at the three plants to modify the ante mortem procedures used at these plants, although one of the three plants had already discontinued the procedure for cows and bulls. Also, our field visits to plants using the alternative inspection procedure noted that cattle over 30 months of age were not always presented for ante mortem inspection in separate lots as envisioned by FSIS. As a result, the alternative procedures were applied to these older animals.

Two FSIS district offices did not have documentation on file justifying the use of the alternative procedures for 8 of the 33 plants. Also, three FSIS district offices had not updated the slaughter establishment approvals for using the alternative ante mortem inspection procedures within the last 5-years, as required.

Our visits to six[78] establishments using the alternative ante mortem inspection procedure disclosed that a significant number of cattle were determined to be 30 months old or older by plant personnel during detention checks. We found FSIS inspection personnel could not provide any documentation as to how the alternative ante mortem methodology was used at each location. Specifically, there was no documentation to show which lots of cattle received the traditional ante mortem inspection and which lots of cattle received the alternative ante mortem inspection. Also, because of the lack of records identifying the age of the animals, it was not possible for the establishment to identify and segregate cattle 30 months of age or older prior to ante mortem inspection. FSIS inspectors rely on the plant to segregate and hold abnormal and diseased (suspect) animals for inspection.

Cattle Slaughtered Without Any Ante Mortem Inspection

FSIS issued noncompliance notices on ante mortem inspection problems at 6 of the 33 plants using the alternative ante mortem inspection. During the period October 1, 2003, through May 31, 2005, FSIS issued 8 noncompliance records (NR) where they identified 277 cattle slaughtered without receiving any ante mortem inspection. In addition, 42 cattle at an additional 6 plants using the traditional ante mortem inspection procedures were slaughtered without any ante mortem inspection. In at least two cases, the cattle had been identified as suspect animals by plant personnel prior to slaughter. Because noncompliance was identified, FSIS did post mortem examinations of the carcasses and offal.[79]

[78] The six plants included three plants in our original sample and three added plants that reported slaughtering adult cattle.
[79] FSIS advised that the NRs identified situations where cattle had not been presented for ante mortem inspection. FSIS concluded that, at 4 of these 12 establishments, 224 head of cattle referenced on the NRs entered commerce. These four establishments slaughtered about 3.2 million head in 2004. At the other eight establishments, none of the animals referenced on the NRs entered commerce.

Conclusion

During the audit, FSIS officials agreed that the alternative ante mortem policy needed to be re-evaluated. On July 12, 2005, FSIS issued Notice 46-05 that discontinued the alternative ante mortem inspection for cattle, effective July 26, 2005. Also, this notice reiterated the appropriate disposition of livestock failing to receive ante mortem inspection; the carcasses cannot be permitted to be marked as inspected. Therefore, we are making no further recommendations.

Finding 6 — Effectiveness of SRM Slaughter Controls and FSIS Oversight Could Not Always be Determined

Federal regulations require establishments to develop, implement, and maintain written procedures regarding the removal, segregation, and disposal of SRMs. The establishments were to incorporate the procedures into their HACCP plans, SSOPs, or other prerequisite programs.[80] FSIS inspectors were to review the SRM plans for sufficiency and ensure compliance. We could not, however, determine whether SRM procedures were followed and/or were adequate in 9 of 12 establishments reviewed due to the lack of specificity in some SRM plans, as well as records documenting establishment compliance and FSIS process validation. We did not identify SRMs entering the food supply; however, in one plant, the FSIS inspector accompanying us identified SRM in a product, immediately issued an NR, and held the product until it was reworked to remove the SRM.

Reliable Documentation of Age is Lacking

Without an animal identification system, APHIS and FSIS rely on meat establishments to determine the age of cattle slaughtered. While meat establishments determine the age of cattle slaughtered, FSIS inspection procedures[81] require that those determinations be periodically spot checked to determine accuracy. FSIS also provides procedures[82] for determining, by dentition, whether cattle are 30 months of age and older. The guidance states that veterinary medical officers (VMO) are to examine establishment records that report the age of cattle (i.e., birth certificate, cattle passport, or other form of identification) because cattle 30 months of age and older contain additional SRMs that are prohibited from entering the food supply. If the VMOs examine the records and find significant reasons for questioning their validity, they are to verify the age of the cattle through dental examination. We found no documentation of the verification of dentition by FSIS inspectors, other than when NRs were issued for noncompliance.[83]

[80] FSIS Notice 4-04, dated January 9, 2004, FSIS Notice 5-04, dated January 12, 2004, and FSIS Notice 9-04, dated January 23, 2004.
[81] FSIS Notice 9-04, dated January 23, 2004.
[82] FSIS Notice 5-04, dated January 12, 2004.
[83] See the discussion on the SRM verification tasks scheduled under the performance based inspection system (PBIS).

During our visits to 12 plants, we found that records generally did not exist to document the ages of cattle presented for slaughter. However, to ensure compliance with SRM restrictions, establishments informed us that when animals under 30 months of age are slaughtered with older cattle, they process those animals as if they were 30 months of age and older, i.e., removing SRMs. Five of the 12 plants reviewed stated they also identify age through dentition.

Establishment SRM Plans Were Inadequate

FSIS issued a notice that directed the agency's inspection personnel at establishments that slaughter cattle or process carcasses to conduct awareness meetings with management.[84] These meetings were to (1) make managers aware of regulatory requirements for handling SRMs, (2) directed them to incorporate the appropriate controls and procedures into one of three types of preexisting operational plans (HACCP, SSOP, or program prerequisite), and (3) asked them specific questions that their controls and procedures would be expected to address. At a following meeting, the inspection personnel were to verify that the establishments' plans had incorporated the appropriate controls and procedures. In a subsequent notice, FSIS provided a methodology for inspectors to use to verify the establishments had properly designed and executed their procedures.[85]

Despite the notices, at one plant we visited, the FSIS inspector was not aware of the requirements for verifying how the establishment's controls and procedures were implemented. Although inspectors at the other plants indicated that they had followed the verification procedures, they did not document what they did or found. Accordingly, we could not validate that the verifications were done properly, or at all. This proved to be a concern because in four plants reviewed, we found the procedures were not followed, were general in nature, or did not include specific processes and/or procedures for the removal, segregation, or disposal of SRMs.[86]

Also, in three establishments visited, there were no written procedures in place to ensure that SRMs remaining in meat shipped to a downstream processing plant were removed. FSIS' verification instructions for properly executed controls, however, specify that plants must "have procedures to ensure that SRMs are removed at the receiving establishment."[87] Instead, the shipping plants included notations on bills of lading that the meat product contained SRMs, or marked carcasses with blue ink to identify target cattle (30 months old or older) for downstream processors.

[84] FSIS Notice 4-04, January 9, 2004.
[85] FSIS Notice 9-04, January 23, 2004.
[86] 9 CFR 310.22 (d)(4) provides that establishments shall maintain daily records sufficient to document the implementation and monitoring of the procedures for the removal, segregation, and disposition SRMs and any corrective actions taken.
[87] FSIS Notice 9-04, January 23, 2004.

Originating Plants Did Not Control Downstream Processors

The four downstream plants we visited properly handled all carcasses they received. However, in the absence of specific SRM shipping procedures, we did observe control weaknesses that had the potential to be problematic. For example, we found a bill of lading at a downstream facility that identified 4 carcasses as being from cattle 30 months old or older; there were actually 11. The plant properly handled the carcasses because they had been marked with blue ink. At another downstream plant, we found that shipping companies did not always mark carcasses containing SRMs and the downstream processor relied only on bills of lading.

The downstream processors we visited responded to such potential problems by processing all carcasses as if they were 30 months old or older. In spite of their diligence, regulatory requirements place responsibility on the shipping plants to develop appropriate procedures and controls to ensure that the downstream plants properly handle SRMs. On October 6, 2005, FSIS issued notice 68-05 to clarify verification activities inspection personnel are to conduct at establishments that transport or receive cattle carcasses or parts that contain SRMs. This notice details the requirements to be followed by inspection personnel and establishments in transporting, controlling, and disposing of SRMs in carcasses or carcass parts when the SRMs are not removed during the slaughter process.

Inspectors Did Not Always Identify Deficiencies in SRM Controls

FSIS provided a methodology to VMOs and inspection personnel at each establishment to guide them in verifying that slaughter and processing establishments properly designed SRM removal controls and procedures. While the VMOs and inspectors appeared knowledgeable about the plant inspection program they oversaw, they are not as experienced in evaluating the various types of HACCP, SSOP, and prerequisite operational plans as Consumer Safety Officers, Technical Service Center, or District office personnel. Consequently, they did not always identify SRM plans that did not meet regulatory requirements. Since proper procedures and controls over handling SRMs serve as a key BSE firewall, FSIS should ensure that qualified, technical personnel review and assess the adequacy of SRM plans.

PBIS Does Not Assign SRM Verification Tasks

The inspection tasks conducted by FSIS inspectors are partly determined by FSIS' performance based inspection system (PBIS). Each morning, this system creates a list of tasks that direct the inspectors to review different aspects of the plant's operation. The system has general codes that may include SRM handling procedures and practices, but nothing specifically directs the inspection personnel to examine them. Instead, an inspector may examine another part of the plant's operation that falls within the general inspection task category.

Since inspection personnel are not required to document what specifically they inspected (just that they did an inspection in a given category), there is no record of what specific operation is reviewed. In addition, plants that have

incorporated SRM handling procedures into prerequisite programs may not be inspected since they do not have associated PBIS tasks; all 12 plants visited during the audit included SRM procedures in their prerequisite programs. As a result, we could not evaluate the effectiveness of FSIS' controls over SRMs removal and disposal.

PBIS generates tasks to perform under the SSOP and HACCP programs. However, it is up to the inspector to determine what specific checks to make under each assigned task. For example, if PBIS generates an 01 or 02 task under SSOP,[88] the inspectors may review SRM controls, or they may check some other SSOP controls on that day. When they enter their task as completed in the system, the PBIS record shows only what type of procedure (e.g., an 01 or 02 procedure), but not specifically what they examined.

With some general tasks, inspectors have been instructed to review SRM controls. Specifically, inspectors were instructed to verify the proper execution of prerequisite programs as one of the activities that could be selected for review when performing HACCP 01 or 02 tasks, or while verifying the effectiveness of SSOPs under 01B or 01C procedures. In other words, the SRM controls were to be treated as if they were part of the HACCP program or SSOPs, but not a separate program area for review.

With one exception, inspection personnel at the plants we visited stated that they had performed the required procedures. However, without documentation, FSIS lacks an effective means of ensuring compliance. Evidence that establishments and FSIS have followed the proper procedures for the removal, segregation, and disposal of SRMs is necessary to assure the public and U.S. trading partners that BSE controls measures are effective.

Recommendation 11

Implement a review and evaluation program to be conducted by FSIS' Office of Program Evaluation, Enforcement, and Review to verify the adequacy of SRM control programs at all beef slaughter and processing establishments.

Agency Response.

OPEER will conduct a review and evaluation program to verify the adequacy of SRM control programs at beef slaughter and processing establishments. OPEER will complete the review and evaluation by the end of FY06.

[88] An 01 task requires record review; 02 requires observation of plant performance of the activity being inspected.

OIG Position.

We accept management decision.

Recommendation 12

Develop and incorporate tasks within PBIS specific to verify compliance with SRM control procedures and to confirm procedures are followed for properly aging cattle.

Agency Response.

The Performance Based Inspection System (PBIS) was originally designed as a system for scheduling inspection. As FSIS has begun implementing a more robust risk-based inspection, it has relied upon PBIS more and more for data collection. FSIS recently has made a major enhancement to PBIS to facilitate data collection, but realizes that in the future new systems for collecting inspection and compliance data will be needed. FSIS is in the process of developing these systems.

FSIS has developed an enhancement to PBIS that records noncompliance related to the SRM control requirements already in the regulations, through a dropdown menu of keywords and regulatory citations. It will facilitate more comprehensive searches of PBIS data. The regulatory citations in NRs will not only be more accurate but will provide a means by which FSIS analysts can search the PBIS database for NRs relevant to a specific topic or regulatory citation. Aggregate information from the revised NR database will be routinely analyzed to assess trends in non-compliance nationally, by district, by segment of industry, or within other categories. Results will be used to identify specific areas of concern that need to be addressed through enhanced policy development, guidelines for industry, or improved training materials for FSIS personnel.

FSIS provided instructions for the use of the PBIS enhancements in FSIS Notice 79-05. Training is also being prepared to reinforce instructions and ensure consistent usage. Inspection personnel began using the PBIS enhancements in December 2005.

FSIS is also implementing a multi-layered management control system. That system addresses SRM controls in its performance measures for HACCP procedures and control of condemned and inedible material. These performance measures are overlaid with system design control functions via food safety assessments, and IPPS. The IPPS system will consist of a database with information on the assessment of individual employee skills in using the correct inspection method, decision-making, documentation, and

enforcement. Standard and customized management reports will be generated at all management levels. Once Phase II of AssuranceNet is implemented in June 2006, as described in Recommendation 13, reporting features will include flags for performance measures that are not in conformance with the quantitative performance targets (see exhibit G for FSIS' response in its entirety).

OIG Position.

We accept management decision.

Recommendation 13

Develop a management reporting system that documents what controls and records were reviewed when assigned tasks are performed by inspectors.

Agency Response.

FSIS Management Control System

FSIS has developed and is in the process of implementing a management control system that provides multi-layered, in-depth management oversight of the public health regulatory activities carried out by its Office of Field Operations (OFO). As described below, full implementation of the management control system is expected by June 2006. This system gives OFO the ability to verify its effectiveness in protecting public health by achieving and maintaining specific levels of performance in its daily food safety and food defense operations. Performance measures for all public health control activities are continuously monitored and any performance that falls below the targeted level is flagged for supervisory intervention. Current management control functions include ante mortem/postmortem, HACCP/pathogen reduction (PR) execution, HACCP/PR design, Recall Management, Enforcement, and Food Defense Reporting of Non-routine incidents. As discussed in the response to Recommendation 12, the management control system includes performance measures for HACCP procedures and control of condemned and inedible material that encompass verification of a plant's control of SRMs.

In designing this system, FSIS has included performance measures related to BSE. This is achieved by closely controlling at ante-mortem all cattle with central nervous system (CNS) disorders, dead and nonambulatory disabled cattle and all other ante mortem condemned cattle to assure proper destruction of these condemned animals. FSIS has also initiated a Management Control to assure all condemned animals and products are controlled and properly destroyed. Public Health Veterinarians are required

to either sample ante-mortem condemned animals on-site or to ensure that sampling is performed at an alternative off-site location.

Evaluating Effectiveness of Management Controls

Management control data entered into AssuranceNet is summarized and reported to the FSIS headquarters in the *District Management Control Monthly Report.* Senior managers review the information to ensure that specific performance targets for each control activity have been met and to identify problem areas. However, the primary means of assuring the effectiveness of its overall management control system is through the OFO In-Plant Performance System (IPPS) that monitors and assesses on-the-job employee performance. Management controls are only as good as the knowledge, skills and abilities of the onsite inspection program personnel. For this reason, IPPS is now directly linked to OFO's public health management controls and specifically assesses inspector performance in carrying out those controls. The System holds supervisors at each level of the organization accountable for regularly performing IPPS reviews that assess the inspector skills, knowledge and abilities that are necessary to effectively monitor in-plant management controls. Deficiencies and failures identified in the *District Management Control Monthly Report* are linked to inspection findings and accomplishments on a plant specific basis.

Implementation Schedule

All OFO management controls are monitored by a database system known as AssuranceNet. The purpose of AssuranceNet is to provide a system for recording and monitoring the performance level for each control activity. This provides assurance that the food safety/food defense function, of which each control activity is an integral part, is being carried out in a manner that protects the public health. AssuranceNet also provides for standardized data collection and reporting across the 15 District Offices by providing a common format and recording procedures for all Districts. Implementation of AssuranceNet is occurring in two phases.

Phase I

Phase 1 of AssuranceNet is the development and use of a SharePoint application that will produce a *District Management Controls Report* that uses an Excel spreadsheet for the reporting tool. FSIS implemented this phase of AssuranceNet on December 18, 2005. This is an interim stage that permits all of the District Offices to enter their information in a central repository and gain experience in management control procedures. Reports will be run for each District on a monthly basis shortly after the end of the defined reporting period.

Phase II

Phase 2 of AssuranceNet, which is under final development, will be the fully mature management control application that will be used to submit data and run reports. It is scheduled to be implemented in June of 2006.

