United States Department of Agriculture

OFFICE OF INSPECTOR GENERAL

Implementation of the Public Health Information System for Domestic Inspection

24601-0001-23

August 2015

Implementation of the Public Health Information System for Domestic Inspection

Audit Report 24601-0001-23

What Were OIG's Objectives

We evaluated FSIS' implementation and oversight of the domestic module of PHIS.

What OIG Reviewed

We evaluated activities relating to PHIS design and implementation and performed visits to 22 FSIS-inspected establishments. At the time of our review in these establishments, FSIS was using PHIS version 2.1. According to FSIS, the current PHIS version in production is 4.1.

What OIG Recommends

OIG recommended that FSIS provide a written assessment of the current status of PHIS' implementation and develop and implement controls that require ongoing monitoring. In addition, we recommended that FSIS develop and implement a plan to: review and correct establishment profile data; ensure inspectors are assigned a manageable number of tasks; that the most important tasks are routinely performed; and effectively implement the actions agreed to from our prior audit work.

OIG reviewed PHIS to determine if the system was meeting FSIS' needs

What OIG Found

The Food Safety and Inspection Service (FSIS) launched the web-based Public Health Information System (PHIS) in April 2011 as an effort to collect and analyze near real-time food safety data.

As of January 2012, FSIS in-plant personnel were using the domestic module of PHIS to record inspection results. During our visits to establishments in 2012 and 2013, we observed inspectors using PHIS, although they were only able to do so with an adequate internet connection. While the Office of Inspector General (OIG) agrees that PHIS is used in establishments nationwide, we identified weaknesses during its design and implementation. This included cost overruns during PHIS development, inconsistent plant internet connection, and inaccurate establishment profiles. We also found that inspectors were not always utilizing a function in PHIS that let them record reasons inspection tasks were incomplete. In addition, we found issues with FSIS access privileges for separated employees and prior PHIS-related OIG audit recommendations that were not properly implemented. OIG's work did not identify contaminated or uninspected product released into commerce as a result of identified weaknesses.

This occurred because FSIS did not implement sufficient internal controls to effectively monitor and evaluate the performance of PHIS, ensure that the system was accessible, that it was operating as designed, and that its information was both complete and accurate. FSIS' policy placed the responsibility on inspection personnel to ensure that data were accurate and complete. FSIS generally agreed with our recommendations, but expressed concerns with our findings.

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

DATE: August 18, 2015

AUDIT NUMBER: 24601-0001-23

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

ATTN: Steven Fisher
Chief Financial Officer

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: Implementation of the Public Health Information System for Domestic Inspection

This report presents the results of the subject audit. Your written response to the official draft report, dated July 27, 2015, is included in its entirety at the end of this report, with excerpts and the Office of Inspector General's position incorporated into the relevant sections of the report.

Based on your written response, we accept management decision on Recommendations 2, 3, 4, 7, and 8. We are unable to accept management decision on Recommendations 1, 5, and 6. The actions needed to reach management decision for these recommendations are described under the relevant OIG Position sections.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decisions have not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions.

This report contains publically available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

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Background and Objectives

Background

The Food Safety and Inspection Service's (FSIS) mission is to ensure the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. In September 2007, FSIS awarded a contract to design the Public Health Information System (PHIS). PHIS was designed to replace many of FSIS' older systems and automate FSIS' paper-based business processes into one comprehensive and fully automated data-driven inspection system. PHIS is a web-based application[1] that requires internet connection and an eAuthentication account[2] in order to obtain system access, and it was designed to include four inspection modules: domestic, import, export, and predictive analytics. In-plant personnel are currently using the domestic inspection module to perform inspection-related activities;[3] however, the food safety assessment component[4] of this module was not operational until fiscal year (FY) 2014. For the remaining PHIS modules, FSIS stated that the import and predictive analytics modules are fully operational and the export module is expected to be ready for implementation in the spring of 2015.

PHIS replaced legacy systems such as the Performance-Based Inspection System (PBIS) and the Electronic Animal Disposition Reporting System (eADRS). PBIS was the system of record FSIS used to manage Hazard Analysis and Critical Control Points (HACCP)[5] related activities at FSIS-inspected meat and poultry establishments, while eADRS collected, stored and reported information about the disposition of livestock and poultry presented for slaughter.[6] FSIS officials believed that integrating the functions of these legacy systems into PHIS would save time and effort because food safety information would be contained in one location. An FSIS national office official stated that the vast majority of users stopped using PBIS in January 2012 and eADRS has not been used for reporting slaughter data since January 2012; however, both systems are still active. Since eADRS is considered part of PBIS, they will both be deactivated together.

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[1] A web-based application is an application in which all or some parts of the software are downloaded from the web each time it is run.
[2] eAuthentication is a password-based system used by Department of Agriculture (USDA) employees that allows them access to web-based applications and services via the internet.
[3] In-plant personnel use PHIS to record the results of their inspection related activities, maintain establishment profiles, enter disposition results, and manage samples (i.e., tracking the status of submissions to laboratories and reviewing test results).
[4] A food safety assessment is a comprehensive assessment of the execution and design of an establishment's food safety system. The food safety assessment component in PHIS is designed to capture the results of these assessments in a format that allows for review and analysis.
[5] HACCP is a food safety system that analyzes each step in the production of food for microbiological, physical, and chemical hazards. HACCP includes product flowcharts, hazard analysis of hazards reasonably likely to occur, and plans to control food safety hazards.
[6] Additional legacy systems integrated into PHIS are Resource Information System (RIS), a system that included inspector assignments, circuit structures and employee information; Automated Import Information System (AIIS), which stored daily inspection results from all ports of entry; and eSample, which documented the results of kidney inhibition swab samples.

In 2011, FSIS began implementing the domestic module of PHIS on a "circuit by circuit"[7] basis, and it was operational at all FSIS-inspected establishments in January 2012. PHIS was designed to draw upon data directly from establishment profiles, including data on the type of products produced, production volume, and establishment size when generating tasks for IPP. PHIS was also designed to facilitate product sampling for subsequent testing and analyses. In plant tasks and product sampling are activities FSIS performs to ensure the safety and wholesomeness of the supply of meat and poultry.[8] Using documentation such as the Grant of Inspection[9] and HACCP plans, FSIS District Office and inspection staff were responsible for creating establishment profiles.[10] Additionally, FSIS personnel at the establishments are required to verify the accuracy of establishment profile information in PHIS on a monthly basis and ensure it is current and accurate at all times.

Internet connection is essential for inspectors to access PHIS. Based on the connectivity requirements, FSIS relies on various connection methods such as cable wiring, and enhanced voice-data optimized (EV-DO) cards.[11]

To address internet connectivity issues, FSIS developed an offline version of PHIS, referred to as the Disconnected User (DCU) application. The DCU application allows inspection personnel to work in an offline capacity when connection is not available to them. The DCU allows inspection personnel to view PHIS establishment profile information and record information like inspection task results, on their computer without connecting to the internet. However, inspectors must access the live version of PHIS every 10 days to upload information recorded while working in the DCU.