(See exhibit G for FSIS' response in its entirety.)

OIG Position.

We accept management decision.

Finding 7 — FSIS Management Information System Could Not Readily Identify Trends in SRM Violations

FSIS' management information system was not designed to allow FSIS to readily monitor and identify trends or weaknesses in establishments' compliance with specific regulatory requirements, such as controlling SRMs. Noncompliance violations are not indexed to allow the identification of specific violations. Instead, programmers must develop ad-hoc reports to query the narrative (looking for words that may relate to SRMs) and relevant regulation sections of each Noncompliance Record (NR).[89] Also, because the total number of inspection procedures covering SRM compliance is not captured, we could not evaluate the effectiveness of controls or extent of compliance with SRM requirements (i.e., was a violation found for every 100 or 1,000 times the inspectors reviewed SRM compliance). As a result, FSIS does not have timely information to monitor and determine the extent of compliance with SRM removal, segregation, and disposal requirements.

In December 2004, allegations were made that FSIS did not properly control SRMs and that some inspectors had been prevented from writing SRM related NRs.[90] During our audit, we requested FSIS provide us with all NRs issued and recorded in its PBIS specifically related to SRM violations. PBIS was not designed to readily produce such data inquiries; therefore, ad-hoc programs had to be written to search the narrative in the database to identify possible SRM terms and regulatory citations.[91]

[89] An NR serves as FSIS' official record of an establishment's noncompliance with one or more regulatory requirements. Each time performance of an inspection procedure results in a finding of noncompliance, agency personnel are to complete an NR and provide the establishment's management with a copy and an opportunity to respond. The NR is considered "open" until the establishment has brought itself into compliance with the regulatory requirement that has resulted in the issuance of the NR. When the establishment has brought itself into compliance, the NR is considered "closed."

[90] Interviews and observations during the audit did not disclose any evidence to support the allegation that FSIS inspectors were prohibited from writing NRs relating to SRMs.

[91] Instructions for use of PBIS are presented in FSIS Directive 5400.5, dated November 21, 1997.

We requested data from January 12, 2004, through May 31, 2005, and worked with FSIS to define word search queries for SRMs; over 90 different queries were made because the NRs varied depending on the writing styles of the FSIS employees.[92] FSIS identified 1,036 NRs relating to SRM violations. FSIS categorized the violations identified as follows:

- 406 NRs were written for inadequate SRM plans;
- 183 NRs were for cross contamination;
- 22 NRs were for head dressing[93] 30 months or older;
- 57 NRs were for improper age determination and dentition;
- 164 NRs were for record keeping; and
- 204 NRs were for SRM removal.

We further analyzed each NR to determine whether adequate corrective actions were taken in response to the NRs (see next section). We also determined the following:

- 177 NRs were written at large plants;
- 339 NRs were written at small plants;
- 516 NRs were written at very small plants; and[94]
- 4 NRs were written at plants where the size was not categorized.
- In addition, 693 NRs were written at slaughter establishments and the remainder at processing establishments.

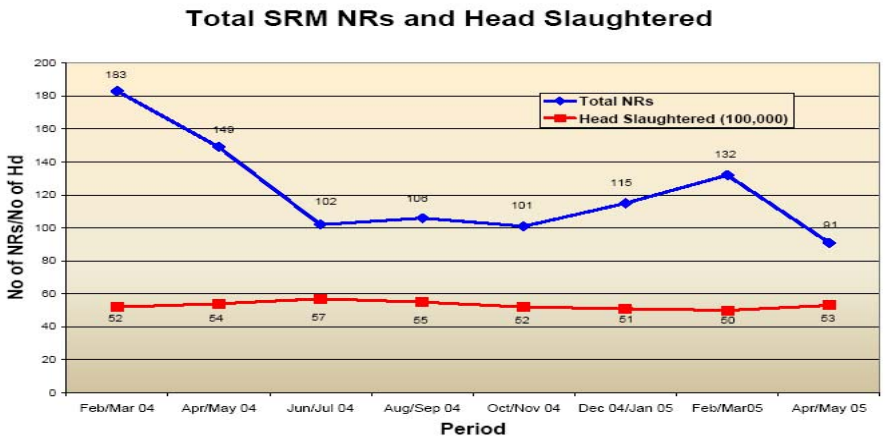
We also noted that between February/March 2004 and October/November 2004, the NRs written generally decreased; between October/November 2004 and February/March 2005, there was a 30 percent increase in NRs written. In the next 2 months, NRs written decreased by about 30 percent. While it would be reasonable to expect NR citations to steadily decrease over time after implementation of controls, there is no apparent explanation for the 30 percent increase and subsequent 30 percent decrease in NRs written.

[92] An example of some of the queries used on the narrative and/or relevant regulation sections of the SRM NRs included: "30 months," "thirty months," "30 plus," "thirty plus," "thirty+," "thirty +," "30 +," and "over 30."

[93] Head dressing NRs were written for violations such as knock holes on heads not plugged, brain material leaking from knock holes, heads from cattle 30 months of age or older being processed in areas where product from younger cattle was processed, etc.

[94] FSIS considers large establishments to have 500 or more employees, small plants to have 10 or more employees but less than 500, and very small plants to have fewer than 10 employees.

The following chart show trends in NRs written as compared to cattle slaughtered.[95]



Had FSIS management been aware of what violations were occurring and where, they would have been able to determine why they occurred and if specific actions were necessary to correct the root causes. OIG recommended in two prior audits,[96] that FSIS needed to design a management control process to allow FSIS to timely accumulate, review, and analyze inspection data to monitor compliance with regulatory requirements.

FSIS officials advised they have developed an enhancement to its Performance Based Inspection System (PBIS) that will provide the agency with a tool to improve searches of PBIS data, as well as to ensure that NRs accurately cite the relevant regulatory requirements. When inspectors write NRs, they will be required to select from a list of specific regulatory cites that describe the types of non-compliances that could be found while performing a given PBIS verification procedure. The list will include key words and links to regulatory text. The PBIS enhancement, scheduled for full implementation by the end of calendar year 2005, will provide the capability to assess trends of non-compliances, and to identify specific areas of concern that will need to be addressed with enhanced policy development, guidelines for industry, or improved training for FSIS personnel.

[95] Slaughter statistics were obtained from http://usda.mannlib.cornell.edu/reports/nass/livestock/pls-bb/2004/ and http://usda.mannlib.cornell.edu/reports.nass.livestock.pls-bb/2005/. SRM NR and slaughter data for January 2004 were not included in the chart to simplify the presentation.

[96] Audit Report No. 24601-2-KC, FSIS Oversight of ConAgra Recall, dated September 2003 and Audit Report No. 24601-3-Ch, Use of Food Safety Information Systems, dated September 2004.

Corrective Actions on SRM Violations

To verify that corrective actions had been taken on SRM violations, we analyzed 385 SRM NRs that FSIS categorized as an establishment having an inadequate plan to control the removal, segregation, and disposal of SRMs. When there was insufficient information in the database, we worked with FSIS to obtain evidence the establishments took sufficient actions to correct the violations. We concluded that adequate corrective actions were taken in response to the SRM NRs.

In addition, our analysis of the SRM NRs found that there were 253 establishments that primarily slaughter fat cattle and 143 establishments that primarily slaughter adult cattle (cows/bulls) that had no SRM NRs written. During the audit, we visited 2 of the 143 establishments that slaughtered adult cattle and did not have any SRM NRs written by FSIS. We found conditions during our visits that indicated SRM requirements had not been adequately implemented.

Plant G

- Plant personnel were not following their SRM plan or prerequisite programs for controlling SRMs; and
- The plant's documentation and recordkeeping related to the removal of SRMs was incomplete.[97]

Plant L

- The plant did not adequately document their system to remove, segregate, and dispose of SRMs.

FSIS needs to have a management information system that provides timely information to identify trends or indicators of noncompliance and/or other anomalies. Also, FSIS needs to use this data to determine if corrective actions have been taken on violations identified through NRs.

Recommendation 14

Modify PBIS to allow for timely analyses of trends in SRM violations and other food safety concerns. These modifications should also allow FSIS to analyze noncompliance trends well beyond the operation of any single establishment and track corrective actions.

[97] For example, we found 20 out of 133 SRM monitoring forms were missing, improperly marked, or were not documented as completed. Additionally, after the plant completed an audit of their records to improve compliance with their SOPs, we found 23 of 57 days when SRM monitoring reviews were either not conducted or were not documented.

Agency Response.

FSIS developed an enhancement to its PBIS that provides the agency with a tool to improve searches of PBIS data as well as to ensure that noncompliance reports (NRs) accurately cite the relevant regulatory requirements. As a result of a change that FSIS has made in PBIS, when inspectors write NRs, they will be required to select from a list of specific regulatory cites that describe the types of non-compliances that could be found while performing a given PBIS verification procedure. The list also includes key words that describe the thrust of each regulation, and there are links to the regulatory text. The regulatory citations in NRs will not only be more accurate, but they will provide a means by which FSIS analysts can search the PBIS database for NRs relevant to a specific topic. Information from the NR database will be used to assess trends of non-compliances and to identify specific areas of concern that need to be addressed through enhanced policy development guidelines for industry, or improved training materials for FSIS personnel.

Also, FSIS will be developing new approaches to measure effectiveness of policy beginning in FY06. Specifically, FSIS will ensure that management controls are in place describing how the Office of Policy, Program and Employee Development (OPPED) will routinely assess and respond to the data captured as part of IPPS and AssuranceNet. The analysis conducted by OPPED will focus on nationwide trends that may reflect the need for enhancements to policy, including training, in order to better ensure that the policies are effectively accomplishing the intended purpose. OPPED will have the management controls drafted and tested for effectiveness by the end of this fiscal year 2006, with the goal of full implementation at the start of fiscal year 2007.

Once the AssuranceNet System is deployed in June 2006, District level reports will be generated on at least monthly basis. The District Analyst will assess findings and inform the District Manager or Deputy District Manager of the results.

Instructions have been provided for the use of the PBIS enhancements in FSIS Notice 79-05. The agency is also preparing training, as well as modifying PBIS training for field personnel to supplement and reinforce the instructions in Notice 79-05 and ensure consistent usage. Inspection personnel began using the PBIS enhancements in December 2005 (see exhibit G for FSIS' response in its entirety).

OIG Position.

We accept management decision.

Finding 8 — Lack of Physical Pre-Operation Inspections by FSIS

Our review at the six slaughter establishments[98] that processed beef using AMR systems disclosed that FSIS in-plant inspectors performed pre-operation sanitation inspections less frequently at four plants on unscheduled workdays (Saturdays) than they did during the normal workweek. PBIS only schedules reviews of the plant's sanitation procedures for the plant's predetermined schedule of operations (workweek). FSIS procedures do not specifically address what unscheduled tasks the inspection staff is to perform when a plant operates on unscheduled workdays (e.g., weekends). Therefore, there is reduced assurance that plants used appropriate pre-operational sanitation procedures on those days FSIS did not perform inspections.

The plant profiles entered in the PBIS for the six plants showed they operated Monday through Friday. Plants are permitted to operate on days that fall outside the normal work schedule shown in PBIS with the prior approval of FSIS. When plants operate outside the normal hours of operation, the in-plant inspection staff determines what inspection procedures need to be performed; the PBIS does not schedule tasks for work performed outside the hours/days specified in the plant profile.

Inspected establishments must meet sanitation regulations,[99] including pre-operational cleaning, operational cleaning, and sanitation of equipment and surfaces that may contact product directly. When scheduled by PBIS, FSIS in-plant inspectors are to verify that establishments are complying with sanitation requirements. Even when PBIS does not schedule a review of the establishment's pre-operation sanitary conditions, FSIS inspectors have the responsibility to perform pre-operation sanitation reviews on a basis consistent with the scheduled rate and FSIS directives.

We performed an analysis at 6 of the 12 slaughter establishments visited to determine whether the FSIS inspection staff was performing pre-operational sanitation reviews on Saturdays (PBIS procedure code 01B02). We noted that, normally, FSIS inspections at these six plants were scheduled to review the pre-operational sanitation condition of the plant 45 percent of the time or more (on scheduled workdays).[100] Occasionally, these slaughter facilities found it necessary to operate a few Saturdays during the year. Whenever the

[98] Allegations regarding how FSIS conducts pre-operation sanitation inspections were raised during the course of the audit. This coincided with work in process at six slaughter facilities that used AMR processing; therefore, we looked into this allegation at these six establishments.

[99] FSIS regulations in 9 CFR 416.2 to 416.5 set forth more specific performance standards that each official establishment must meet to prevent the creation of unsanitary conditions that could cause the adulteration of meat products.

[100] For the six plants reviewed, the 01B02, pre-operational sanitation inspection, was scheduled at a rate of between 45 and 54 percent on weekdays the plant operated.

plant is in operation, FSIS inspectors must be on duty to monitor their production activities. Since Saturday was not a normal day for plant operations, PBIS did not schedule tasks for the FSIS inspection staff to perform. We looked at FSIS pre-operation physical inspection activities for 70 weeks (starting in January 2004) at these six plants. We found the following.

Plant Code	Number of Saturdays Worked	Number of Saturdays where Pre-Op Inspections Were Performed	Average Daily Slaughter
A	10	**0**	4,446
I	9	**0**	1,050*
J	12	**4**	500*
F	1	**0**	1,200*
H	16	16	4,000
E	17	17	4,000

*All cattle slaughtered at plants I, J, and F were considered 30 months of age or older.

FSIS National Office officials explained that:

> *"PBIS procedures are scheduled based on the approved hours of operation. During an overtime situation, PBIS procedures should be performed, on an unscheduled basis, in a manner consistent with the scheduled rate, and consistent with the procedure substitution concepts described in FSIS Directive 5400.5.*[101] *Inspection personnel at the establishment would make a decision on whether to perform hands on (01B02) pre-op sanitation for that particular Saturday. Currently, PBIS procedures are scheduled approximately 3 weeks in advance. Any PBIS task at any time can be performed as an unscheduled task… FSIS expects that the Inspector in Charge would make the decision to perform a hands-on or records review based on the history of pre-op inspections performed at the establishment."*

FSIS needs to clarify its guidance for conducting pre-operational sanitation inspections for unscheduled workdays. The six plants we reviewed processed between 500 and 4,400 head of cattle everyday; FSIS inspectors did not conduct pre-operational sanitation inspections at three plants on any Saturday. These three plants averaged between 1,050 and 4,400 cattle slaughtered each day. Two of the three plants operated on nine or more

[101] FSIS Directive 5400.5 part X.B.3 (Procedure Priorities and Substitutions), states that, "Inspection program personnel may use professional judgment in substituting unscheduled procedures for ones specified…consistent with the Agency's food safety priorities, and for the purpose of achieving FSIS' regulatory objectives."

Saturdays in our 70-week timeframe without any pre-operational sanitation inspections.

Establishments are required to control SRMs from entering the slaughter process; plants that process both young cattle and cattle 30 months of age and older must segregate banned material and ensure that the slaughter line is properly cleaned after older animals are processed. Thus, FSIS needs to confirm that SRM procedures are being followed.

Recommendation 15

Clarify guidance for conducting pre-operational sanitation inspections and SRM verification activities on workdays that fall outside the normal work schedule. Develop a process to confirm the inspections are done in accordance with established procedures.

Agency Response.

FSIS will provide guidance to inspection program personnel for conducting pre-operational sanitation inspections and other HACCP and SSOP verification activities on workdays that fall outside the normal work schedule, through revision to FSIS Directive 5000.1. The revisions will instruct inspection personnel to perform PBIS procedures, on an unscheduled basis, in a manner consistent with the scheduled rate and to use their professional judgment to decide which procedures to perform based on the Agency's food safety priorities. Inspection procedures, when performed outside of the normal work schedule, will be entered into PBIS as unscheduled procedures. These revisions are expected to be completed by March 2006. The District Analyst will have primary responsibility for correlating, on at least a quarterly basis, that the rate of procedures performed outside of the normal work schedule is consistent with the rate of scheduled procedures for that establishment. Supervisory personnel will use this PBIS data along with several other data sources to help prepare for IPPS reviews of inspection program personnel. PBIS data regarding performance of pre-operational sanitation inspections during both normal work schedules and workdays outside of the normal work schedule would be examined to provide context for an IPPS review.

OIG Position.

We accept management decision.