A prior OIG audit found that FSIS needed to develop a comprehensive, agency-wide data analysis and distribution system.[12] In addition, the prior audit found FSIS needed to closely monitor administration of the PHIS contract, development, testing, and implementation of the new system to ensure it was progressing as intended. Based on our analysis of the audit recommendations, we found that final action for 13 of 35 recommendations in this audit were contingent on PHIS implementation.[13] In addition, 3 of 25 recommendations from a second OIG report were also contingent on the implementation of PHIS.[14]

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[7] FSIS Directive 1010.2, dated September 2008, defines a circuit as an organizational structure of plants and positions designed to deliver program services and provide supervision in an efficient and effective manner to in-plant personnel.
[8] These establishment data are contained in the establishment profile that resides in PHIS.
[9] An FSIS-approved grant of inspection is required before an establishment can sell products in interstate commerce for resale.
[10] The establishment profile is a series of webpages in PHIS that inspectors use to record information about FSIS-inspected establishments, including products produced, HACCP systems, and other general information about the establishment.
[11] An EV-DO card is a device used to obtain an internet signal through a cellular telephone network.
[12] Audit Report No. 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, dated December 2007.
[13] Final action is the completion of all actions that management has concluded, in its management decision, are necessary with respect to the findings and recommendations in an audit report.
[14] Audit Report No. 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, dated November 2008.

Objectives

We evaluated FSIS' implementation and oversight of the domestic inspections module of PHIS. Specifically, we evaluated whether the design and subsequent implementation of PHIS adequately addressed its key mission elements; evaluated FSIS' collection of establishment profile data for each establishment's food safety systems, operations, and demographics; evaluated whether the agency established policies and procedures to secure and protect data within PHIS; whether FSIS has a documented interagency system agreement (if connecting to other agencies or organizations); assessed FSIS' overall timeframes for PHIS' implementation; and evaluated whether the system was implemented within its budget. Lastly, we reviewed prior OIG audit recommendations related to the implementation of PHIS to determine if corrective action was adequate.

We did not identify any concerns related to FSIS' interagency system agreement. As such, our report contains no findings and recommendations associated with this portion of our objectives.

Section 1: PHIS Implementation and Design

Finding 1: FSIS Needs to Re-Assess PHIS to Ensure that the System Will Serve Agency Needs

Although FSIS developed PHIS to modernize the USDA food safety inspection system, we found the agency did not implement the system within its established timeframes or budget. In addition, FSIS did not ensure that FSIS inspectors could reliably use the system to timely complete inspection tasks and record the results in PHIS. In our visits to slaughter and processing establishments in 2012 and 2013, we found problems such as inspectors who were unable to use PHIS due to connectivity problems, and establishment profiles that were inaccurate and therefore resulted in incorrect sample project[15] assignments. We also found that inspectors were not always using a function in PHIS that allowed them to record the reasons that inspection tasks were not completed. In addition, we found issues with how FSIS managed access privileges for separated employees and prior OIG audit recommendations related to PHIS that were not properly implemented. These problems occurred because FSIS did not proactively create sufficient internal controls to monitor and evaluate the performance of PHIS, nor did the agency ensure that the system was accessible, operating as designed, and that its data were complete and accurate. Instead, FSIS' policy placed the responsibility on inspection personnel to ensure that data were accurate and complete. The agency also expected establishment personnel to notify them of any issues they encountered. OIG's work did not identify contaminated or uninspected product released into commerce as a result of weaknesses we identified with PHIS.

FSIS officials acknowledged our findings and noted that the agency began taking actions to correct deficiencies as they became aware of them. This included actions to address preliminary findings we discussed with FSIS in 2013. The agency also provided us with documentation between January and March 2015, stating, for example, that it has taken steps to control costs for similar projects in the future, improved connectivity in the field, and used compensating controls such as non-PHIS data or prior sampling history during the implementation of PHIS to ensure establishments were scheduled for accurate pathogen sampling. We believe that these types of actions are positive steps towards resolving the issues. We believe our additional recommendations will assist FSIS to ensure PHIS will fully serve its intended function of using near real-time data to analyze and predict food safety outcomes.

Office of Management and Budget (OMB) Circular No. A-123 states internal controls need to be in place over information systems. It further states that application controls should be designed to ensure transactions are properly authorized and processed accurately and the data are valid and complete.[16] USDA requires agencies to ensure that systems, as developed, satisfy functional requirements and business needs; adhere to all mandates, physical constraints, and service level agreements; and operate as described in the user and operator manuals.[17]

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[15] A sampling project is an individual sampling for a specific pathogen such as HC01-*Salmonella*. The HC01-*Salmonella* sampling project tests products to ensure *Salmonella* pathogen reduction standards are met.
[16] Management's Responsibility for Internal Controls, Section II (dated December 21, 2004).
[17] USDA Information Technology System Development Lifecycle Guide, Section 7.1.

Overall, we found problems that need addressing so PHIS can be relied upon to serve its intended function when it is fully implemented. Specifically, we found problems related to the following areas:

- The cost, design, and implementation of PHIS.
- Connectivity problems that compromised the ability of FSIS inspectors to facilitate timely completion of inspection tasks and record the results in PHIS.
- Establishment profiles containing inaccurate information that was then used to develop sampling projects.
- PHIS access privileges for separated employees could be better managed.
- PHIS-generated inspection tasks that were not performed.
- Prior audit recommendations, contingent on the implementation of PHIS, that went unaddressed, or for which corrective actions were ineffective.

Each of these findings is discussed in detail below along with the actions FSIS has taken to address these matters.

Cost, Design, and Implementation of PHIS

FSIS did not implement PHIS within the budget or timeframes agreed to in the initial PHIS contract. In September 2007, FSIS awarded a contract for $15.6 million to develop and implement PHIS by October 2010. FSIS officials stated that additional system needs and processes were identified during development of PHIS that they did not consider while drafting the initial Statement of Work. For example, in January 2009, FSIS requested an additional $2.46 million for application software development.[18] As a result, more than 7 years after awarding the initial contract, PHIS is not fully operational. FSIS expects the total costs to increase to over $79.3 million by FY 2018.

OMB Circular No. A-130 states that, as part of the control component of the capital planning process, agencies must use a performance based management system that provides timely information regarding the progress of an information technology investment. The system must also measure progress towards milestones on an independently verifiable basis in terms of cost, capability of the investment to meet specified requirements, timeliness, and quality. Also, the agency must ensure that major information systems proceed in a timely fashion towards agreed-upon milestones in an information system life cycle.[19]

Prior to awarding a contract for the development of PHIS, FSIS estimated that the system could be developed in 3 years at a cost of $8.7 million. However, it did not receive any bids for this amount and subsequently awarded a contract in September 2007 to build PHIS within 3 years (by October 2010) at a cost of $15.6 million. As of December 2011,

[18] This included adding high level business requirements that were not explicitly addressed in the original Statement of Work.
[19] Transmittal Memorandum No. 4, Management of Federal Information Resources, Section 8 a (9)(c)(i)&(iii), dated November 28, 2000.

the total costs had increased to over $39 million and none of the four modules (domestic, import, export, or predictive analytics) were fully operational. In addition, during this same period, FSIS estimated that the development, modernization, and enhancement costs for PHIS would rise to over $71 million by FY 2018. However, 3 months later (in March 2012), FSIS requested an additional $8.3 million, which included system enhancements for the district offices, and increased the total cost estimate to $79.3 million by FY 2018.