Finding 9 — Inconsistent Application of Procedures for Slaughter of Nonambulatory Cattle (Downers)

FSIS issued a policy that allows cattle that become nonambulatory due to an acute[102] injury after it passes ante mortem policy to proceed to slaughter. This policy is inconsistent with both published regulations and public policy announcements, and is not consistently interpreted and applied by FSIS inspectors. At 2 of the 12 slaughter establishments reviewed, plant records/auditor observations found that for the period June 17, 2004, to April 12, 2005, 29 nonambulatory animals were slaughtered; 20 of them were identified as downers with no documentation of any acute injury. FSIS officials do not believe its policy is contrary to published regulations prohibiting downers from entering the food supply because, in the opinion of the professional VMOs, these animals were healthy and suitable for slaughter after they passed ante mortem inspection.[103] We could find no records, other than the plant daily disposition records, documenting the condition of the animals. Stated public policy must be clear and transparent.

The policy stated in the preamble to 9 CFR 309.2(b)[104] states that FSIS has excluded all nonambulatory disabled cattle from the human food supply, ***regardless of the reason for their nonambulatory status or the time at which they became nonambulatory*** (emphasis added). If an animal becomes nonambulatory in route to the establishment due to an acute injury, it must be humanely removed from the truck, humanely euthanized, and the carcass properly disposed of. Likewise, cattle that become nonambulatory on the establishment premises, such as an animal that breaks its leg as it is unloaded from the truck, are also required to be humanely moved, humanely euthanized, and the carcass disposed of properly.

However, an FSIS notice[105] states that if cattle are ambulatory at ante mortem inspection and become nonambulatory disabled prior to slaughter, the VMO should verify that the animal suffered an acute injury and allow the animal to proceed to slaughter and post mortem inspection. FSIS would expect such situations to be extremely rare because cattle, when handled and moved under proper humane handling conditions, should not be injured while being moved in pens. For cattle that become nonambulatory disabled after ante

[102] Acute is defined as brief and severe as opposed to chronic.
[103] Nothing came to our attention that unfit animals were improperly passed for slaughter at the initial ante mortem inspection. Our concerns involve the animals that went down after the ante mortem inspection but before entering the slaughter facility.
[104] Federal Register / Vol. 69, No. 7, Monday, January 12, 2004, / Rules and Regulations Page 1870.
[105] FSIS Notice 5-04, Interim Guidance for Nonambulatory Disabled Cattle and Age Determination, dated January 12, 2004.

mortem inspection, if the VMO cannot determine that a specific, acute injury occurred that caused the animal to become nonambulatory disabled, the animal is to be condemned and cannot enter the slaughter establishment.

There appears to be inconsistent USDA policies related to slaughtering downers/nonambulatory cattle. Regarding animals for slaughter, it is clear that downers will not be slaughtered. In fact, one report[106] states: "The U.S. Policy is to condemn all cattle that are nonambulatory or disabled when presented for slaughter." The Department has widely publicized that one of the firewalls put in place to prevent the spread of BSE is the prevention of downers from entering the food supply.

Our review at the 12 plants visited showed the following variations in application of the policy for condemning or passing nonambulatory cattle for slaughter.

Plant	Inspectors Stated All Non-Ambulatory Cattle Were Condemned	Inspectors Stated Non-Ambulatory Cattle Could Pass for Slaughter If Caused By Acute Injury	Confirmed Number of Non-Ambulatory Cattle Passed For Slaughter	Number of Non-Ambulatory Cattle Condemned During FY 2004
A		X	0	40
B	X		0	126
C	X		0	306
D	X		0	4
E		X	0	11
F	X		0	108
G	X		0	41
H		X	0	2
I	X		0	190
J	X		0	122
K		X	27	41
L		X	2	1

The daily disposition sheets and State inspection records at Plants K and L (June 17, 2004, to April 12, 2005) showed the following cattle were passed for slaughter.

- downer or down - 20
- down due to the disease of mastitis - 1
- splitter (legs have splayed) - 5
- injury - 3

[106] North Americans Chief Veterinary Officers on Harmonizing a BSE Strategy – Minimum Standards.

This was the only documentation of the condition of the cattle available at the plants. Plant inspection personnel believed that FSIS Notice 5-04 allowed the slaughter of nonambulatory cattle if the cattle had passed ante mortem inspection and then went down as the result of an acute injury. Therefore, they had allowed the plant to slaughter these cattle for human consumption. We observed use of a forklift and a rail above the pens to transport nonambulatory cattle to the slaughter area.

We advised FSIS of the high number of downers being slaughtered at Plant K. FSIS reviewed the situation and offered the following comments.

> *The 26 animals[107] were deemed, in the professional judgment of the public health veterinarian performing the reassessment of each animal's condition following the acute injury, fit to continue to slaughter. All evidence indicates that they were reassessed in accordance with FSIS Notice 5-04. During the 9-month period examined by OIG, 26 cattle becoming nonambulatory after passing ante mortem inspection because of acute injury is not remarkable for an establishment that slaughters 13,000 head per month, and, that receives distressed cull cattle. The district veterinary medical specialist, following a site-visit on March 29, 2005, was of the opinion that these 26 acute injuries were related to the underlying condition of each animal, and not related to any humane handling non-compliance.*

We question what evidence FSIS reviewed to make their determination since only plant daily disposition records were available showing the condition of the animals. For Plant L in the same district as plant K, documentation for one cow that became nonambulatory after passing ante mortem inspection showed the cow had bilateral rear foot cellulites lesions associated with foot rot. The diagnosis was shown as local foot cellulites. This diagnosis raises a question as to whether the cow suffered an acute injury after ante mortem inspection.

Recommendation 16

USDA should clarify its policy for slaughtering nonambulatory cattle. Documentation should be kept to support any decisions for passing such animals for slaughter. FSIS should develop controls to ensure that USDA policy is consistently applied.

Agency Response.

FSIS will clarify its policy for slaughtering nonambulatory cattle by providing inspection program personnel with clarification instructions related

[107] OIG actually identified a total of 27 animals before audit field work was completed at the plant.

to FSIS Notice 5-05, "Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination." The guidance will provide instructions for tagging animals and for documenting observations to better ensure the accountability of such situations. FSIS expects to issue guidance by February 2006.

OIG Position.

We accept management decision.

Finding 10 AMR Has Processing and Process Verification Vulnerabilities

FSIS cannot demonstrate there are adequate controls in place to minimize the risk that SRMs do not enter the food supply when meat is processed by AMR. Over time, FSIS has added testing and product content requirements; meat establishments have had difficulty complying with those requirements. Although product testing is required, and FSIS conducts verification testing to detect CNS tissue, neither process has been designed to provide an overall assessment of compliance with the SRM ban or other product requirements. Therefore, there is reduced assurance controls are adequate to prevent SRMs from entering the food supply. FSIS verification tests in 2004 showed a 6 percent noncompliance rate for CNS tissue in AMR.

The number of companies processing meat products through AMR systems has decreased from over 30 to about a dozen since FY 2003. FSIS does not maintain records of the amount of product processed by AMR, but there are estimates that about 45 million pounds of product is produced. AMR has been banned in Europe[108] and many other countries due to risks associated with the product. USDA does not permit the use of AMR in product for the school lunch and other food programs.[109] FSIS assumes there is a risk that AMR product will contain the dorsal root ganglia (DRG) where backbones are used; this assumption is also supported by the Harvard Risk Assessment.[110]

History of AMR

AMR technology was first introduced in 1994. AMR systems emulate the physical action of hand-held high-speed knives for the removal of skeletal muscle tissue from bone through the use of hydraulic pressure. Some of the bones used in AMR systems may have fragments of kidney, liver, or other organ tissues attached due to incomplete removal of the organ tissues. As FSIS gained experience with the product, they recognized there was a risk of

[108] EC Regulations 999/2001. European Union member countries are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, the Netherlands, Portugal, Spain, Sweden, the United Kingdom, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, and Slovenia. Other countries banning AMR include Barbados, Cayman Islands, Chile, Dominican Republic, Jamaica, Mexico (all ground meat), St. Kitts and Nevis, and Trinidad.

[109] "Technical Requirements Schedule – GB – 2005, For USDA Purchases of Ground Beef Items, Frozen, III.B.2." *Boneless Beef Requirements*, April 2005.

[110] *Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, dated November 26, 2001, states if the spinal column is processed using AMR, the DRG are likely to contaminate the AMR product. For young animals, only a fraction of the vertebral column and DRG will be processed using AMR because parts of the backbone are contained in high value bone-in cuts of meat. For older animals, such as bulls or cows, all vertebrae are likely to be processed using AMR.

excessive calcium content if the recovery systems were not properly operated; bone shavings could be removed along the meat.

In 1996, FSIS established a limit for calcium content and plants were required to conduct AMR product testing to verify compliance with calcium limits.[111] The next year, FSIS required complete removal of the spinal cord from bones processed in AMR systems[112] and initiated a sampling program to determine if spinal cord was present in finished product. Additional restrictions were added in 1998, when FSIS established a limit for iron in AMR.[113] Due to continuing concerns about spinal cord in the product, FSIS initiated a regulatory testing program for spinal cord in 2003 and added enforcement procedures to require additional testing when spinal cord was detected.[114] The FSIS program was initiated because a survey of AMR testing in 2002 showed the presence of spinal cord tissue in about 35 percent of the samples.

In 2004, plants were required to test for CNS tissue on a daily basis. If FSIS finds a sample testing positive for CNS tissue, plants are required to demonstrate, through testing, that CNS tissue is no longer in the product. If spinal cord is found in a sample, FSIS confiscates the product labels and does not permit sales of AMR product until the company can demonstrate their system is under control and spinal cord is removed.

In early 2004, following the discovery of the first BSE infected cow, FSIS required meat establishments to test for calcium, iron, and CNS tissue and to maintain daily records of the testing.[115] The iron limit was also changed and FSIS specifically stated that AMR product could not contain any amount of CNS tissue. The vertebral bones from cattle 30 months of age or older were also banned from AMR systems.[116] FSIS stopped testing for CNS tissue at plants where no vertebral bones were processed. Most recently, in 2005, FSIS reduced the calcium content limit for AMR product.[117]

[111] FSIS Directive 7160.1, Attachment, dated September 13, 1996. Calcium not to exceed 0.15 percent or 150 milligrams /100 grams of product.
[112] FSIS Directive 7160.2, VI, dated April 14, 1997.
[113] 9 CFR Parts 301, 318, and 320, dated April 13, 1998. "Iron content [(protein content x 0.067)] > 1.80 milligrams per 100 grams of beef product."
[114] FSIS Directive 7160.3, Revision 1, VI. B, C, and D, dated August 25, 2003.
[115] 9 CFR Part 318.24(b), dated January 12, 2004.
[116] 9 CFR Part 318.24(a), dated January 12, 2004.
[117] 9 CFR Part 318.24, dated January 1, 2005. The product would not be considered meat if calcium "…measured by individual samples and rounded to the nearest 10th, is more than 130.0 milligrams per 100 grams."

Inherent Limitations of the Sampling and Testing Programs

AMR testing is conducted to determine if the product meets the definition of meat[118] and is properly labeled, i.e., does not contain CNS or offal tissues and does not exceed the limits for calcium and iron content. The AMR product is considered to be mislabeled if testing shows that it contains CNS tissue, offal tissue, or exceeds the iron and calcium limits. However, establishment testing programs for CNS tissue are generally not as specific or sensitive as the FSIS testing program.[119] Establishments use a rapid screening test that cannot confirm the type of CNS present (e.g., spinal cord or DRG). Usually, an ELISA test is used to detect the presence of Glial Fibrillary Acidic Protein, a cellular marker for CNS. Also, this test cannot detect the presence of other non-meat tissues such as organ meat. FSIS, however, uses a validated histological procedure that can specifically identify spinal cord, DRG, and other tissues. According to FSIS officials, FSIS does not test AMR to verify compliance with the calcium or iron limits due to resource limitations; they consider noncompliance in this area as a labeling issue, not a health issue.

FSIS officials said its monitoring program for CNS tissue in AMR product tests product at a higher rate than pathogen testing programs (about every 3 weeks for AMR testing compared to three times a year for pathogens). Unlike the pathogen testing program, however, the AMR/CNS monitoring program is not statistically designed and only 2 pounds[120] are collected for testing, regardless of the lot size. This level of sampling is not representative of the production being tested; also FSIS does not specify how the grab sample is to be collected. FSIS officials recognize the limitations of the AMR verification test and acknowledge that its testing program provides reduced compliance confidence.

When testing is performed, the establishments hold the product until test results are known. In-plant inspectors monitor the company testing program and verify that no product is released for sale that does not comply with requirements. Consequently, according to FSIS officials, there have not been any voluntary recalls of the product to date. FSIS officials believed that there would not be a BSE hazard associated with AMR because the vertebral columns from animals 30 months of age and older were banned from AMR processing; any CNS tissue found in AMR product would come from younger animals and would not present a health risk.

If an AMR sample tests positive for CNS tissue, five followup samples are collected and tested from one lot according to FSIS procedures. If these sample test results are confirmed to be negative, then five more followup samples are collected and tested from another lot. The purpose of this testing

[118] 9 CFR Part 318.24(b), dated January 12, 2004.
[119] Docket No. 03-038IF, Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems.
[120] FSIS Directive 7160.3, Revision 1, VI.A, dated August 25, 2003.

is to determine if the AMR system is under control.[121] FSIS officials said followup AMR samples after an initial positive are sometimes tested by FSIS, or sometimes by the establishment or private laboratories. According to FSIS instructions, establishments can use whatever testing procedure they choose to verify that CNS tissue is not present in the product. After company testing has demonstrated the AMR system is under control, FSIS takes one additional followup sample and tests it to verify CNS tissue is not in AMR product. [122]

FSIS officials said there are no requirements for accreditation or FSIS approval of the laboratories conducting AMR testing. Also, FSIS officials acknowledged that the rapid tests used by meat establishments are not as comprehensive as the testing by FSIS; specific CNS tissues present in AMR product cannot be identified. FSIS does not want to discourage plants from using rapid tests because they can indicate that CNS tissue may be present in AMR product.

Production Problems

Many plants have had difficulty meeting the product specifications for meat and preventing spinal cord, CNS tissue, and other unacceptable tissues from contaminating the product. Consequently, the number of plants producing beef AMR has significantly declined since 1996. In 1996, when FSIS did the first survey of AMR testing results, about 50 or 60 establishments used advanced meat and bone separation (includes beef and pork processors). By 2002, 34 beef plants produced AMR product. In 2003, there were 31 beef AMR establishments. When we started our review in the fall of 2004, the number of plants producing beef AMR had declined to 20. Two plants we visited discontinued AMR production because company officials did not consider it to be economically viable.

Product testing has shown problems with compliance with product specifications:

- 1996 FSIS survey of AMR found spinal cord tissue in some samples of AMR.
- 2002 FSIS survey[123] of AMR found 35 percent of finished product samples contained unacceptable nervous system tissues – 29 percent contained spinal cord tissue and 10 percent contained DRG.
- 2003 FSIS survey[124] of AMR regulatory testing results showed 6.7 percent of the samples were positive for spinal cord tissue. Followup verification tests at plants with initial positive tests resulted in a

[121] FSIS Directive 7160.3, Revision 1, VI.B,C, and D dated August 25, 2003.
[122] FSIS Directive 7160.3, Revision 1, VI.D.6, dated August 25, 2003.
[123] Analysis of 2002 FSIS Bovine AMR Products Survey Results, dated February 2003.
[124] Summary of Calendar Year 2003 AMR Testing, dated January 2004, pages 2 and 3.

13.8 percent positive test rate indicating plants with initial positive tests were having difficulty eliminating spinal cord from the product.

- 2004 FSIS survey of AMR testing results (unpublished) showed 6 percent of samples contained nerve tissue (4 percent were positive for CNS and 2 percent were positive for DRG). Followup verification tests resulted in 5 percent of samples containing nerve tissue (3 percent positive for CNS and 2 percent positive for DRG).

Our review at the six plants visited that produced AMR showed frequent unacceptable test results for at least one of the test criteria. We verified that all non-conforming lots of AMR product were destroyed.

	CNS[125]	**CNS**	**Calcium**	**Calcium**	**Iron**	**Iron**
Plant	No. of Tests	No. of Positives	No. of Tests	No. > Limit	No. of Tests	No. > Limit
A	98	14	98	19	98	0
E	170	1	170	15	170	12
I	330	0	578	26	323	47
F	418	0	418	1	418	82
J	318	0	598	0	318	3
H	327	0	327	0	327	2
Totals	1,661	15	2,189	61	1,654	146

Plant A had difficulty meeting product requirements for about a year. On April 12, 2004, Plant A had a positive test for DRG. A followup test was negative and the plant resumed product sales on April 28, 2004. On July 26, 2004, the plant had another positive DRG test and could not pass the verification testing until February 22, 2005. Plant testing records[126] showed 34 test failures (14 for CNS or DRG tissue) on the followup verification testing. On February 22, 2005, after passing the verification test series, FSIS returned the product labels and permitted sale of the product. The following day, a random FSIS test sample was positive for CNS. FSIS immediately "tagged" the AMR system and took action to prevent the company from selling AMR. Since FSIS has issued a Notice of Intended Enforcement, we are not making any further recommendations concerning the oversight of this plant's AMR production.

[125] Test results shown for CNS and iron are for 2004 and through May 18, 2005. Tests were not required in 2003.

[126] Test records were reviewed for the period April through September 2004 and January 2005. No testing was done for iron or calcium for the last 3 months of 2004 because of continuing CNS test failures.

Processing Controls - Cattle 30 Months of Age

Plants were required to develop process controls to prevent vertebral bones from cattle 30 months of age or older from entering AMR systems[127] because these bones were determined to be SRMs.[128] FSIS discontinued testing for CNS tissue in AMR at plants that reported they do not process any vertebral bones in the AMR system. FSIS officials said they do not sample AMR for CNS tissue when the vertebral columns are not used because it would be scientifically unsound and wasteful.

In the plants visited, we observed that process controls usually involved directing all prohibited bones to inedible rendering; eligible bones were selected by hand for AMR processing. Although the process controls were to provide a "fail safe" procedure, there is a risk for human error in selecting bones eligible for AMR processing. For example, FSIS inspectors at two plants we visited had written noncompliance records (NR) for adulterated AMR product when they observed vertebral bones from cattle 30 months of age or older in the AMR systems.

Mislabeled AMR

AMR product does not require a label identifying it as AMR product because the product is required to meet the definition of meat.[129] The product is tested to determine if it contains banned and unacceptable tissues (CNS tissue, organ or offal tissue, bone, etc) and to verify it meets the requirements for iron and calcium content. We found that inspectors at one plant (Plant J) did not understand the test results and allowed one lot[130] of product containing organ tissue to enter commerce. The inspectors stated they did not recognize the test results showed the presence of organ tissue because this noncompliance is found so infrequently (3 of approximately 550 AMR samples tested).

A laboratory test of an AMR sample taken at Plant J on March 25, 2004, indicated that the product contained excessive amounts of liver. The AMR product was allowed to enter commerce. The FSIS inspectors at the plant stated that they had not been given any information on the laboratory codes and may have been confused by the form showing "SATISFACTORY" under condition on receipt.

Since organ tissues would not be expected components of boneless meat, FSIS advised it would assess such situations on a case-by-case basis to determine whether to take further action, including asking for product to be

[127] FSIS Notice 4-04, dated January 9, 2004, Checklist and FSIS Notice 9-04, dated January 23, 2004, III.D.5.

[128] Interim final rule and request for comment (Docket No. 03-038IF) dated January 12, 2004, states that skulls and vertebral column bones from cattle 30 months of age and older are inedible and cannot be used for human food. Therefore, if skulls or vertebral column bones from cattle 30 months of age and older are used in AMR systems, the product exiting the AMR system is adulterated, and the product and spent bone materials are inedible and cannot be used for human food. For AMR product derived from the bones of cattle younger than 30 months, the presence of CNS-type tissues will render the product misbranded.

[129] 9 CFR 301.2, Federal Register Vol. 69, No. 7, page 1876, dated January 12, 2004, and 9 CFR 318.24 (a) and (b).

[130] A lot is a day's production. This plant produced an average of about 4,000 pounds of AMR per day.

removed from commerce. FSIS plans to address this issue when it updates its policy issuance on AMR systems.

Recommendation 17

Reassess the risk associated with processing meat by AMR systems and determine whether banned SRMs can be effectively controlled and prevented from entering commerce.

Agency Response.

The agency has extensively modeled the risk of AMR as a vehicle for the spread of BSE and issued an interim final rule that explicitly prohibits the use of SRMs in the manufacture of AMR. There is international agreement that the definitions for SRMs applied by FSIS in its interim final rule are appropriate for the U.S., and that properly produced AMR from cattle younger than 30 months of age is safe. However, FSIS agrees that an essential factor in proper production of AMR from cattle is to ensure that SRMs are not used. Consequently, FSIS has taken a number of steps, as described in the earlier response to recommendation 13, to enhance the Agency's management controls through IPPS and AssuranceNet to increase our confidence that regulated products are not adulterated or misbranded. Regarding testing for CNS tissue, testing AMR for CNS-type tissue would not be appropriate or practical in ascertaining whether the source materials were from prohibited sources. Verification testing for CNS-like tissues in AMR meat is a useful measure to ascertain compliance with the regulatory requirements regarding whether the resulting product is misbranded.

As noted in the response to recommendation 13, the IPPS process, when integrated with other management control information, will be utilized to ensure that inspection personnel are using the appropriate inspection method, decision-making, recordkeeping and enforcement process when conducting AMR verification procedures. IPPS results will be reported into the AssuranceNet database, for tracking and reporting of inspection outcomes.

OIG Position.

We accept management decision.

Recommendation 18

Develop a supportable sampling and testing program to provide assurance that the SRM ban and other regulatory requirements are met.

Agency Response.

Through the management control systems and IPPS system described in response to recommendations 13 and 17, FSIS believes that it has provided an effective alternative to the recommendations provided by OIG in order to enhance the Agency's confidence that beef AMR is being properly produced and is not adulterated or misbranded. This alternative solution offered by FSIS does not affect the current testing program by FSIS or testing that is conducted by industry as part of the regulatory requirements. Rather, this alternative solution focuses on better ensuring that the segregation procedures used to ensure that SRMs are not being used as source materials are in place and effectively working.

FSIS will be developing new approaches to measure effectiveness of policy beginning in FY06. This effort is separate from establishment of the OFO management controls. Specifically, FSIS will ensure that management controls are in place describing how the Office of Policy, Program and Employee Development (OPPED) will routinely assess and respond to the data captured as part of IPPS and AssuranceNet. The analysis conducted by OPPED will focus on nationwide trends that may reflect the need for enhancements to policy, including training, in order to better ensure that the policies are effectively accomplishing the intended purpose. OPPED will have the management controls drafted and tested for effectiveness by the end of this fiscal year 2006, with the goal of full implementation at the start of fiscal year 2007. OPPED will use this approach to measure the effectiveness of various policies, including the effectiveness of SRM segregation procedures to ensure SRMs are not being used as source material for AMR.

OIG Position.

We accept management decision.

Recommendation 19

Develop and issue guidance to inspectors on how to interpret laboratory test results and actions that should be taken when AMR product does not meet requirements.

Agency Response.

FSIS will clarify laboratory test results sent to in-plant personnel, and outline actions that should be taken if test results show the presence of organ tissue via a new FSIS notice or directive by July 2006.

OIG Position.

We accept management decision.

Finding 11 — Meat Industry Registration Requirement Was Not Adequately Implemented

FSIS and APHIS did not maintain current and comprehensive listings of renderers[131] and related businesses because this requirement was considered a low priority. These entities are required to register with FSIS as a condition of engaging in business.[132] We found incomplete and inconsistent information maintained by APHIS and FSIS; as well as within divisions of FSIS. As a result, should serious animal diseases be detected in the United States, USDA's ability to quickly determine and trace the source of infections to prevent the spread of the disease could be impaired. Also, APHIS could not use the registrations to identify potential sources to mitigate geographical gaps in BSE testing.

FSIS issued a notice[133] pointing out the need for it to have registration information and required all businesses subject to the Federal Meat Inspection Act, including those previously registered, to complete a new registration form and submit it to FSIS by May 24, 2004. APHIS also issued a final rule providing that any persons who move livestock or poultry interstate for slaughter or rendering may only move the animals to a slaughter or rendering establishment listed by the Administrator [of APHIS].[134]

We found that the FSIS and APHIS renderer listings were incomplete and inconsistent, internally and to other sources as shown in the following chart.

[131] For purposes of this report, the term renderers also includes pet food manufacturers and plants that handle dead, dying, disabled, or diseased livestock.

[132] 9 CFR 320.5, states that every person that engages in business in or for commerce, as a meat broker, renderer, or animal food manufacturer … shall register with the Administrator [of FSIS].

[133] Federal Register Notice, Volume 68, Number 122, dated June 25, 2003, states essentially that since 1970, FSIS has required registration by meat brokers, renderers, animal food manufacturers, wholesalers, warehousemen, and persons that engage in the business of buying, selling, transporting in commerce, or importing, any dead, dying, disabled, or diseased livestock or parts of the carcasses of livestock that have died otherwise than by slaughter. Registration information is critical in any FSIS investigation related to public health, food safety, or misbranding of meat or poultry products. For example, should BSE or hoof and mouth disease be introduced into the United States, registration information could be crucial in tracing the source of an infection and in preventing its spread. FSIS intends to increase its enforcement of the registration requirements to ensure that all businesses subject to the Federal Meat Inspection Act that are required to be registered with FSIS are doing so. In this notice, FSIS also informed the public that the Agency had developed a new registration form. Because this form required that registrants provide certain information that was not required on the previous form, all parties, including those that were currently registered, were to complete the new form and submit it to FSIS by March 22, 2004, (extended to May 24, 2004).

[134] 9 CFR 71.21, dated March 4, 2004.

Agency/Group	Number of Rendering and Similar Businesses (Rounded)
FDA	570
National Renderers Association	220
FSIS Renderers Listing[135]	1,050
FSIS OPEER*[136]	100
APHIS	140

* Office of Program Evaluation, Enforcement, and Review

FSIS' Renderers List

FSIS' list of renderers omitted important contact information including a complete address, phone number, e-mail address, and hours of operation. In addition to having incomplete data, these lists also included numerous establishments that closed or that had been combined with other businesses. FSIS supplied us with a listing of rendering firms[137] generated from its prior registration system. Using this information, we attempted to determine the differences between information maintained by APHIS and FSIS. To illustrate, in one State, APHIS information differed from FSIS information for 37 firms listed on FSIS records as follows:

- 19 firms were no longer operating (51 percent were out of business).
- 35 firms (95 percent) did not have a complete mailing address.

We also found that two other APHIS area offices we visited had similar discrepancies with the FSIS rendering lists related to their States.

FSIS officials advised that they did not have a process in place to update its records when registration information changed. At one time, FSIS planned to put the registration form on-line, but that did not materialize. Instead, FSIS has been working on a new version of its registration database, called Registration Activity Management System, which is undergoing development and testing. FSIS estimated that it has hundreds, perhaps a thousand or so registration forms that need to be entered into the new system. FSIS intends to have the Registration Activity Management System available for program investigators to use by October 1, 2005.[138] FSIS is also working on a protocol for program investigators to follow to alert agency officials when firms close or change names, etc., so adjustments can be made.

[135] Previous Registration Database – Renderer, 4D, and Animal Foods Operators.
[136] Registration Data on Renderers, Animal Food Manufacturers, and Buying, Selling, Transporting, or Importing Product maintained by FSIS compliance for the Planned Compliance Program.
[137] The list was dated October 28, 2004.
[138] While the RAMS database contains information on only those firms that have registered with the Agency and was not designed to handle the requirements for OPEER's compliance program database, we believe there are advantages to linking the systems to allow both groups to more effectively accomplish their missions.

FSIS Maintains Several Lists of Renderers

In addition to the Registration Activity Management System, the FSIS Office of Program Evaluation, Enforcement, and Review (OPEER) maintains its own automated list of renderers.[139] OPEER's database contains pertinent information on the firms to be monitored in its compliance program, as well as in accordance with FSIS Notice 33-04, dated June 14, 2004, Protocol for Off-Site Collection of Brain Samples for BSE Testing. FSIS officials stated that the Registration Activity Management System database was not designed to handle the requirements for OPEER's compliance program. The two databases have different objectives that require different information; in the future, FSIS hopes to link the two systems.

APHIS' Renderer List

APHIS area offices did not obtain FSIS' listings of renderers to assist in identifying those firms that deal in dead/dying/disabled/diseased livestock. In 11 States where APHIS did not have a sampling agreement and where sampling goals were not obtained, FSIS' records showed 81 possible entities that may have been able to participate in the surveillance program. Also, APHIS is not maintaining its list of slaughter and rendering firms that receive livestock. An APHIS notice[140] stated that to facilitate the collection of blood and tissue samples, any firms that accept livestock for slaughter or rendering would have to be listed with APHIS. We requested and reviewed APHIS' listing dated April 1, 2005; their listing identified only about 140 firms even though the numbers of renderers and related business were shown by other sources as being significantly higher. They attached an explanation showing that:

> *"…we do not claim this to be a complete list. We are in the process of revising the policy memo relative to this regulation, as there was some confusion about the initial implementation issues. Therefore, this has not been assigned a high priority for our field personnel."*

FSIS and APHIS need to maintain accurate and current registration information relating to their regulatory responsibilities. This information is necessary to be able to promptly investigate incidents related to public health, food safety, or misbranding meat or poultry products. Also, these lists could be beneficial to future surveillance programs by sharing/linking the database systems.

[139] OPEER maintains a system to produce a listing entitled "Registration Data on Renderers, Animal Food Manufactures, and Buying, Selling, Transporting or Importing Product" to assist in their Planned Compliance Program.
[140] Federal Register Notice, Volume 69, Number 43, dated March 4, 2004.

Recommendation 20

Coordinate data gathering and sharing to improve accuracy and prevent duplication of effort. Expeditiously implement planned computer systems, and timely obtain and enter information into the systems from any backlog of registration forms. Conduct periodic reviews to ensure complete, accurate, and comprehensive lists of renderers are immediately available for use when required.

Agency Response.

APHIS concurs with this recommendation. APHIS and FSIS will share lists and cross-check them regularly but APHIS believes that the various lists reflect different purposes, and therefore they should not necessarily be identical. APHIS also expressed concern regarding the number of "rendering and similar businesses" shown in the report since not every renderer on each list is relevant to the BSE surveillance program (see exhibit G for APHIS' response in its entirety).

The Registration Activity Management System (RAMS) was released for use to OPEER Evaluation and Enforcement Division (EED) headquarters personnel in October 2005, and will be made available to field users by June 2006. Since the time of the audit, OPEER has caught up with the backlog of registration forms and now has approximately 1800 to 2000 firms entered into the registration database. Additionally, the agency plans to implement an online registration form. Development of an "on-line" system would expedite the registration of those firms with access to the Web and would allow the agency to allocate resources in other areas.

As a result of emerging food safety events, OPEER has focused greater attention on high risk firms, such as renderers, by visiting them on a more frequent basis and collecting more comprehensive information during those visits. Investigators currently inquire about each firm's registration status, provide needed registration forms, and proactively educate industry on food safety and food security issues. In addition, OPEER will conduct reviews to ensure the completeness and accuracy of renderers data.

FSIS supports the development and implementation of new systems to carry out our food safety and food security mission. The development of new systems that link to other systems and share information will help coordinate data gathering and sharing, improve accuracy, and prevent duplication of effort. The RAMS database would be linked to such a system. These new systems are being developed and will be operational in calendar year 2007.

OIG Position.

We accept management decision.

Finding 12 BSE Program Costs Inconsistently Determined and Reported

One of the five APHIS area offices reviewed paid costs for sampling and carcass transportation, storage, and disposal that exceeded national cost recovery guidelines and/or that were ineligible for reimbursement. The State area office entered into 10 reimbursable agreements before national office cost recovery guidelines had been issued. Rather than adjusting the reimbursable agreements, as instructed by the national office, the Veterinarian-in-Charge (AVIC) included the questionable costs in amounts proposed (by third parties) and approved in other allowable cost categories. The State AVIC stated he changed supporting records because he believed he should honor the prior negotiated costs. Although the APHIS regional office reviewed the reimbursable agreements, they identified only questionable disposal costs[141] because the AVIC submitted adjusted documents for their review. Further, the regional office did not followup to ensure that appropriate changes were made to the agreements for those costs that were questioned. As a result, at least $1.2 million of about $11,158,000[142] paid were unsupported program costs. We also found inconsistent accounting for program costs in two States.

Cost Guidelines Not Followed

In August 4, 2004, APHIS issued final cost recovery guidelines as follows:

Activity	Fees Paid
Identification and storage of carcasses awaiting laboratory results	Up to $100 per carcass
Transportation of carcasses for BSE sampling	Up to $2 per loaded mile
Sample collection – includes collection of the brainstem, data processing, and submission of samples	Up to $40 per sample
Removal/presentation of the head	Up to $10 per sample
Disposal of carcasses	Up to $100 per carcass for on-farm burial, composting, or in approved landfill. Up to $500 per carcass for incineration.