We discussed the nature of cost escalations with an FSIS national official. He stated that during the development of PHIS, there were differences between what FSIS headquarters was conceptually requesting for system design compared to what would be usable at establishments. For example, the official stated that large and small establishments operate differently, but FSIS did not foresee the need for operational flexibility until PHIS was implemented. Therefore, necessary modifications resulted in increased costs because FSIS had not planned for establishment differences. As a further example, he stated that the original PHIS programming was unable to accommodate FSIS' organizational changes. For instance, when FSIS downsized from 15 to 10 districts, PHIS required additional reprogramming to accommodate such a fundamental need. This resulted in increased costs for the contract.

In July 2012, the Government Accountability Office (GAO) issued a report that evaluated FSIS' implementation of cost-estimating processes for PHIS as part of a larger review of eight Federal agencies.[20] The report found that PHIS' cost estimations did not exhibit all of the qualities of a reliable cost estimate. In light of these findings, FSIS management officials explained that they immediately took steps to improve its cost estimations by establishing a Capital Planning and Cost Analysis Branch within the Office of the Chief Financial Officer. Further, FSIS later established a dedicated Program Management Division and Investment Planning and Control Branch within the Office of the Chief Information Officer to ensure that Federal and Department policies on Capital Planning and Investment Control were implemented and followed. FSIS officials have found that these practices have led to a comprehensive well-documented cost estimation approach for PHIS.

On February 6, 2015, FSIS stated that, while it recognizes that initial project estimates made when the project was in the early planning phase could have been more accurate, it has proactively taken steps to maximize the effectiveness of the system design, ensure implementation achieved necessary functionality, and control costs.

FSIS also provided documents showing its management oversight activities and USDA's since late FY 2013. These documents included a rebaseline[21] request and approval in

[20] *Information Technology Cost Estimation*, GAO-12-629, dated July 12, 2012.

[21] Departmental Regulation, 3130-006, Version 2 , Information Technology Earned Value Management, paragraph 13q, dated May 1, 2008 defines a performance measurement baseline (PMB) as the time-phased budget plan against which project performance is measured. It is the schedule for expenditure of the resources allocated to accomplish program scope and schedule objectives. Paragraph 10d (1) states that the program/investment manager will establish and maintain a PMB for the total investment and notify the agency and USDA Chief Information Officers

March 2014 and a USDA Capital Planning and IT Governance Division review that rated the PHIS investment at 4.83, out of a possible score of 5.0, in March 2015.[22]

The actions described by FSIS appear to be necessary steps to prevent similar problems in the future. However, since PHIS is not fully implemented, we continue to believe that FSIS needs to reevaluate the expected costs of PHIS and the estimated completion dates. As part of the evaluation, the agency needs to determine the items that still need to be completed and develop a realistic plan for completing the remainder of the system in an efficient, timely, and cost effective manner.

Connectivity Problems Compromised FSIS Inspectors' Ability to Use PHIS to Timely Complete Inspection Tasks and Record The Results

As of January 2013, FSIS had 6,187 meat and poultry slaughter and processing establishments nationwide. All of these establishments were documented in PHIS. At 11 of the 22 establishments (50 percent) we visited that were not selected statistically, FSIS inspectors could not establish consistent access to PHIS so they could review their scheduled tasks and record the task completion. This occurred because establishments did not have reliable internet connection and/or the DCU that FSIS implemented to address poor connection issues was either not functioning properly on the inspectors' computers, or it was not working at all. As a result, the time spent dealing with connectivity issues kept the inspectors from performing inspection-related activities needed to carry out FSIS' mission of ensuring the safety of our food supply (see Exhibit B for examples).

Between April 2011 and October 2012 for establishments we visited, 2 percent[23] of all scheduled tasks (including those considered high priority-sanitation and HACCP verification procedures) were not performed because of computer and connectivity issues. In addition, there were approximately 76,000 (of 116,381) tasks that were scheduled and not performed during this period; however, the inspectors did not document the reason(s) why these tasks were not completed. Therefore, we could not determine if these incomplete tasks were attributable to computer and internet connectivity issues.

(by way of a corrective action plan) when significant changes to the PMB are required. A significant change is any change that results in a change in total investment cost or schedule performance of more than plus or minus 5 percent, or that results in a scope change that impacts the functionality of the system.

[22] The USDA Information Technology Capital Planning and Investment Control Guide, revision 1, dated May 1, 2013, states that USDA's Capital Planning and Investment Control Process allows USDA to manage IT investments. This process relies on a systematic investment review process that ensures that each investment's objectives support the business and mission needs of the Department. Paragraph 5.1 indicates that during the control phase, the process monitors the planning, acquisition, deployment, and maintenance/operational phases of the IT investment lifecycle. Agencies with major investments are currently required to report monthly performance data to the Department for evaluation and scoring.

[23] Inspectors did not perform 2,379 out of 116,381 tasks due to computer and connectivity issues.

Also, we reviewed 1,894 Footprint tickets[24] FSIS inspectors submitted between August 1, 2012, and April 18, 2013. We found 203 of these tickets were for DCU-related problems such as installation and synchronization. FSIS national office officials stated that they are aware of DCU installation issues, and they would continue to work on improving the DCU's functionality. They also stated the slow connection speeds were due to limited bandwidth and they were working with USDA officials to improve the connection speed.[25]

In July 2013, we briefed FSIS officials on our preliminary findings regarding connectivity problems associated with PHIS. In addition, around this time, the Administrator asked for a review into usage of the DCU application and overall field connectivity. In response, FSIS officials explained that the agency implemented actions to improve connectivity and the DCU application.

In January 2015, FSIS stated that field connectivity has improved since we visited establishments during audit fieldwork. FSIS provided us with the reissued DCU Directive, user guide, and quick reference guide. It stated that the DCU now comes pre-installed on all laptops and it has implemented a process for immediate elevation of DCU related issues. FSIS stated that it tested the newest DCU version on these new laptops and performance had improved over the prior version. FSIS also stated that it upgraded connectivity at over 50 establishments in 2013 and over 100 establishments in 2014, with plans to upgrade connectivity at over 100 additional sites in FY 2015. These upgrades included introducing MiFi[26] devices in the field and expanding from one major wireless provider to three of the major providers.

We believe the agency's stated actions are positive steps in improving access to PHIS. The timing of these actions occurred after OIG completed its onsite fieldwork at establishments; we did not conduct additional work to verify improved access to PHIS. As part of current work-in-progress, we will test whether inspectors have consistent access to PHIS.[27] Accordingly, we are not making recommendations regarding connectivity as part of this report.