[141] Disposal costs can be an eligible cost for those firms that are not equipped to perform such operations (such as a firm that only removes hides); however, firms whose primary business is the disposal of carcasses are not eligible for this reimbursement.

[142] State expenditures include $6,959,000 identified as Identification/Storage costs, $3,476,000 in transportation costs, and $723,000 in head removal costs. As of May 31, 2005, the total cost for the national program was about $54 million.

The guidelines stated, "Every effort should be made to pay only the costs associated with the particular transaction and to stay within these BSE cost recovery fees guidelines." Those proposed costs that were not eligible or exceeded the maximum reimbursement rate were to be reduced or eliminated or were to be properly documented, justified, and approved by the APHIS regional office. Also, APHIS established a general policy that the regional office should examine all agreements.

In May 2004, when APHIS announced its intention to implement an expanded BSE sampling program, the area office contacted firms that might be interested in participating and asked them to submit a detailed estimate of anticipated costs to obtain BSE samples. Based on these estimates, the area office entered into 10 reimbursable agreements.

Reimbursements for sampling were initially approved by the AVIC based on the third parties' original proposal.[143] In about mid August 2004, the area office re-categorized the itemized costs before submitting the agreements to the regional office for review. Regional office officials noted in their reviews that the proposed disposal costs were not eligible for reimbursement. In mid-September, the AVIC adjusted the proposed costs with the intention of compensating the third parties for the elimination of disposal costs[144] and retained the same reimbursement rate, as initially agreed at the start of the program. The allocation of ineligible costs to other eligible categories was documented on a "BSE Sampling Agreement Cost Recovery Worksheet" maintained in the area office. With the exception of one agreement, the area office was not able to provide documentation supporting the final cost determination.

Unsupported Transportation Costs

Transportation costs in this area office were not supported by estimates of, or reimbursements paid for, actual loaded miles driven. Cost recovery guidelines provide for reimbursement of up to $2 per loaded mile for transporting carcasses. In some cases, the third parties estimated the number of loaded miles they expected to drive and in other cases, the cost per loaded mile was not specified. The AVIC adjusted the costs without documentation to support the changes; the AVIC agreed that transportation costs were not paid on the cost per loaded mile actually driven.

Inconsistent Use of Budget Object Codes

Two area offices used inconsistent accounting codes for BSE program costs. This occurred because of the lack of clear and specific guidance on how BSE costs were to be recorded in the agency accounting records. The regional offices did not detect the accounting errors. As a result, APHIS' accounting records do not consistently and accurately reflect its BSE related expenditures.

[143] The itemized costs in the proposals did not always fit precisely within the agency's six cost categories.
[144] One sample did not show disposal cost; however, the firm's proposed cost was still re-categorized.

Area offices were provided a memo that addressed the Budget Object Codes to be used in the National Surveillance Plan. The APHIS memo does not provide any specific direction or examples on how area office personnel are to record cost associated with the sampling program (i.e. Transportation, Disposal, Storage, etc.).

- One area office correctly recorded payments as lump sums in Budget Object Code 2550.
- A second area office recorded payments as lump sums in Budget Object Code 2540 (Contractual Services - Other).
- A third area office divided payments into Budget Object Codes 2540, 2222 (Local Transportation), and 2570 (Miscellaneous Services).

APHIS regional and national office officials agreed that the State area office did not properly record costs. During our review, the regional offices instructed the area offices to correct accounting errors.

Recommendation 21

Review the questioned financial transactions and supporting documentation and determine if improper payments have been made. Initiate recovery as appropriate.

Agency Response.

APHIS concurs with the recommendation and is in the process of reviewing results. Preliminary results found concerns about the agreements with BSE collection facilities, including the way they were entered into and the way they were managed. APHIS' investigation found that due to a lack of documents maintained by the cooperators, it was not possible to determine the actual amount of unsupported payments.

On September 29, 2005, the Veterinary Services Regional Office contacted the Area Office and instructed them to terminate all agreements for collection of targeted animals for enhanced BSE surveillance. To bring samplers back on line for the enhanced program, APHIS will institute a contracting process consistent with proper contracting standards. APHIS will continue to review the investigation results and finish all appropriate action by March 31, 2006.

OIG Position.

We accept management decision.

Recommendation 22

Reinforce the proper accounting for BSE program costs.

Agency Response.

APHIS concurs with this recommendation. By January 15, 2006, APHIS will provide written communication to all appropriate offices to refine and direct program accounting for the BSE program.

OIG Position.

We accept management decision.

Scope and Methodology

We performed our reviews at APHIS and FSIS Headquarters, and made field visits to:

- The APHIS regional office and Centers for Epidemiology and Animal Health in Fort Collins, Colorado; the National Veterinary Services Laboratories (NVSL) and Center for Veterinary Biologics (CVB) in Ames, Iowa; five APHIS area offices; and four State diagnostic laboratories.

- FSIS district offices in Boulder, Colorado; Dallas, Texas; Des Moines, Iowa; Lawrence, Kansas; and Minneapolis, Minnesota, and Compliance and Investigations Division regional offices in Lawrence, Kansas, and Dallas, Texas.

- 12 Federally inspected slaughter establishments (including 2 Talmadge-Aiken plants.) (We also visited three other federally inspected slaughter plants solely to review ante mortem inspection procedures).

- Five rendering/pet food companies that collect brain tissue samples for BSE testing.

- Four processing facilities that receive and process carcasses containing SRMs (including one slaughter plant listed above).

See exhibit B for a complete list of locations visited.

FSIS provided review officers from its technical service center in Omaha, Nebraska, to assist in our reviews at the slaughter plants and provide technical advice on FSIS regulations, procedures, and instructions. Fieldwork was performed from October 27, 2004, through September 2, 2005.

To accomplish our audit objectives, we performed the following audit procedures:

- Interviewed responsible FSIS and APHIS program officials.

- Reviewed written policies and procedures relating to the BSE surveillance program, as well as regulatory functions associated with SRMs and AMR.

- Interviewed plant personnel concerning the surveillance program and actions to address the new food safety initiatives announced by the Department immediately after the BSE positive was identified.

- Observed establishment and FSIS activities related to ante mortem inspection of cattle, condemnation of suspect animals, euthanizing condemned cattle, obtaining brain tissue samples, and disposition of carcasses after BSE sampling.

- Observed the transfer of carcasses to off-site BSE sampling locations and BSE sampling activities at these locations at establishments where BSE testing of ante mortem condemned cattle was not done at the official premises.

- Reviewed establishments' written procedures for the removal, segregation, disposition, and disposal of SRMs.

- Reviewed FSIS and establishments' procedures for preventing processing of vertebral bones for cattle 30 months of age and older in AMR systems and testing programs for CNS tissue in AMR meat. Reviewed FSIS testing records at the FSIS Eastern Laboratory and at the local plants visited for AMR product produced during the period of review.

- Observed operations of the AMR systems and CNS tissue testing programs at six establishments with AMR systems.

- Evaluated two assessment reviews performed by AMS of BSE surveillance program operations, as well as, corrective actions APHIS took on recommendations made in our BSE surveillance program Phase I audit report.[145]

- Interviewed three complainants regarding allegations related to FSIS' monitoring of SRM regulations and procedures and APHIS' BSE surveillance program activities.

- Reviewed APHIS National Office BSE program management and monitoring operations relating to sample collection, testing, and program payments.

- Reviewed individual APHIS BSE sampling agreements and selected payments associated with these agreements.

- Evaluated the role and responsibilities of the NVSL and BSE contract laboratories regarding the BSE surveillance program.

[145] OIG Audit Report No. 50601-9-KC, dated August 2004.

- Interviewed contract laboratory officials regarding BSE testing policies and laboratory procedures, observed sample processing at the contract laboratories, and determined if the BSE contract laboratories were meeting APHIS and NVSL requirements.

- Contacted various international experts and knowledgeable individuals.

- Interviewed Centers for Epidemiology and Animal Health officials regarding the design and implementation of the BSE database.

In addition to the above audit procedures, the audit team performed various types of data analysis during the audit. We obtained database information from FSIS and APHIS related to animal condemnations, slaughter volume, inspection system activities including Noncompliance Records (NR) issued by FSIS inspectors, BSE sample collection and testing, and payments for BSE samples. We performed the following:

- Reconciled sample counts from the BSE database to APHIS' BSE Weekly Surveillance Report.

- Analyzed critical fields of the BSE database for errors, omissions, and inconsistencies.

- Analyzed the BSE database to determine the location of animals sampled by region and State.

- Reviewed the recorded identification information.

- Reviewed the samples of animals too young to count in the target population according to the surveillance guide.

- Verified APHIS sample data to FSIS ante mortem condemned data.

- Analyzed the FSIS NR database from October 2003 through May 2005. By running search term queries of the database, we isolated those NRs that related to SRM violations.

- Performed an analysis of 1,036 SRM NRs to show the number of NRs by establishment, NRs by size, and whether the NRs were a food safety or non-food safety related item by date.

- Used slaughter data to identify slaughter facilities and establishments that predominately slaughter old cattle and compared this information to the

number of SRM NRs by the size of the establishment versus the class of animals they slaughter.

- Analyzed NRs issued for BSE surveillance, SRM and AMR issues. Reconciled NRs identified by FSIS as SRM/BSE related to those identified by OIG.

The audit was performed in accordance with Government Auditing Standards.

Exhibit A – Summary of Monetary Results

Finding No.	Description	Amount	Category
12	Area Office Improperly Supported Payments	$1.2 million	1/

1/ Unsupported Costs - Recovery Recommended

Exhibit B – Sites Visited

APHIS National Office – Washington, DC
FSIS National Office – Washington, DC
AMS National Office – Washington, DC
APHIS Western Regional Office – Fort Collins, Colorado
APHIS Centers for Epidemiology and Animal Health – Fort Collins, Colorado
APHIS National Veterinary Services Laboratories (NVSL) – Ames, Iowa
APHIS Center for Veterinary Biologics (CVB) – Ames, Iowa
APHIS Area Office – Madison, Wisconsin
APHIS Area Office –Topeka, Kansas
APHIS Area Office – Sacramento, California
APHIS Area Office – Des Moines, Iowa
APHIS Area Office – Austin, Texas
ARS Meat Animal Research Center – Clay Center, Nebraska
ARS National Animal Disease Center – Ames, Iowa
Texas Veterinary Medical Diagnostic Laboratories - College Station, Texas
California Animal Health and Food Safety Laboratory System - Davis, California
Washington Animal Disease Diagnostic Laboratory - Pullman, Washington
Athens Diagnostic Laboratory (University of Georgia) - Athens, Georgia
FSIS Eastern Laboratory - Athens, Georgia
FSIS District Office – Boulder, Colorado
FSIS District Office – Dallas, Texas
FSIS District Office – Des Moines, Iowa
FSIS District Office – Lawrence, Kansas
FSIS District Office – Minneapolis, Minnesota
FSIS Compliance and Investigation Division Regional Office – Lawrence, Kansas
FSIS Compliance and Investigation Division Regional Office – Dallas, Texas
Very Large Slaughter Plant A – Colorado
Large Slaughter Plant B – Idaho
Large Slaughter Plant C – Texas
Small Slaughter Plant D – Texas
Very Large Slaughter Plant E – Nebraska
Large Slaughter Plant F – Nebraska
Very Small Slaughter Plant G – Nebraska
Very Large Slaughter and Processing Plant H – Kansas
Large Slaughter Plant I – Minnesota
Very Small Slaughter Plant J – South Dakota
Small Slaughter Plant K – North Carolina
Very Small Slaughter Plant L – North Carolina
Large Slaughter Plant M – Wisconsin
Large Slaughter Plant N – Wisconsin
Small Slaughter Plant O - Kansas
Beef Processing Plant P – Colorado

Beef Processing Plant Q – Illinois
Beef Processing Plant R – New York
Rendering Plant – Nebraska
Rendering Plant – Minnesota
Rendering Plant – Minnesota
Rendering Plant – North Carolina
Pet Food Manufacturer – Colorado

Exhibit C – Implementation of the Expanded Surveillance Program and Food Safety Measures

APHIS Implementation Actions
Worked with industry and State personnel to estimate the number of samples that could likely be obtained in the State.
Worked with industries (rendering facilities, 3D/4D or salvage slaughter operations, and other disposal options such as deadstock facilities) to encourage participation and allowed access to not only non-ambulatory animals but all other categories in the targeted population.
Provided for financial reimbursements. For entities that provide samples on a regular basis, to enter into written agreements or contracts. The written agreements or contracts specify the specific responsibilities of each party and the agreed amount of financial reimbursement.
Developed written instructions in the BSE Surveillance Guide.
Developed Veterinary Services Memorandum 580.16, which outlined the policy for the entire BSE surveillance program, including the expectations for obtaining samples from all cattle condemned for non-CNS reasons.
Created a database to capture data to allow for ongoing analysis throughout the surveillance effort. The database would provide the capability to analyze data at all levels – State, regional and national. The database contains specific fields to identify both the location of sample collection and the location of the last place of residence of the animal. This database will allow APHIS to monitor the number of samples received on a State and regional basis.
Designated an epidemiologist at the Centers for Epidemiology and Animal Health responsible for performing the routine program analysis. This person would work closely with the BSE surveillance program manager and the APHIS TSE Working Group in conducting and reporting the analyses to APHIS BSE surveillance program managers.
Conducted outreach campaigns in advertisements, radio spots and other marketing efforts.
Entered into an agreement with AMS, which has experience in establishing and evaluating quality assurance programs, to review compliance with the BSE surveillance plan.
Provided training on the sampling process. Instructed sample collectors on the use of electronic forms and how to accurately record the relevant information necessary to classify samples into the various aspects of the targeted population. Distributed compact disk copies of the entire training sessions to all stakeholders.
Developed Standard Operating Procedures (SOPs) to address all laboratory responsibilities and performance expectations. There are five SOPs: 1) conducting the specified test procedures; 2) addressing all laboratory responsibilities, performance expectations, and communication or reporting requirements; 3) documenting the chain of custody of forwarded tissues from inconclusive tests; 4) proficiency testing; and 5) reimbursement through standard purchase order, which is linked to performance and contingent on proper procedures.

FSIS Implementation Actions
Banned non-ambulatory (downer) animals from the human food supply.
Defined SRMs and prohibiting their use in the human food supply: skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle 30 months of age and older, and the small intestine for cattle of all ages.
Expanded the prohibition that spinal cord in AMR product cannot be labeled as "meat" if it includes dorsal root ganglia and/or clusters of nerve cells connected to the spinal column. In addition, prohibited the use of spinal columns and skulls from cattle 30 months of age and older in AMR product.
Banned the use of air-injection stunning.
Provided training to FSIS personnel on the sample collection process. The personnel trained then provided training to additional FSIS personnel, as necessary, with assistance from local APHIS personnel.
Implemented various Notices including procedures for 1) sample collection, documentation and shipping of samples by inspection program personnel; 2) expectations regarding APHIS arrangements with establishments for sampling condemned cattle at an alternative central location.

FSIS Implementation Actions
Required in-plant inspectors to provide plant management at beef slaughter and bone-in beef processing plants with written documentation of the requirements of the SRM regulations. Inspectors also met with plant management during the first week after the regulations were published (January 9, 2004) to ensure plant personnel understood: 1) the requirements of the SRM regulations; 2) that plants needed to reassess their hazard analysis and 3) that plants needed to develop controls for removing, segregating, and disposing of SRMs.
Required in-plant inspection staff to verify that beef slaughter and bone-in beef processing plants had developed and implemented the required SRM control measures during the second week after the regulations were published (regulations became effective January 12, 2004).
Established inspection procedures for verifying that the requirements for removing, segregating, and disposing of SRMs were implemented at each plant.
Established a program for Compliance and Investigations Division program investigators to visit each off-site location where BSE brain tissue samples were collected from cattle condemned on ante mortem inspection at slaughter plants. The program investigators were to verify that all condemned cattle were received at the off-site location, tissue samples were obtained, and all other program and record keeping requirements were met.
Established a policy requiring inspectors to notify district office and Compliance and Investigations Division personnel each time an animal was condemned that exhibited CNS symptoms. Program investigators were required to visit the sample collection sites and confirm that all cattle condemned at slaughter plants that exhibited CNS symptoms were sampled for BSE testing.