Establishment Profiles Contained Inaccurate Information, Which Was Then Used to Develop Sampling Projects

For 10 of the 22 establishments we visited that were not selected statistically, the establishment profile contained either inaccurate product types or product volumes, with

[24] Footprint is the name of the database used by FSIS officials to submit and manage issues, such as those related to PHIS implementation.
[25] Bandwidth is a term that describes speeds for network or internet connections between two points.
[26] MiFi is a brand name used to describe a wireless router that acts as a mobile Wi-Fi hotspot. FSIS stated that MiFi is a generic reference to wireless hotspots that do not connect directly to the personal computer and require no software installation.
[27] Audit No. 24016-0001-23, *FSIS Follow-up on 2007 and 2008 Audit Initiatives*.

some establishments having multiple errors in the profiles. For example, seven[28] establishments we visited were not in the correct sampling projects[29] due to incorrect product information in PHIS (see Exhibit C). This occurred because the FSIS inspectors did not update the establishment profile information as required because it was considered a low priority. In addition, FSIS supervisors (i.e., front line supervisors) were not required to document whether they reviewed establishment profile data during In-Plant Performance Systems (IPPS)[30] reviews to verify that it was accurate and properly reflected the establishment's operations. As a result, there is reduced assurance that important inspection tasks and vital microbiological testing are performed to ensure that the products entering the food supply are safe for human consumption.

FSIS Directive 5300.1, *Managing the Establishment Profile in the PHIS,* issued April 11, 2011, requires in-plant personnel (IPP) to ensure the establishment profile contains accurate and current data about the establishment's operations. The Directive states IPP are to perform the establishment profile inspection task by reviewing and updating the information in the establishment profile. Also, IPP are to resolve any issues or discrepancies regarding profile information before showing the task as complete in PHIS. However, 10 of the 28 IPP we interviewed gave various reasons for not ensuring that establishment profile information was accurate and properly reflected the establishment's operations. These reasons included not enough time to ensure profile accuracy, the precedence of higher priority tasks, and unfamiliarity with updating the task.[31]

During our site visits, we reviewed the establishment profile in PHIS and verified the location and contact information for the establishment, the types of products produced, and the production volume (see Exhibit C). During one of our site visits, the front line supervisor informed us he identified three establishments that were not in the correct sampling projects.

To determine if inaccurate establishment profile information was a systemic problem, we requested documentation showing the product information needed in an establishment profile to ensure that it was in the correct sampling projects universe.[32] After receipt of this documentation, we obtained product and sampling project information for 4,512 FSIS-inspected establishments with sampling projects shown in PHIS[33] as of

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[28] Based on our calculation on FSIS' originally supplied information, eight establishments were not in the correct sampling projects; however, based on supplemental documentation provided by FSIS in February 2015, we recalculated and the total applicable establishments were reduced to seven.

[29] As stated earlier, a sampling project is an individual sampling for a specific pathogen such as HC01-*Salmonella*. The HC01-*Salmonella* sampling project tests products to ensure *Salmonella* pathogen reduction standards are met.

[30] An IPPS review provides a firsthand, onsite observation of how well employees conduct FSIS inspection and verification procedures in Federally inspected establishments. Supervisors must conduct at least two IPPS assessments for employees covered by IPPS during the performance rating cycle.

[31] In plant personnel include consumer safety inspectors, state inspectors, and public health veterinarians.

[32] FSIS provided us with the following reports: *Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs*, dated December 2011; and *Redesign of FSIS Sampling Methodologies To Improve Detection of E. coli* O157:H7, dated March 2012.

[33] We analyzed the sampling project definitions from FSIS' *Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs,* December 2011, to determine the requirements for all sampling projects in PHIS.

March 5, 2013. Using the two reports previously mentioned, we identified the product information needed in PHIS to include an establishment in seven of the approximately 30 sampling projects mentioned in the December 2011 report on microbiological sampling programs.[34]

Based on this analysis, we found that 1,867 establishments (41.4 percent) contained at least one error in their sampling projects. For example, 160 of the 1,502 establishments were not included in the sampling universe for the MT43[35] sampling project, even though they produced ground beef.

In a January 2015 rebuttal to this condition, FSIS stated that OIG's assessment of the sampling universe for the MT43 sampling project was inaccurate because it appeared to include product groups, such as formed steaks, that were not eligible for ground beef sampling. FSIS further stated that they do not have a technical document that defines the establishment profile data needed for PHIS to include an establishment in a sampling project, and instead rely on FSIS sampling directives and direction from FSIS officials responsible for policy issues. However, this is different from the statements made during our audit when we were provided the reports mentioned earlier.

On February 26, 2015, FSIS provided us with a list of 8 ground beef product groups that are eligible for MT43 sampling, 11 ground beef product groups that are not eligible for MT43 sampling, and also the PHIS identification numbers[36] for these products. We requested documentation supporting eligibility or ineligibility of these products. FSIS provided an FSIS Directive,[37] and that document identified eligible and ineligible product groups. While we acknowledge that the 8 eligible product groups are documented, the documentation only showed 4 of the 11 product groups that FSIS indicated were not eligible for MT43 sampling. An FSIS official agreed that the agency may need to develop a better way to document reasons for not including specific product groups in a sampling project.

In March 2015, we re-calculated the MT43 sampling project, excluding the 4 product groups mentioned above. Based on this analysis, we determined that 1,396 establishments should be included in the sampling universe for MT43 sampling projects; however, 104 of these establishments were not in the MT43 sampling project, even though they produced the required ground beef products. In addition, during our analysis we also found that 196 establishments were included in the universe for MT43 sampling, but they did not produce at least 1 of the MT43 product groups that we determined were eligible for MT43 sampling. FSIS indicated that 1,247 establishments should have been in the MT43 sampling project.

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[34] These seven projects – MT43, MT43S, MT 50, MT54, MT55, MT60, ALLRTE (ready to eat), and RTE001-included risk based testing for either E.coli 0157:H7, Salmonella, and/or Listeria Monocytogenes.

[35] The MT43 sampling project is a risk-based testing for *E.coli* O157:H7 in ground beef products.

[36] The algorithm that FSIS uses to generate MT43 samples uses identification numbers to identify eligible products.

[37] FSIS Directive 10,010.1 Revision 3, *Verification Activities for Escherichia coli 0157:H7 in Raw Beef Products*, March 31, 2010.

At 18 of the 22 establishments we visited, we also found other establishment profile issues that did not relate to inspection tasks. For example, the establishment profile for one establishment showed a retail exemption; however, this exemption was not approved in the grant of inspection.

FSIS officials explained that, based in part on OIG's sharing of its preliminary findings, FSIS realized that the agency needed to make improvements to the completion of establishment profiles. FSIS officials stated that these improvements were realized with the version of PHIS implemented in September 2013. Further, officials explained that step-by-step instructions for IPP to complete establishment profiles are included in the latest PHIS reference feature, which was implemented in January 2015, and is located on the desktop of every IPP computer. FSIS instructions now identify timeframes for completing targeted directed tasks to IPP, which focus specifically on updating profile information. Supervisory and district personnel are now required to verify completion based on PHIS reporting and alerting capabilities.

We agree that FSIS' actions appear to be necessary steps to correct this condition going forward. Accurate establishment profile data in PHIS are critical to ensuring proper inspection tasks are generated and also critical to ensuring FSIS has a complete and accurate universe for its sampling programs. To ensure it has an accurate sampling universe, FSIS must have clear criteria showing the product groups that should be included in each sampling program. Inspection tasks and sampling programs are two of the most critical verification activities FSIS uses to ensure meat and poultry products that are produced are safe, wholesome, and properly labeled and packaged.

FSIS Could Better Manage Access Privileges for Separated Employees

As of May 21, 2012, 501 separated employees retained a user role in PHIS, even though the agency no longer employed them. This deficiency existed because FSIS management did not ensure an employee's user role for PHIS was deactivated after the employee separated from the agency. FSIS officials stated that they rely on the National Finance Center (NFC) to deactivate eAuthentication access[38] for the separated employees, preventing further access into PHIS. However, FSIS could not provide any documentation to show this actually occurred. FSIS also relies on Active Directory[39] account controls to grant access to the FSIS network. However, to deactivate an account after the last logon takes 90 days. As a result, FSIS runs the risk of unauthorized users altering data and jeopardizing the integrity of the data in PHIS.

National Institute of Standards and Technology (NIST) guidelines require organizations to manage information systems, including deactivating accounts of terminated or transferred users.[40] USDA Departmental Regulation 3505-003 states that when an employee or contractor is terminated, all of their identifications and passwords or other

[38] EAuthentication is required to log into PHIS.

[39] Active Directory serves as a single data store for quick data access to all users and controls access to users based on the directory's security policy.

[40] NIST Special Publication 800-53A, Management Control AC-2, dated August 2009.

means of accessing files must be disabled or removed within 48 hours of their departure. If the termination is not amicable, agencies should remove all access prior to the employee or contractor's departure.

FSIS Directive 1306.10, *Information System Access Control*, issued June 15, 2011, states FSIS is responsible for account management, which includes granting, revoking, and modifying user accounts. The directive also requires FSIS to review system accounts every 90 days; require accounts to automatically disable after 90 days of inactivity; notify account managers when users are terminated or separated from the agency in order to secure the accounts; authorize and monitor guest accounts; and remove, disable, or secure unnecessary accounts.

Of these 501 separated employees[41] with access to PHIS, 128 continued to have an account over 1 year after separating from FSIS. The remaining 373 employees had been separated from the agency less than a year. FSIS officials stated access was revoked automatically through NFC when the users' eAuthentication account was disabled. On three separate occasions, we requested a list showing the dates these eAuthentication accounts were disabled. On March 27, 2014, during fieldwork, FSIS officials stated they could not provide the status of these accounts because PHIS does not track the dates that users are deleted from the system. In follow-up communications with us in February 2015, FSIS continued to state that it could not provide historical data showing the exact date that a particular user account was deactivated in PHIS. As a result, there is a potential for a separated employee to access PHIS and change the system data.

FSIS also stated that, while it could not provide data showing the exact date the employees' accounts were deactivated from PHIS, it believes that PHIS is highly secure and there are adequate management controls in place. These controls include the employee's need for valid credentials (e.g., a level 2 eAuthentication account), an active account in Active Directory, and a FSIS issued Government owned computer to gain access to PHIS. In addition, FSIS stated that PHIS undergoes annual security assessments. While there may be existing management controls in place, to better improve PHIS system access security we maintain FSIS must develop and implement controls to ensure user accounts and system access are promptly deleted for separated employees in accordance with NIST, Departmental, and FSIS's guidance.

Nearly Half of the Tasks Generated by PHIS Were Not Performed

FSIS inspectors did not complete nearly half of the routine inspection tasks[42] that PHIS generated for their assigned establishments. In addition, they did not always provide a justification for not completing tasks. Inspectors did not complete routine tasks because FSIS Headquarters officials instructed them to deviate from established procedures and only schedule those tasks they believed they could complete. In addition, six FSIS inspectors we interviewed stated they did not have enough time to provide justifications

[41] As of May 21, 2012, these employees were no longer employed by FSIS.
[42] Routine inspection tasks are the daily monitoring procedures FSIS relies on to ensure establishments are adequately following sanitation, HACCP, humane handling, and labeling requirements.

for tasks they could not complete. As a result, there is reduced assurance the inspectors have identified all potential food safety risks and FSIS does not have all the information it needs to help identify potential food safety issues.

FSIS Directive 13,000.1 states that a task list is a specific list of tasks that FSIS *expects* IPP to schedule and perform at a particular establishment, based on the information in the establishment profile. It further states, at the end of each month, IPP will designate any scheduled tasks that they did not complete as "not performed" and provide a justification by selecting from the list of reason codes[43] provided in PHIS.

The following discusses OIG's analysis of two data sets derived from PHIS generated inspection tasks for the purposes of this report: analysis of scheduled tasks and analysis of assigned tasks.

Analysis of Scheduled Tasks

For three of the four districts we visited, FSIS provided a list of all scheduled tasks between April 2011 and October 2012 that were scheduled and either: (1) completed, (2) not completed with a justification, or (3) not completed with no justification.[44] Using this information, we determined why these tasks were not completed. FSIS' data supported that over 90 percent of the scheduled tasks were performed. Our analysis also showed that – though they were scheduled in the inspectors' task calendar[45] - 192,328 of approximately 2.3 million (approximately 8 percent) of these tasks were not performed, and 76,004 of 192,328 (approximately 40 percent) of the uncompleted scheduled tasks did not contain a justification.[46] For the 18 establishments we visited in these 3 districts, 3,764 out of 41,672 (approximately 9 percent) of the scheduled tasks were not performed, and 1,331 out of the 3,764 (approximately 35 percent) tasks not performed did not contain a justification. Thus, OIG found a number of tasks left undone, as well as a number of tasks for which FSIS inspectors did not use the justification tool in PHIS when they did not complete a task.

In response to these results, FSIS national office officials explained their expectation that inspectors will schedule higher priority tasks first and rely on the front line supervisors to monitor task completion and follow up with inspectors when tasks were not consistently completed.

Analysis of Assigned Tasks

FSIS provided a listing of all assigned tasks. This listing showed that approximately 13.3 million routine inspection tasks were assigned between April 1, 2011, and January 1,

[43] FSIS officials stated PHIS contains 23 different justifications that were agreed upon in the union contract.
[44] We did not collect this data for the Beltsville district office.
[45] Inspectors are required to use the task calendar to schedule the inspection tasks shown in the task list.
[46] This includes the following justifications: double covered assignments; not enough time to complete task; higher priority task took precedent; assigned additional assignments; working the slaughter line; assigned to slaughter duties; assigned other duties; too many plants to physically go to; triple covered assignments; and short staffing.

2013. This list also included over 2.2 million directed inspection tasks.[47] We used this revised data to compute the percentage of routine inspection tasks that went unperformed.

Using Audit Command Language (ACL) to perform our analysis, we determined that inspectors did not schedule and perform over 6.3 million of the approximately 13.3 million (47 percent) routine inspection tasks they were assigned between April 1, 2011, and January 1, 2013, including high priority tasks relating to verification of an establishment's sanitation procedures. These sanitation procedures went unscheduled and unperformed approximately 33 percent of the time. In addition, the inspectors did not have to provide justification in PHIS to explain why they did not schedule all the tasks assigned in the task calendar.