Exhibit D – Point-Based Evaluation Methods

2005 OIE TAHC METHOD

In May 2005, the OIE General Assembly revised international standards for BSE surveillance by approving changes to related articles of the *2005 OIE Terrestrial Animal Health Code* (*TAHC*). Article 3.8.4.3 recommends an approach that assigns 'point values' to each sample based on the animal's age and its "surveillance stream" (or subpopulation) as shown below in Table 2 of Article 3.8.4.4.2 of the *TAHC*.[146]

OIE SURVEILLANCE POINTS (Source: *2005 OIE TAHC* Appendix 3.8.4 Table 2)			
Surveillance subpopulation			
Routine slaughter	Fallen stock	Casualty slaughter	Clinical suspect
Age ≥1 year and < 2 years			
0.01	0.2	0.4	N/A
Age ≥2 years and < 4 years (young adult)			
0.1	0.2	0.4	260
Age ≥4 years and < 7 years (middle adult)			
0.2	0.9	1.6	750
Age ≥7 years and < 9 years (older adult)			
0.1	0.4	0.7	220
Age ≥9 years (aged)			
0.0	0.1	0.2	45

The four "surveillance subpopulations" are described in article 3.8.4.2 as follows:[147]

- *clinical suspects*: "cattle … displaying behavioral or clinical signs consistent with BSE"
- *casualty slaughter*: "condemned at ante-mortem inspection … or downer cattle"
- *fallen stock*: "cattle … found dead on farm, during transport or at an abattoir"
- *routine slaughter*: "apparently healthy cattle presented for slaughter"

The above table reveals the enormous difference between the number of surveillance points assigned to animals classified as clinical suspects compared to those classified as casualty slaughter, fallen stock, routine slaughter. For example, if a 5-year old cow is classified as a "clinical suspect," it is assigned 750 points, instead only 0.9 or 1.6 points if classified as either "fallen stock" or "casualty slaughter,"

[146] The United States is a member of the international community represented by the OIE; USDA provided input into this new point system.

[147] The *2005 OIE TAHC* describes the first three subpopulations as cattle "over 30 months of age" in article 3.8.4.2 and routine slaughter as "over 36 months of age," yet Table 2 assigns point values for all "age ≥ 1 year," with the exception of clinical suspects, have point values for all "age ≥ 2 years."

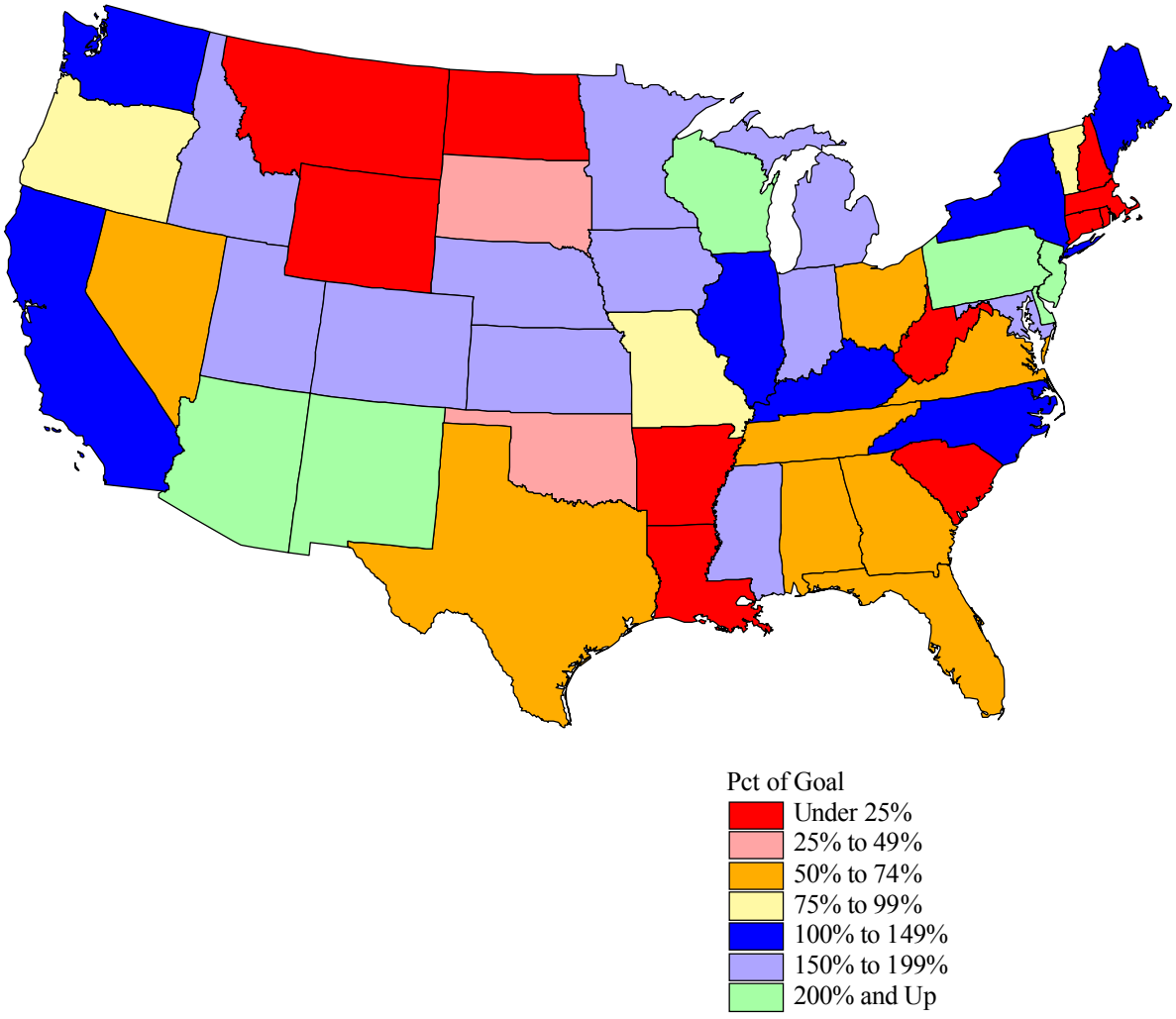
respectively.[148] Therefore, misclassifying the surveillance stream and inaccurate aging of the cattle tested can significantly impact the surveillance points used to estimate the prevalence of BSE.

The *OIE TAHC* represents a simplified version of the point-based system encoded in *BSurvE*.

[148] Because surveillance point values are so high for "clinical suspects," the rest of the *2005 OIE TAHC* article 3.8.4.2.1 description of "clinical suspects" is quoted below.

> Cattle affected by illnesses that are refractory to treatment, and displaying progressive behavioral changes such as excitability, persistent kicking when milked, changes in herd hierarchical status, hesitation at doors, gates and barriers, as well as those displaying progressive neurological signs without signs of infectious illness are candidates for examination. These behavioral changes, being very subtle, are best identified by those who handle animals on a daily basis. Since BSE causes no pathognomonic clinical signs, all countries with cattle populations will observe individual animals displaying clinical signs consistent with BSE. It should be recognized that cases may display only some of these signs, which may also vary in severity, and such animals should still be investigated as potential BSE affected animals. The rate at which such suspicious cases are likely to occur will differ among epidemiological situations and cannot therefore be predicted reliably.
>
> This subpopulation, particularly cattle over 30 months of age, is the one exhibiting the highest prevalence. The recognition greatly depends on the owner's awareness and observation of suspect animals. The reporting of these suspect animals when at the farm will depend on the owner's motivation based on cost and socio-economic repercussions.

Samples as a Percentage
of Goals by State
based on Target Population



Samples as a Percentage
of Goals by Region
based on Target Population

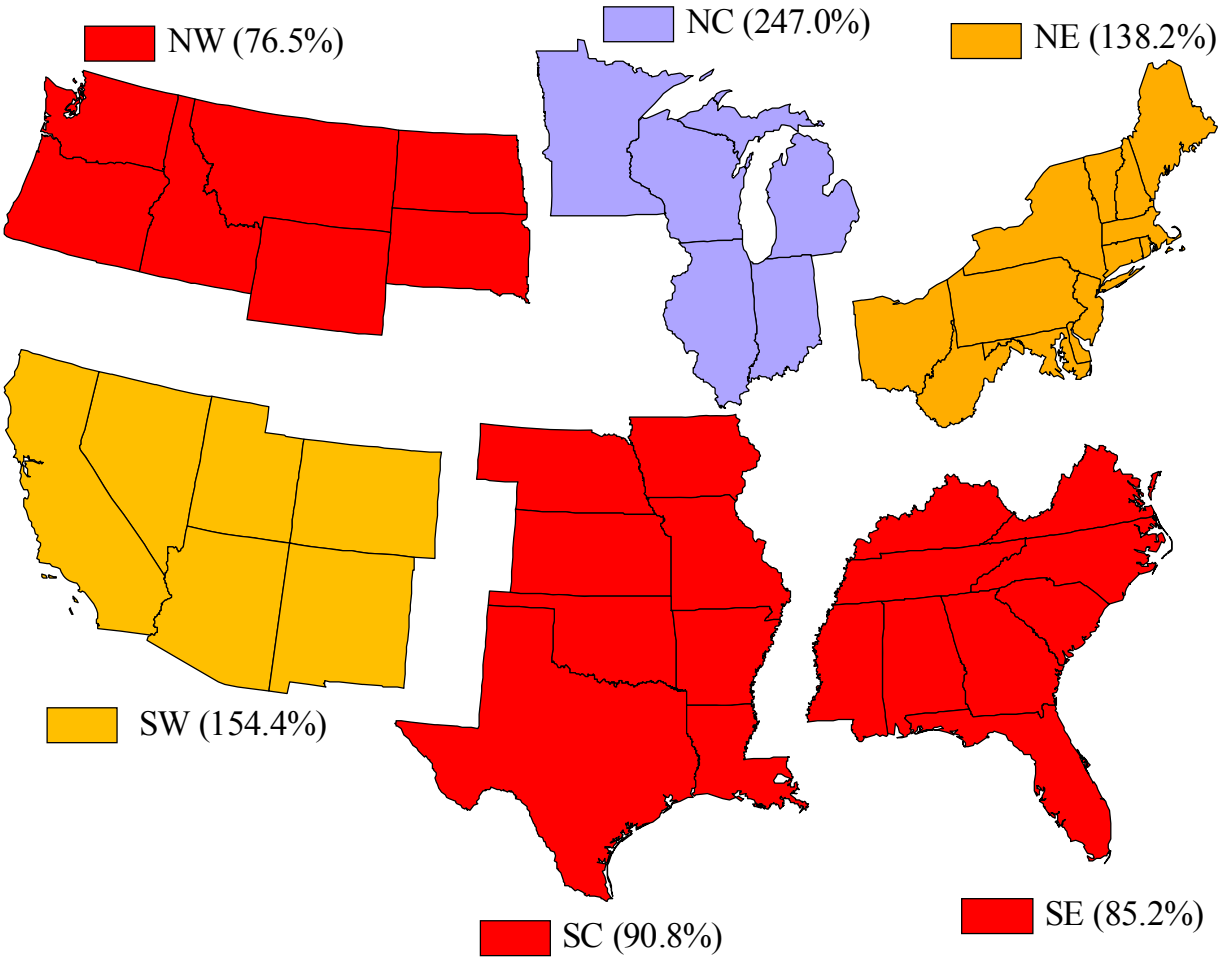
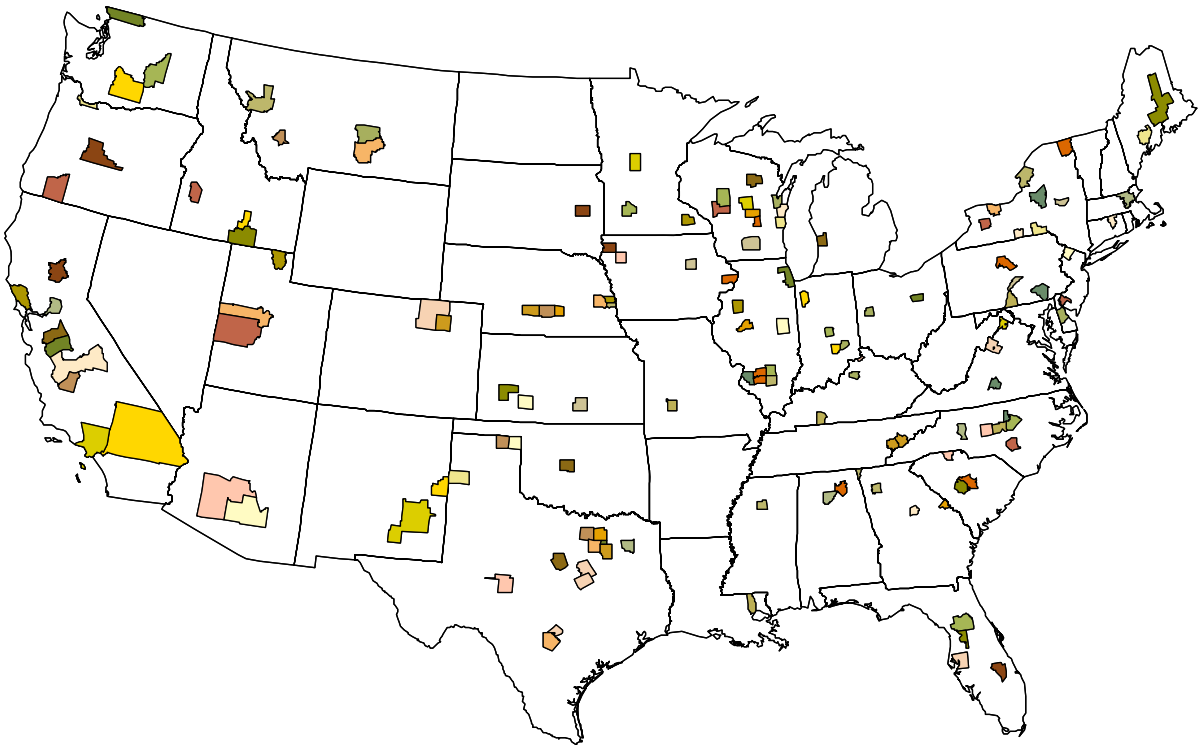


Exhibit F – Location (by County) of Sampling Sites with Agreements in the Expanded BSE Surveillance Program[149] [150]



[149] Different shading is used to differentiate the counties on the map.

[150] APHIS noted that agreements do not necessarily reflect the entire universe of collection sites and that the presentation in exhibit F was incomplete because there were many collection sites without a payment involved or without a formal agreement. We note that over 90 percent of the samples collected were obtained from the 123 collection sites with agreements and; therefore, we believe agreements offer the best source to increase targeted samples in underrepresented areas.

USDA

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

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Room 317 EW
Washington, DC 20250

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

FROM: W. Ron DeHaven JAN 20 2006
Administrator
Animal and Plant Health Inspection Service

Barbara Masters
Barbara J. Masters, D.V.M.
Administrator
Food Safety and Inspection Service

SUBJECT: APHIS and FSIS Response to OIG Report: Animal and Plant Health Inspection Service Bovine Spongiform Encephalopathy (BSE) Surveillance Program (Phase II) and Food Safety and Inspection Service Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Products (Phase III)
Report No. 50601-10-KC

The Animal and Plant Health Inspection Service (APHIS), and Food Safety and Inspection Service (FSIS) are committed to keeping both the United States' agriculture and the nation's food supply safe through an aggressive, well managed BSE surveillance program. APHIS and FSIS appreciate the opportunity to review and comment on this report. Further, both APHIS and FSIS have reviewed the report with great interest and provide the following responses to each of the reports twenty-two audit recommendations.

Enclosure

APHIS and FSIS Response to OIG Report
Bovine Spongiform Encephalopathy (BSE) Surveillance Program (Phase II)
and
Controls Over BSE Sampling, Specified Risk Materials, and Advanced Meat Recovery Products (Phase III)
Report No. 50601-10-KC

Recommendation 1: Ensure transparency of published information so that stakeholders are fully advised of the assumption and procedures used, limitations of data, and the basis of conclusion reached as a result of the BSE surveillance program.

APHIS concurs with this recommendation. We will complete the final analysis on the BSE enhanced surveillance effort by February 28, 2006, and will ensure transparency of the published information as recommended. The initial assignment of regional goals was based on the pre-determined sample estimate of 268,500, which was primarily done to facilitate management of enhanced surveillance program resources. APHIS' intent is to report the actual number of samples tested in each of the six regions alongside the pre-determined goals in the final report. We agree that it is important to clarify the target population estimates used for surveillance planning prior to implementation of the enhanced surveillance program (and the concomitant statistical inferences to be made from those estimates) and how the expansion of the target population occurred resulting in a larger effective target population. This clarification will be supplied in the final analysis document.