In January 2015, FSIS stated that there are circumstances[48]where routine tasks cannot all be performed or situations in which directed tasks should be substituted for routine tasks. They also explained that, while all routine tasks are not always complete, inspectors do regularly schedule and complete directed tasks, such as those related to microbiological sampling. However, based on the data, we could not verify that directed tasks adequately replaced the functions of the routine tasks that inspectors did not perform.

FSIS intended PHIS to capture information about the routine tasks in order to obtain real-time data at meat and poultry establishments to assist in identifying potential food safety issues. However, six inspectors we interviewed believed it was too time-consuming to complete all the scheduled tasks. In addition, FSIS headquarters officials allowed the inspectors only to schedule the tasks they could complete and did not require them to provide justifications for not completing the tasks.

FSIS officials stated that the agency has made improvements in its processes for ensuring inspection tasks performance since 2012. According to FSIS, its data supports that 83 percent of the inspection tasks were performed in 2014. However, in February 2015, an FSIS official stated that they may need to revisit how tasks are assigned and ensure they are better aligned with the workday. He further stated that the agency does not want an inspector to spend the entire workday documenting the reason that tasks were not completed, but rather they want the inspector completing inspection tasks. We agree that FSIS needs to evaluate the tasks PHIS is currently generating for the inspectors and develop a plan to ensure that the inspectors are assigned a manageable number of tasks, the most important tasks are routinely performed, and the front line supervisor is monitoring the inspector's activities and ensuring tasks are completed. Regardless of the reasons why tasks are not performed or the application of directed versus scheduled task, PHIS was conceived as a comprehensive and fully automated data-driven inspection system. Since recording inspection results is essential to PHIS, OIG maintains that FSIS needs to address these factors which inhibit PHIS' design and limits its success.

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[47] Directed inspection tasks are tasks that do not occur on a routine basis in establishments operating under normal circumstances. FSIS may initiate these tasks in response to inspection findings, laboratory results, or other information that requires follow-up verification activity.

[48] These circumstances include: (1) the inspectors' unplanned need to document non-compliances, (2) randomly assigned sampling tasks, or (3) adjustments to establishments' changing of production practices.

Audit Recommendations Contingent upon PHIS Implementation Went Unaddressed or Were Ineffective

We reviewed 16 recommendations from two prior OIG audits[49] where corrective actions were contingent on the development and implementation of PHIS (see Exhibit D). We found that FSIS adequately implemented 11 of these 16. However, we found that 3 of the 16 agreed-upon corrective actions were not implemented and the corrective actions implemented for the remaining 2 recommendations were not effective.

Corrective Actions Not Implemented—Three Recommendations

Recommendation 1 (Audit Report 24601-0007-Hy)—Implement an action plan with specific milestone dates for capturing results of food safety assessments in an appropriate configuration that allows for effective analysis.

FSIS' Enforcement, Investigations and Analysis Officers (EIAO) conduct food safety assessments at meat and poultry establishments at least once every four years. A food safety assessment is a comprehensive assessment of the execution and design of an establishment's food safety system. The food safety assessment component in PHIS will capture the results of these assessments in a format that allows for review and analysis. In response to this recommendation, FSIS agreed to have a functioning domestic inspection module, which included a food safety assessment component, for limited deployment in April 2008, with full implementation by August 2008. On December 20, 2007, OIG informed FSIS that, in order to reach final action on this recommendation, it had to provide the Office of the Chief Financial Officer (OCFO) with a plan for completing PHIS and documentation showing that tracking numbers for each food safety assessment would be recorded in PHIS. On June 3, 2011, FSIS submitted a request for closure to OCFO, stating that it began implementing PHIS in April 2011 and it contained the new food safety assessment reporting system. Based on this request, OCFO agreed the recommendation was addressed and final action achieved.[50] However, at that time, the food safety assessment component in PHIS was not active or complete. An FSIS official stated that the food safety assessment component became operational during fiscal year 2014.

Recommendation 3 (Audit Report 24601-0007-Hy)—Determine how the results of food safety assessments will be used by FSIS in estimating establishment risk.

In response to this recommendation, FSIS agreed to implement a more comprehensive food safety assessment configuration into the domestic inspection

[49] Thirteen of these 16 recommendations were included in Audit Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, dated December 2007, and 3 of these 16 recommendations were included in Audit Report 24601-07-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities*, dated November 2008.

[50] The completion of all actions that management has concluded, in its management decision, are necessary with respect to the findings and recommendations in an audit report.

module in PHIS. In addition, FSIS stated that it established a timeline for initiating the domestic inspection module, and that many of these milestones were expected to be completed during the second quarter of calendar year 2009. On December 20, 2007, OIG informed FSIS that, in order to reach final action on this recommendation, it had to provide OCFO with documentation showing how FSIS incorporated food safety assessment results into estimating establishment risk. On March 19, 2009, FSIS submitted a request for closure to OCFO, stating the new configuration would be incorporated into PHIS, and PHIS would use "flags" to show public health risks and the possible need for a food safety assessment. Based on this request, OCFO agreed the recommendation was addressed and final action was reached on April 2, 2009. As stated above, FSIS officials informed us that the food safety assessment component became operational in fiscal year 2014 and OCFO was not notified of the delay.

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

In response to this recommendation, FSIS stated that the plans for the domestic inspection module addressed this recommendation with an annual review of the latest food safety assessment at each establishment by the inspector-in-charge. On December 20, 2007, OIG informed FSIS that, in order to reach final action on this recommendation, it had to provide OCFO with documentation of the guidance issued for conducting periodic reevaluations of an establishment's food safety system to assess its progress after an initial food safety assessment. On June 3, 2011, FSIS submitted a request for closure to OCFO, stating that through PHIS there would be an inspection task generated for the inspector-in-charge to annually review an establishment's latest food safety assessment as part of the annual reassessment verification procedure. OCFO agreed that FSIS addressed the recommendation and final action was reached. We found the inspection task was generated in PHIS; however, there are no alerts in the system to trigger inspection program personnel to conduct a food safety assessment based on the results of such inspection tasks. As mentioned earlier, the food safety assessment component of PHIS was not operational until fiscal year 2014.

FSIS national office officials stated the food safety assessment component in the domestic module was not included in the version of PHIS that went live in April 2011. FSIS officials stated that they decided the food safety assessment component did not need to be immediately implemented in PHIS because food safety assessment information was already being collected and stored in AssuranceNet[51] and it was more important for them to focus on implementing the import module and implementing PHIS at the establishments. The officials also stated they conducted field testing of the food safety assessment component in August 2013, but it was not ready for nationwide deployment. FSIS could not explain why it requested final

[51] This system provides FSIS with critical data management, reporting, and management control functions to assist FSIS in monitoring operations and achieving performance measures.

action for these recommendations, since the food safety assessment reporting system was not operational.

Food safety assessments provide FSIS officials with a detailed analysis of how an establishment's food safety system is functioning. PHIS was intended to enhance FSIS' ability to capture the results of food safety assessments in a format that allowed for effective analysis. However, without the completion of the food safety assessment component in PHIS, the weaknesses identified in our prior audit report continue to exist. As mentioned earlier, an FSIS official stated that the food safety assessment component became operational in FY 2014; however, this was after we concluded fieldwork, and we did not conduct additional fieldwork to verify this statement.

Corrective Actions Not Effective—Two Recommendations

Recommendation 6 (Audit Report 24601-0007-Hy)—Develop a process to obtain more accurate, verifiable production data (e.g., pounds produced by product type) and regularly update the data from FSIS-regulated establishments.

In response to this recommendation, FSIS officials agreed that production data, such as volume produced per product type, are critical. They stated that FSIS expected to implement a mechanism in PHIS for in-plant personnel to collect data from production records and provide establishment management an opportunity to review this data for accuracy. FSIS stated that nationwide readiness for the domestic module in PHIS would be ready in the second quarter of calendar year 2009. On December 20, 2007, OIG informed FSIS that, in order to reach final action on this recommendation, it had to provide OCFO with documentation of the mechanism for inspection program personnel to obtain more accurate, verifiable production data. On August 2, 2011, FSIS submitted a request for closure to OCFO, stating that through PHIS implementation there would be a mechanism for inspection program personnel to record production data (e.g., pounds of product produced, by product type). Based on this request, OCFO agreed the recommendation was addressed and final action was reached.

While we found the inspectors are required to verify the accuracy of the product and volume data and make the necessary corrections in the establishment profile in PHIS, this did not always occur. We found that at 6 of the 22 establishments we visited, the establishment profile contained either inaccurate product or inaccurate volume information. In addition, for 5 of the 22 establishments we visited, inspection program personnel did not conduct a review of the establishments' shipping and production records. As stated earlier, accurate establishment profile data are critical to ensuring proper inspection tasks are generated and also critical to ensuring FSIS has a complete and accurate universe for its sampling programs.

Recommendation 16 (Audit Report 24601-0007-Hy)—Closely monitor the administration of the PHIS contract and the development, testing, and

implementation of the new system to ensure it is progressing as intended to attain satisfactory assurance that it can support the operations necessary to carry out a complex, scientifically-based risk-based inspection program.

In response to this recommendation, FSIS officials agreed to appoint a Contracting Officer's Technical Representative (COTR) to play a critical role during all phases of the acquisition process. They also stated that they would develop a project management plan and that the first version of this plan would be deployed by December 31, 2007. On December 20, 2007, OIG informed FSIS that, in order to reach final action on this recommendation, it had to provide OCFO with the Project Management Plan showing appropriate control of PHIS to support risk-based inspection. We determined FSIS accomplished this task; however, we determined final action was not effective to ensure that PHIS progressed as intended. For example, as stated earlier, the initial contract required a fully implemented system by October 2010 at a cost of $15.6 million, but currently the system is not fully operational and FSIS expects costs to increase to over $79.3 million by FY 2018. In addition, the export module of PHIS is not expected to be operational until the spring of 2015.

We believe FSIS needs to review and evaluate PHIS' domestic inspection module to make sure the system is designed so it can be effectively used by inspectors in the field and provides accurate and useful tasks that inspectors then act upon. At this point in PHIS' implementation, FSIS needs to assess where the system stands, and take meaningful and appropriate action to mitigate the problems we have found.

We provided the draft of this report to FSIS in December 2014. In response to concerns raised by FSIS officials in January 2015, we reviewed and considered additional information and documentation provided by the agency from February through April 2015. And accordingly, we made revisions to the draft report. The agency's July 27, 2015, response is included in its entirety at the end of this report. The agency's response continued to express concerns with our findings. For example, FSIS stated that OIG reported on the number of routine tasks not performed by inspectors but is silent on the number of directed tasks, which are tasks not generated by PHIS systemically and routinely, that were also performed by inspectors. Since the routine inspection tasks represent the systemic daily monitoring procedures that FSIS relies on to ensure the establishments are adequately following sanitation, HAACP, humane handling, and labeling requirements, OIG contends that it is important to ensure these tasks are routinely performed and recorded in PHIS. OIG agrees that directed tasks are a vital aspect of food safety and we acknowledge that they are initiated by the inspectors on an as needed basis, not systemically by PHIS; however, the audit fieldwork and related report adequately discusses the audit results and finding as they relate to the audit objectives and subject matter of PHIS. In a second example, FSIS stated that from 2013 to 2015 it has attempted to clarify OIG's misapplication of FSIS' sampling eligibility criteria. FSIS also stated that OIG did not carefully review the sampling algorithms nor did it request a meeting to discuss the algorithms as FSIS offered. During the course of our audit and after issuance of the draft report, OIG discussed with and provided to FSIS documentation showing our methodology and conclusions. Additionally, it should be noted that the audit results and related findings are based on the eligibility criteria and

sampling algorithm documentation the agency provided. Lastly, FSIS stated that the report contains numerous errors and improper assumptions and the agency questions the fairness and objectivity of the audit team. During this audit, we conducted interviews, observed the operation of PHIS at the establishments, reviewed and evaluated records, and repeatedly discussed our findings and concerns with officials charged with governance. In addition, our audit documentation and the resulting report was subject to our system of quality control to ensure that sufficient documentation was obtained to support the findings presented, that these findings were discussed with officials charged with governance, and that the audit was conducted in accordance with Generally Accepted Government Auditing Standards. We believe this report fairly presents the issues found during the audit.

FSIS' response also represented improvements the agency has made to PHIS during the conduct of our fieldwork and in subsequent periods. After consideration of the represented improvements, we modified the language of the report where appropriate, based on our audit documentation and in accordance with Generally Accepted Government Auditing Standards.

Recommendation 1

Complete a written assessment of the current status of PHIS implementation that includes prioritized corrective actions with specific timeframes for completion. Also, implement a process to verify that the corrective actions are completed within the established timeframes.

Agency Response

In its July 27, 2015 response, FSIS stated that it has taken steps to improve PHIS since its implementation and on its own initiative it brought in a third-party to conduct a top to bottom assessment of PHIS. In June 2014, this third party completed an assessment of the current status of PHIS and made several recommendations of areas where FSIS can improve the system and its related infrastructure and processes. The written assessment also included an action plan for the Agency to consider in moving forward with recommendations. In its response, FSIS provided details on the areas reviewed by the third-party and the actions FSIS has taken since the completion of this assessment. FSIS also stated that it has identified short-term and long-term actions for each area of emphasis and incorporated these actions into ongoing PHIS application development and infrastructure development and maintenance.

OIG Position

While we agree with FSIS' corrective actions, we are unable to reach management decision for this recommendation. To reach management decision, FSIS needs to provide the specific timeframes for completing the short and long term corrective actions it identified based on the assessment performed. In addition, FSIS needs to describe the process it has implemented to ensure that these corrective actions are completed within the established timeframes.