A detailed discussion of the potential biases incurred with over sampling in one region as compared to another and the effects these biases may have on the overall enhanced surveillance program will also be included in the final analysis report.

APHIS would like to clarify footnote number 26 on page 11, however. The implication is that APHIS had State goal allocations, which were subsequently not met, and that those State goals were posted on APHIS' website. However, in actuality, the legend on the posted map clearly indicates that there are not specific State goals, but the distribution is an example only based on population data, and that the evaluation of the data will be done at a national level. The legend on the website states:

"These are examples of what could be considered appropriate geographic distributions of sample collections for our BSE testing program. These are estimates only, based on population data derived from NASS surveys and weighted for some assumed differences in death losses between dairy and beef cattle populations. Our evaluation of the data obtained in this testing effort will be done at a national level, and will reflect the US cattle population. ***It will not be done individually at a State level. These distribution examples are therefore flexible and should only be***

considered in the overall analysis as part of the national picture." (Emphasis added).

APHIS had regional collection goals, which have been exceeded. There was never an attempt to meet specific State goal numbers. Therefore, APHIS feels that page one of Exhibit E is misleading, as there were no specific State targets set by APHIS.

Recommendation 2: In future surveillance programs enforce management controls over the integrity of surveillance testing data.

APHIS concurs with the need to maintain the integrity of surveillance testing data. The National Surveillance Unit is currently developing data standards to be used in all surveillance programs. The projected time period for the completion of the initial data standards is March 31, 2006. Future surveillance programs will utilize those data standards, and will have safeguards to prevent data errors.

Recommendation 3: Determine whether FSIS and/or APHIS need additional authorities to perform inspection and BSE sampling activities in pre-screening areas immediately adjacent, or contiguous to, official slaughter establishments.

The question as to whether FSIS has jurisdiction is not determinable merely on the basis of proximity of where certain activities take place. FSIS' ability to conduct activities in pre-screening areas is related to the relationship between the activities the establishment performs in the pre-screening areas and the slaughter process. The closer and more exclusively those activities are related to the slaughter process, the more likely it is that FSIS would be able to exercise jurisdiction in the pre-screening area. The available information, however, does not allow us to make a judgment on the concern raised by OIG. FSIS will, however, remain open to learning more about the situations raised by OIG and pursue any leads that indicate that such activities directly relate to slaughter and are under the control of the establishment.

APHIS does not believe that we need additional authorities to perform inspection and BSE sampling in pre-screening areas immediately adjacent, or contiguous to, official slaughter establishments. As stated in the report, OIG observed animals that were down or dead in those areas that were to be picked up by renderers. OIG also states that they observed that animals that arrived at a sale barn that were sick/down/dead or would die or go down while at the sale barn were also left for the renderer to collect. APHIS utilized the knowledge of industry practices regarding the disposition of animals presented at these facilities and then rerouted, and designed the surveillance system to collect at renderers where these animals were ultimately destined. OIG visited a renderer in the area of a slaughter facility and found the renderer had a contract with APHIS to collect samples for BSE testing. OIG also states that "…there was a financial incentive for transport drivers to dispose of their dead

animals at this renderer." The goal of the enhanced surveillance program is to test a sufficient number of animals to allow us to draw conclusions about the level of BSE in the American herd, not to test every animal in the target population. APHIS does not think it would be a prudent use of taxpayer dollars to seek and use new authorities to seize and test these few animals. We can draw credible, scientifically valid conclusions without spending the taxpayers' money to comply with this recommendation.

APHIS would also like to comment on OIG's conclusion that their analysis showed that there are sampling gaps in two large areas of the United States where APHIS did not have contracts with collection sites, and the chart referencing that point on page 24. OIG's assumption was based on plotting the locations of 123 APHIS sampling agreements and contracts with firms. The commentary and the chart purport to make the case that APHIS failed to meet State by State surveillance goals. We believe that this is inaccurate and unnecessarily and unfairly questions the overall validity of the program. Again, APHIS was not trying to meet particular levels in particular States. APHIS worked to meet regional goals, and those are the goals that should be evaluated.

In addition, agreements do not necessarily reflect the entire universe of collection sites we work with. For a collection site where we are collecting but at which there is no payment involved, there is no agreement in place. Attempting to determine distribution of sampling by plotting only collection sites with agreements is misleading, since it is an incomplete list of collection sites. In fact, the random tool we used to develop allocations for maintenance surveillance planning drew from approximately 165 large sites and more than 260 small ones, far more than the 123 with which we had reimbursement agreements.

Group 1 on the table included MT, SD, ND, and WY, and Group 2 included LA, OK, AR, and TN. APHIS cross-checked the National Renderer's Association listings for these States and confirmed that there are few rendering facilities in those States. In fact, there are no NRA facilities listed in MT, ND, or WY. While the lists for LA, OK, AR, and TN do indicate some NRA members in these States, the facilities in AR include companies that are poultry processing facilities; and may have LA one non-poultry facility.

Further, Exhibit F is an inaccurate representation of collection sites. OIG states *"However, as shown in exhibit F, APHIS was not always successful in establishing agreements with non-slaughter collection sites in some States. APHIS stated that agreements do not necessarily reflect the entire universe of collection sites and that the presentation in exhibit F was incomplete because there were many collection sites without a payment involved or without a formal agreement. We note that over 90 percent of the samples collected were obtained from the 123 collection sites with agreements and; therefore, we believe agreements offer the best source to increase targeted samples in underrepresented areas."*

In summary, based on our knowledge of the industry, APHIS focused collection efforts at animal disposal facilities such as rendering facilities, and salvage and slaughter facilities. In many areas of the country, such facilities do not exist. APHIS worked with existing facilities and entered into agreements with those facilities. Those States without agreements are States without animal disposal facilities of the sort that are crucial to us in our BSE surveillance program. In those cases, we collected samples through other mechanisms, which resulted in approximately 5,000 collection sites without agreements referenced above.

Recommendation 4: Consult with technical experts and determine what ages of animal of rabies negative cattle should be tested for BSE. Perform additional outreach and personal contacts to emphasize the age of the target animals and to ensure laboratory personnel understand procedures for submitting the desired samples. Provide periodic monitoring of laboratory submissions and follow-up with laboratories that appear to be providing an insufficient number of samples.

APHIS concurs with the recommendation. Once the final analysis of the BSE surveillance effort is completed, APHIS will make a final determination on the ages of rabies negative animals that should be tested for BSE, and will notify laboratories within 30 days of that determination, no later than April 15, 2006. Veterinary Services personnel at NVSL and in the field will personally contact all involved laboratories by June 1, 2006, to ensure that the laboratories have received and understood the procedures for submitting samples. By April 30, 2006, APHIS will establish a monitoring process that includes a threshold on the number of samples expected from laboratories based on those laboratories' particular situation. That process will include an action step to contact any laboratory not meeting reasonable expectations given their circumstances.

Recommendation 5: Continuously re-evaluate, and adjust, testing protocols based on emerging science.

APHIS concurs with the recommendation. The National Veterinary Services Laboratories (NVSL) has in the past re-evaluated and adjusted its testing protocols based on emerging science, and will continue to do so. For example, NVSL has revised laboratory standard operating procedures (SOPs) to include the use of the OIE scrapie associated fibril (SAF) immunoblot procedure as a mandatory confirmatory test (in addition to IHC already required) for confirmation testing with inconclusive results. Additionally, based on the recommendations of OIG, NVSL scientists, and other internationally recognized experts, NVSL will incorporate additional language into the IHC SOP. That language will allow NVSL scientists to incorporate the flexibility of adding additional antibodies, chromagens, and variations in specific tissue treatments (including fixation methods) as needed to further clarify

interpretation of the IHC results. These changes will be considered normal variations of the SOP and not considered research procedures. Additional tests and flexibility will be utilized when conflicting or unexplained anomalies in test results occur, and will only be performed after consultation with appropriate Agency and Department officials. If such further testing is requested and approved, NVSL will provide the Deputy Administrator with a specific testing protocol together with a written explanation of that protocol. APHIS will implement the new SOP when we move from the enhanced surveillance program level of testing to a level commensurate with the OIE guidelines. We estimate that will occur during the Spring of 2006.

Recommendation 6: Strengthen controls over contract laboratories to ensure that the samples are not frozen and that the laboratory testing results are properly documented and reported by NVSL.

APHIS agrees with the recommendation and has issued NVSL standard operating procedure GPPISOP0032.06, which contains the following instructions to the BSE contract laboratory personnel: "Do not freeze the obex or place it in formalin. The obex will be shipped refrigerated." An additional footnote states: "Note: If it is not possible to ship the obex in order for it to be received at NVSL within 48 hours, the entire sample should be frozen. Every effort should be made, however, to insure that **refrigerated** obex will arrive at NVSL within 48 hours." APHIS added this language in late June 2005, after the initial OIG inquiry on this matter. ASPHIS also emphasized the instructions in an e-mail to and a conference call with the BSE network laboratory Directors. By March 15, 2006, APHIS will establish further procedures for ensuring test results are properly documented and reported by NVSL.

Recommendation 7: Expedite the process for the NVSL, and other APHIS laboratories, to become ISO 17025 accredited. Establish the necessary management control review processes, including peer reviews, to achieve and maintain accreditation.

NVSL is implementing its 2003 Plan for Quality Assurance. The plan includes full-time quality managers in each laboratory (and one for common services) and a contract consultant, which are all in place. The laboratory system and a variety of high-consequence tests across all laboratories and multiple technologies, including BSE testing, will be accredited to the ISO/IEC 17025 standard by December 31, 2006. Internal audits of the high-consequence testing areas have been accomplished, corrective actions are being formulated, and management reviews are scheduled. In the case of the transmissible spongiform encephalopathy (TSE) testing internal audit, the results of the 2003 internal audit were incorporated and corrective actions for all findings written. NVSL plans to assist other APHIS (e.g., State-Federal) and network laboratories in improving their quality assurance systems using established international guidelines as it progresses in its accreditation.

To ensure the most appropriate technical methods are being followed within the quality system, the external, international peer review process will continue, with reviews of high-impact program areas being reviewed approximately annually, on a five-year cycle. Its findings will be incorporated into the NVSL corrective action and management review system. NVSL scientists will continue to participate in international conferences and collaborations to stay abreast of the latest techniques.

Recommendation 8: Develop and implement a formal and regular laboratory proficiency testing program at the NVSL and any APHIS laboratory that will participate in future animal disease surveillance and/or testing programs.

APHIS concurs with this recommendation. We will review all current proficiency testing programs and revise them as appropriate by December 31, 2006. NVSL will ensure that formal and regular laboratory proficiency testing programs are in place for all future animal disease surveillance and/or testing programs.

Recommendation 9: Develop controls to ensure that all established laboratory quality assurance processes are followed and any conditions noted are reviewed for followup and action, as appropriate.

APHIS concurs with this recommendation. By December 31, 2006, we will develop controls to ensure that all current laboratory quality assurance processes are followed and to ensure that any necessary follow-up action is taken.

Recommendation 10: Review and analyze continuously, OD values for contract laboratories and resolve any trends that warrant further evaluation or corrective actions.

APHIS concurs with this recommendation. NVSL has an SOP in place that describes how it will review and analyze OD values. The SOP "Quality Assurance: Proficiency Testing of BSE Testing Laboratories by NVSL," (GPPISOP0033.03) states that weekly monitoring will be performed by NVSL until no longer deemed necessary by the Chief of the Pathobiology Laboratory, NVSL. Each laboratory will provide NVSL with the Excel spreadsheet output from all runs to cover testing for the previous 7 days. NVSL will collate the data and provide mean OD values from each laboratory to all of the network laboratories. This will be coded so as not to reveal laboratory identity of other laboratories. This data will allow both NVSL and the partner laboratories to observe the ODs on control and surveillance samples, which can indicate technical proficiency and allow problems to be identified before they affect program integrity. It will also allow validation of numbers of samples run in the network. NVSL will also review data as deemed scientifically justified such as on

special request, upon inspection, and during the review of proficiency data. It should be noted that there are no methods recognized by the test manufacturer or by international standards to determine how BSE ELISA OD data should be analyzed. Accordingly, NVSL will, by March 1, 2006, begin to analyze the weekly OD values by laboratory to determine what seems to be a normal range of values. After looking at this data for two months, NVSL will establish an acceptable range of OD values that do not of themselves raise concerns. After establishing that range, NVSL will contact any laboratory which submits samples for a week which do not fall within the range to determine if there are important concerns.

Recommendation 11: Implement a review and evaluation program to be conducted by FSIS' Office of Program Evaluation, Enforcement and Review to verify the adequacy of SRM control programs at all beef slaughter and processing establishments.

OPEER will conduct a review and evaluation program to verify the adequacy of SRM control programs at beef slaughter and processing establishments. OPEER will complete the review and evaluation by the end of FY06.

Recommendation 12: Develop and incorporate tasks within PBIS specific to verify compliance with SRM control procedures and to confirm procedures are followed for properly aging cattle.

The Performance Based Inspection System (PBIS) was originally designed as a system for scheduling inspection. As the Agency has begun implementing a more robust risk-based inspection, it has relied upon PBIS more and more for data collection. FSIS recently has made a major enhancement to PBIS to facilitate data collection (described below), but realizes that in the future new systems for collecting inspection and compliance data will be needed. FSIS is in the process of developing these systems.

FSIS has developed an enhancement to PBIS that records noncompliance related to the SRM control requirements already in the regulations. The enhancement, a dropdown menu of keywords and regulatory citations, provides the Agency with a tool to ensure that noncompliance records (NRs) accurately cite the relevant regulatory requirements. It also will facilitate more comprehensive searches of PBIS data. When inspectors write NRs, they will be required to select from a dropdown list of specific regulatory citations that describe the types of noncompliance that could be found while performing a given PBIS verification procedure. The list also includes key words that describe the nature of each regulation (e.g. requirements for controlling SRM) and there are links to the regulatory text. So, for example, when an inspector performs an 03J HACCP verification procedure for beef slaughter and finds noncompliance regarding the control of SRMs, he/she will be able to select from a list

of regulatory citations and choose the appropriate provision under 9 CFR 310.22 "Specified risk materials from cattle and their handling and disposition." If an establishment fails to properly age cattle and thus allows SRMs from cattle 30-months of age or older into edible product, that would be reflected by the regulatory citations under section 310.22 selected by the inspector from the dropdown menus. As a result, the regulatory citations in NRs will not only be more accurate, but they will provide a means by which FSIS analysts can search the PBIS database for NRs relevant to a specific topic or regulatory citation. Aggregate information from the revised NR database will be routinely analyzed to assess trends in non-compliance nationally, by district, by segment of industry, or within other categories. Results will be used to identify specific areas of concern that need to be addressed through enhanced policy development, guidelines for industry, or improved training materials for FSIS personnel.

FSIS provided instructions for the use of the PBIS enhancements in FSIS Notice 79-05. The Agency is also preparing training, as well as modifying PBIS training for field personnel to supplement and reinforce the instructions in Notice 79-05 and ensure consistent usage. Inspection program personnel began using the PBIS enhancements in December 2005.

The response to recommendation 13 discusses a multi-layered management control system. That system addresses SRM controls in its performance measures for HACCP procedures and control of condemned and inedible material. For example, if an inspector was not verifying that an establishment was properly disposing of 100% of product containing SRM, that would be reflected in the results of a management control review. These performance measures are overlaid with system design control functions via food safety assessments, and IPPS. The IPPS system will consist of a database with information on the assessment of individual employee skills in using the correct inspection method, decision-making, documentation, and enforcement. The inter-relationship of all of these performance measures, by establishment, in the management control database, markedly enhances Agency management and oversight of these critical activities. Standard and customized management reports will be generated at all Agency management levels. Once Phase II of AssuranceNet is implemented in June 2006, as described in the implementation schedule in Recommendation 13, reporting features will include flags for performance measures that are not in conformance with the quantitative performance targets.

Recommendation 13: Develop a management reporting system that documents what controls and records were reviewed when assigned tasks are performed by inspectors.

FSIS Management Control System

FSIS has developed and is in the process of implementing a management control system that provides multi-layered, in-depth management oversight of the public health regulatory activities carried out by its Office of Field Operations (OFO). As described below, full implementation of the management control system is expected by June 2006. This system gives OFO the ability to verify its effectiveness in protecting public health by achieving and maintaining specific levels of performance in its daily food safety and food defense operations. Performance measures for all public health control activities are continuously monitored and any performance that falls below the targeted level is flagged for supervisory intervention. Current management control functions include antemortem/postmortem, HACCP/pathogen reduction (PR) execution, HACCP/PR design, Recall Management, Enforcement, and Food Defense/Reporting of Non-routine incidents. As discussed in the response to Recommendation 12, the management control system includes performance measures for HACCP procedures and control of condemned and inedible material that encompass verification of a plant's control of SRMs.

In designing this system, FSIS has included performance measures related to BSE. This is achieved by closely controlling at ante-mortem all cattle with central nervous system (CNS) disorders, dead and non ambulatory disabled cattle and all other ante mortem condemned cattle to assure proper destruction of these condemned animals. FSIS has also initiated a Management Control to assure all condemned animals and products are controlled and properly destroyed. Public Health Veterinarians are required to either sample ante-mortem condemned animals on-site or to ensure that sampling is performed at an alternative off-site location. Identification numbers (Z-tags) for identified animals are then entered into the FSIS' Electronic Animal Disposition Reporting System (*e*ADRS) and APHIS' Bovine Spongiform Encephalitis Standardized Information System (BSESIS). The results of these screening activities are also entered into the FSIS Management Control System database, Assurance Net, by way of a series of questions that must be answered for each identified animal. The database summarizes these results and reports the results monthly to assure proper collection for sampling has occurred. In addition, SRM control is linked to a management control under HACCP/Pathogen Reduction Execution which assures proper execution for removal of SRMs from edible products at slaughter and processing. Under the multi-layered system, SRM controls are addressed in performance measures for HACCP procedures, control of condemned and inedible material. These performance measures are an integral part of the overall OFO management control system which includes additional system design control functions via IPPS and food safety assessments. The IPPS system will consist of a database with information on the assessment of individual employee skills in using the correct inspection method, decision-making, documentation, and enforcement. The results of food safety assessment can be used by inspection program personnel to better understand how to verify the efficacy of an establishment's food safety controls. The inter-relationship of all of these performance measures, by establishment, in the management control database, markedly enhances Agency management and oversight of these critical activities.

Evaluating Effectiveness of Management Controls

Management control data entered into AssuranceNet is summarized and reported to the FSIS headquarters in the *District Management Control Monthly Report*. Senior managers review the information to ensure that specific performance targets for each control activity have been met and to identify problem areas. However, the primary means of assuring the effectiveness of its overall management control system is through the OFO In-Plant Performance System (IPPS) that monitors and assesses on-the-job employee performance. Management controls are only as good as the knowledge, skills and abilities of the onsite inspection program personnel. For this reason, IPPS is now directly linked to OFO's public health management controls and specifically assesses inspector performance in carrying out those controls. The System holds supervisors at each level of the organization accountable for regularly performing IPPS reviews that assess the inspector skills, knowledge and abilities that are necessary to effectively monitor in-plant management controls. Deficiencies and failures identified in the *District Management Control Monthly Report* are linked to inspection findings and accomplishments on a plant specific basis.

Implementation Schedule

All OFO management controls are monitored by a database system known as AssuranceNet. The purpose of AssuranceNet is to provide a system for recording and monitoring the performance level for each control activity. This provides assurance that the food safety/food defense function, of which each control activity is an integral part, is being carried out in a manner that protects the public health. AssuranceNet also provides for standardized data collection and reporting across the 15 District Offices by providing a common format and recording procedures for all Districts. Implementation of AssuranceNet is occurring in two phases.

Phase I

Phase 1 of AssuranceNet is the development and use of a SharePoint application that will produce a *District Management Controls Report* that uses an Excel spreadsheet for the reporting tool. FSIS implemented this phase of AssuranceNet on December 18, 2005. This is an interim stage that permits all of the District Offices to enter their information in a central repository and gain experience in management control procedures. Performance monitoring will be greatly facilitated because there will be a standard report used by all Districts. Data will be inputted at varying degrees of regularity based on the requirements of the individual management controls and performance measures and the specific needs of each District Office. Reports will be run for each District on a monthly basis shortly after the end of the defined reporting period. The reporting period will run from the 15th of one month to the 15th of the next month. For example, January reports will be generated after February 15th.

Phase II

Phase 2 of AssuranceNet, which is under final development, will be the fully mature management control application that will be used to submit data and run reports. It is scheduled to be implemented in June of 2006. It will be a web-based tool that will allow the user to enter, approve and modify data and run reports. It will use Business Objects and Crystal Reports to allow users to take advantage of the latest in reporting functionality. All information will be stored in a central location, allowing audits and on-demand reporting options that are not currently available in the SharePoint application.

Recommendation 14: Modify PBIS to allow for timely analyses of trends in SRM violations and other food safety concerns. These modifications should also allow FSIS to analyze noncompliance trends well beyond the operation of any single establishment and track corrective actions.

FSIS has developed an enhancement to its Performance Based Inspection System (PBIS) that records noncompliance related to the SRM control requirements already in the regulations. The enhancement, a dropdown menu of keywords and regulatory citations, provides the Agency with a tool to ensure that noncompliance records (NRs) accurately cite the relevant regulatory requirements. It also will facilitate more comprehensive searches of PBIS data. When inspectors write NRs, they will be required to select from a dropdown list of specific regulatory citations that describe the types of noncompliance that could be found while performing a given PBIS verification procedure. The list also includes key words that describe the nature of each regulation (e.g. requirements for controlling SRM) and there are links to the regulatory text. Thus, for example, when an inspector performs an 03J HACCP verification procedure for beef slaughter and finds noncompliance regarding the control of SRMs, he/she will be able to select from a list of regulatory citations and choose the appropriate provision under 9 CFR 310.22. As a result, the regulatory citations in NRs will not only be more accurate, but they will provide a means by which FSIS analysts can search the PBIS database for NRs relevant to a specific topic or regulatory citation. Aggregate information from the revised NR database will be routinely analyzed to assess trends in non-compliance nationally, by district, by segment of industry, or within other categories. Results will be used to identify specific areas of concern that need to be addressed through enhanced policy development, guidelines for industry, or improved training materials for FSIS personnel.

Also, FSIS will be developing new approaches to measure effectiveness of policy beginning in FY06. Specifically, FSIS will ensure that management controls are in place describing how the Office of Policy, Program and Employee Development (OPPED) will routinely assess and respond to the data captured as part of IPPS and AssuranceNet. The analysis conducted by OPPED will focus on nationwide trends

that may reflect the need for enhancements to policy, including training, in order to better ensure that the policies are effectively accomplishing the intended purpose. OPPED will have the management controls drafted and tested for effectiveness by the end of this fiscal year 2006, with the goal of full implementation at the start of fiscal year 2007.

Once the AssuranceNet system is deployed in June 2006, District level reports will be generated on an at least monthly basis. The District Analyst will assess findings and inform the District Manager or Deputy District Manager of the results. Headquarters officials will have custom reporting capabilities using the Business Objects and Crystal Reports applications.

FSIS provided instructions for the use of the PBIS enhancements in FSIS Notice 79-05. The Agency is also preparing training, as well as modifying PBIS training for field personnel to supplement and reinforce the instructions in Notice 79-05 and ensure consistent usage. Inspection program personnel began using the PBIS enhancements in December 2005.

Recommendation 15: Clarify guidance for conducting pre-operational sanitation inspections and SRM verification activities on workdays that fall outside the normal work schedule. Develop a process to confirm the inspections are done in accordance with established procedures.

FSIS will provide guidance to inspection program personnel for conducting pre-operational sanitation inspections and other HACCP and SSOP verification activities on workdays that fall outside the normal work schedule, through revision to FSIS Directive 5000.1. The revisions will instruct inspection personnel to perform PBIS procedures, on an unscheduled basis, in a manner consistent with the scheduled rate and to use their professional judgment to decide which procedures to perform based on the Agency's food safety priorities. Inspection procedures, when performed outside of the normal work schedule, will be entered into PBIS as unscheduled procedures. These revisions are expected to be completed by March 2006. The District Analyst will have primary responsibility for correlating, on at least a quarterly basis, that the rate of procedures performed outside of the normal work schedule is consistent with the rate of scheduled procedures for that establishment. Supervisory personnel will use this PBIS data along with several other data sources to help prepare for IPPS reviews of inspection program personnel. PBIS data regarding performance of pre-operational sanitation inspections during both normal work schedules and workdays outside of the normal work schedule would be examined to provide context for an IPPS review.

Recommendation 16: USDA should clarify its policy for slaughtering nonambulatory cattle. Documentation should be kept to support any decisions

for passing such animals for slaughter. FSIS should develop controls to ensure that USDA policy is consistently applied.

FSIS will clarify its policy for slaughtering nonambulatory cattle by providing inspection program personnel with clarification instructions related to FSIS Notice 5-05, "Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination." The guidance will provide instructions for tagging animals and for documenting observations to better ensure the accountability of such situations. We expect to issue guidance by February 2006.

Recommendation 17: Reassess the risk associated with processing meat by AMR systems and determine whether banned SRMs can be effectively controlled and prevented from entering commerce.

The agency has extensively modeled the risk of AMR as a vehicle for the spread of BSE and issued an interim final rule that explicitly prohibits the use of SRMs in the manufacture of AMR. There is international agreement that the definitions for SRMs applied by FSIS in its interim final rule are appropriate for the U.S., and that properly produced AMR from cattle younger than 30 months of age is safe. However, FSIS agrees that an essential factor in proper production of AMR from cattle is to ensure that SRMs are not used. Consequently, FSIS has taken a number of steps, as described in the earlier response to recommendation 13, to enhance the Agency's management controls through IPPS and AssuranceNet to increase our confidence that regulated products are not adulterated or misbranded. Regarding testing for CNS tissue, testing AMR for CNS-type tissue would not be appropriate or practical in ascertaining whether the source materials were from prohibited sources. Verification testing for CNS-like tissues in AMR meat is a useful measure to ascertain compliance with the regulatory requirements regarding whether the resulting product is misbranded.

As noted in the response to Recommendation 13, the IPPS process, when integrated with other management control information, will be utilized to ensure that inspection personnel are using the appropriate inspection method, decision-making, recordkeeping and enforcement process when conducting AMR verification procedures. IPPS results will be reported into the AssuranceNet database, for tracking and reporting of inspection outcomes.

Recommendation 18: Develop a supportable sampling and testing program to provide assurance that the SRM ban and other regulatory requirements are met.

Through the management control systems and IPPS system described in response to recommendations 13 and 17, FSIS believes that it has provided an effective alternative to the recommendations provided by OIG in order to enhance the

Agency's confidence that beef AMR is being properly produced and is not adulterated or misbranded. This alternative solution offered by FSIS does not affect the current testing program by FSIS or testing that is conducted by industry as part of the regulatory requirements. Rather, this alternative solution focuses on better ensuring that the segregation procedures used to ensure that SRMs are not being used as source materials are in place and effectively working.

FSIS will be developing new approaches to measure effectiveness of policy beginning in FY06. This effort is separate from establishment of the OFO management controls. Specifically, FSIS will ensure that management controls are in place describing how the Office of Policy, Program and Employee Development (OPPED) will routinely assess and respond to the data captured as part of IPPS and AssuranceNet. The analysis conducted by OPPED will focus on nationwide trends that may reflect the need for enhancements to policy, including training, in order to better ensure that the policies are effectively accomplishing the intended purpose. OPPED will have the management controls drafted and tested for effectiveness by the end of this fiscal year 2006, with the goal of full implementation at the start of fiscal year 2007. OPPED will use this approach to measure the effectiveness of various policies, including the effectiveness of SRM segregation procedures to ensure SRMs are not being used as source material for AMR.

Recommendation 19: Develop and issue guidance to inspectors on how to interpret laboratory test results and actions that should be taken when AMR product does not meet requirements.

FSIS will clarify laboratory test results sent to in-plant personnel, and outline actions that should be taken if test results show the presence of organ tissue via a new FSIS Notice or Directive by July 2006.

Recommendation 20: Coordinate data gathering and sharing to improve accuracy and prevent duplication of effort. Expeditiously implement planned computer systems, and timely obtain and enter information into the systems from any backlog of registration forms. Conduct periodic reviews to ensure complete, accurate, and comprehensive lists of renderers are immediately available for use when required.

APHIS concurs with this recommendation. Data gathering and sharing to improve accuracy and prevent duplication of effort is worthwhile. APHIS and FSIS will share lists and cross-check them regularly. However, the discussion in the report implies that APHIS' and FSIS' lists of renderers should be the same, and that they are not. APHIS believes that the various lists reflect different purposes, and therefore they should not necessarily be identical. On page 66, there is a table that lists the number of "rendering and similar businesses." APHIS feels these numbers are very

misleading, since not every renderer on each list is relevant to the BSE surveillance program. Poultry rendering facilities are prime examples of this point. APHIS asked our FDA colleagues about the 570 number in the table attributed to FDA, and FDA could not tell us from where that number was derived. In fact, FDA noted that they had been criticized by GAO for not having such a list. In addition, in their most recent update on feed inspection activities, FDA notes that a total of 274 rendering facilities have been inspected to date; and of these, only 185 handle materials prohibited from use in ruminant feed (i.e., only 185/274 are handling mammalian material - the others are only poultry or fish or do not handle protein). Thus, not every renderer of importance to FDA would be of importance in the BSE program. Similarly, it is difficult to compare the list APHIS used to that of the National Renderers Association, where they conveniently list the products produced by each member facility. There are a total of 208 active members listed; of these, 15 are located in Canada - so they clearly are not of interest to APHIS for sampling purposes. Approximately 43 others are identified as producing strictly poultry meal, fish meal, or only non-protein product. This leaves about 150 possible plants of interest, and the names of those facilities indicate that many of these are affiliated with swine plants and therefore are not of interest, and many others are affiliated directly with large slaughter plants and, therefore, probably don't take deadstock – only offal – from the plants. Therefore, since the various lists of renderers are created for differing purposes, it is not unexpected that different agencies would have different lists.

The Registration Activity Management System (RAMS) was released for use to OPEER Evaluation and Enforcement Division (EED) headquarters personnel in October 2005, and will be made available to field users by June 2006. Since the time of the audit, OPEER has caught up with the backlog of registration forms and now has approximately 1800 to 2000 firms entered into the registration database. Additionally, the Agency plans to implement an online registration form. Development of an "on-line" system would expedite the registration of those firms with access to the Web and would allow the Agency to allocate resources in other areas.

As a result of emerging food safety events, OPEER has focused greater attention on high risk firms, such as renderers, by visiting them on a more frequent basis and collecting more comprehensive information during those visits. Investigators currently inquire about each firm's registration status, provide needed registration forms, and proactively educate industry on food safety and food security issues. In addition, OPEER will conduct reviews to ensure the completeness and accuracy of renderers data.

FSIS supports the development and implementation of new systems to carry out our food safety and food security mission. The development of new systems that link to other systems and share information will help coordinate data gathering and sharing, improve accuracy, and prevent duplication of effort. The RAMS database would be

linked to such a system. These new systems are being developed and will be operational in CY 2007.

Recommendation 21: Review the questioned financial transactions and supporting documentation and determine if improper payments have been made. Initiate recovery as appropriate.

APHIS concurs and is in the process of reviewing results. Preliminary results found concerns about the agreements with BSE collection facilities in Wisconsin, including the way they were entered into and the way they were managed. The investigation also stated that due to a lack of documents maintained by the cooperators, it was not possible to determine the actual amount of unsupported payments.

On September 29, 2005, the VS Regional Office contacted the Wisconsin Area Office and instructed them to terminate all agreements for collection of targeted animals for enhanced BSE surveillance. To bring samplers back on line in Wisconsin for the enhanced program, we will institute a contracting process consistent with proper contracting standards. We will continue to review the investigation results and finish all appropriate action by March 31, 2006.

Recommendation 22: Reinforce the proper accounting for BSE program costs.

APHIS concurs with this recommendation. By January 15, 2006, we will provide written communication to all appropriate offices to refine and direct program accounting for the BSE program.

Informational copies of this report have been distributed to:

Administrator, FSIS	
ATTN: Assistant Administrator for OPEER,	(20)
Administrator, APHIS	
ATTN: Deputy Administrator for Marketing Regulatory Program Business Services	(9)
Government Accountability Office	(1)
Office of Management and Budget	(1)
Office of the Chief Financial Officer	(1)