Recommendation 2

Enhance internal controls by ensuring management oversight of PHIS encompasses ongoing monitoring and periodic evaluation of PHIS to ensure the system is accessible, operating as designed, and includes both complete and accurate information.

Agency Response

In its response dated July 27, 2015, FSIS outlined the internal controls it has implemented over the last couple years to monitor and evaluate PHIS. These controls include topics such as a quarterly investment review that is conducted in collaboration with FSIS' Office of the Chief Information Officer (OCIO), FSIS' Office of the Chief Financial Officer, FSIS stakeholders, and USDA's OCIO to review the PHIS investment including project activities, earned value management, issues and risks.

OIG Position

We accept FSIS' management decision for this recommendation.

Recommendation 3

Develop and implement a plan to review and correct the data in PHIS' establishment profiles. This should include procedures for FSIS supervisors to conduct ongoing reviews of data in establishment profiles.

Agency Response

In its July 27, 2015 response, FSIS stated that it has implemented a process through targeted FSIS policy issuances to utilize directed PHIS task functionality to target updates of specific profile elements, such as a task to update pork products. FSIS also stated that it intends to continue using this approach to update specific data elements under a systematic scheduled timeline ending in July 2016. It also stated that by July 31, 2016, it will develop and begin the implementation of a plan that will continually maintain updated establishment profiles and it will develop a process for periodic supervisory reviews of the establishment profile data for completeness and accuracy.

OIG Position

We accept FSIS' management decision for this recommendation.

Recommendation 4

Develop instructions that define the specific data fields, such as product produced, that are required for an establishment to be included in a sampling project.

Agency Response

In its July 27, 2015 response FSIS stated (in part) that by July 31, 2016, it will develop a reference document that defines the PHIS data elements used in sampling algorithms. This reference guide will describe how sampling algorithms are implemented in terms of PHIS data elements on products produced, volumes, intended uses, exclusion criteria, and other relevant parameters.

OIG Position

We accept FSIS' management decision for this recommendation.

Recommendation 5

FSIS needs to strengthen its procedures to ensure that a separated employee's user role, user account, and system access is promptly disabled and/or removed, in accordance with Federal guidance.

Agency Response

In its July 27, 2015 response, FSIS stated that OIG has not demonstrated that the cited list of PHIS employees actually had PHIS access, just that at some time there was an employee account (enrolled or unenrolled). FSIS also stated that it has leveraged compensating controls that are entirely appropriate, and its approach to PHIS' security provides a very low risk of unauthorized users gaining access to the system. FSIS further stated that it is working to strengthen its off-boarding notification procedures and to ensure that there is timely notification to the accounts operation team of user departures for account disabling. FSIS stated that by June 2016, it will issue a policy on on-boarding and off-boarding procedures.

OIG Position

We are unable to reach management decision on this recommendation. In order to reach management decision, FSIS needs to specifically indicate how it will strengthen its procedures to ensure that a separated employee's user role, user account, and system access are promptly disabled and/or removed and how it will ensure that these procedures are in accordance with Federal IT standards.

Recommendation 6

Review and evaluate the tasks PHIS currently generates for inspectors, as well as the inspectors' workload. Develop and begin implementing a plan that ensures the inspectors are assigned a manageable number of tasks and that the most important tasks are routinely performed at each establishment. The plan should require the front line supervisors to: monitor the inspectors' completion of the tasks and to document the results of this review, take corrective actions needed to ensure compliance, and monitor the status of those corrective actions.

Agency Response

In its July 27, 2015, response, FSIS stated that by July 31, 2016, it will develop and begin implementing a plan to address inspection task assignment. This plan will include an assessment of the current task scheduling and task completion data to identify specific areas for improvement and focus on developing new methodologies for assigning tasks. FSIS also stated that it will also review its instructions to supervisors for conducting reviews of inspection task performance and make updates as appropriate.

OIG Position

We cannot accept FSIS' management decision on this recommendation. In order to reach management decision on this recommendation, FSIS needs to explain the steps it plans to take to ensure that the most important tasks are routinely completed at each establishment. In addition, FSIS needs to not only review its instructions to supervisors on conducting reviews of inspection task performance, but require the front line supervisors to monitor the completion of the tasks, document the results of the review, take appropriate corrective actions to ensure compliance, and monitor the status of the corrective actions as stated in this recommendation.

Recommendation 7

Develop an action plan with specific timeframes for implementing the actions agreed to in Recommendations 1, 3, and 13 of Audit Report 24601-0007-Hy.

Agency Response

In its July 27, 2015 response, FSIS stated that as of February 2014, the FSAs are now in a configuration in PHIS that allows for effective analysis (prior Recommendation 1).

FSIS also stated that it revised how it uses inspection history criteria for prioritized scheduling of FSAs to take advantage of new data collected through PHIS by identifying public health regulations (PHR) and included instructions on prioritizing FSAs in response to whether establishments had received PHR noncompliance record. This prioritized scheduling is included in Directive 5100.4, Prioritized Scheduling and FSIS started using this PHR criteria in scheduling FSAs in May 2013 (prior Recommendation 3). Finally, FSIS stated that it is currently using the PHR decision criteria for scheduling FSAs. It also stated that this new methodology uses a risk-based decision making process to determine whether to conduct an FSA or take enforcement action (prior Recommendation 13).

OIG Position

We accept FSIS' management decision for this recommendation.

Recommendation 8

Develop an action plan with specific timeframes to ensure the effective implementation of the corrective actions put in place to address Recommendations 6 and 16 of Audit Report 24601-0007-Hy.

Agency Response

In its July 27, 2015, response, FSIS acknowledged the importance of accurate product type and volume information for the successful implementation of FSIS' sampling programs and identified actions taken and in process to accurately maintain this data (prior Recommendation 6). Also, as noted in response to Recommendation 1 of this report, FSIS noted that it is working to formalize a structure and operation for how the agency manages and prioritizes changes for PHIS (prior Recommendation 16).

OIG Position

We accept FSIS' management decision for this recommendation.

Scope and Methodology

To accomplish our objectives, we reviewed FSIS documentation related to implementation of the PHIS domestic module. This documentation included a review of contracts and other information related to the planned system costs and the timeframe for completion. The audit was performed at FSIS Headquarters in Washington, D.C., and at four non-statistically selected FSIS district offices in Alameda, California; Beltsville, Maryland; Denver, Colorado; and Philadelphia, Pennsylvania.

In these districts, we visited 22 non-statistically selected meat and poultry slaughter or processing establishments located in California, Colorado, Maryland, New York, Pennsylvania, and Virginia (see Exhibit A). During these visits, we reviewed plant documentation to verify the accuracy of establishment profile data, reviewed the accuracy of sampling project and inspection task data, and analyzed the adequacy of inspector access to PHIS, including the type of internet connection used. In total, we interviewed 67 FSIS personnel to identify the policies and procedures for using PHIS during our visits.

We performed site visits to the 22 establishments in 2012 and 2013. At the time of our review in these establishments, FSIS was using PHIS version 2.1. According to FSIS' July 27, 2015, response, the current version in production is 4.1, which we did not audit.

We performed fieldwork from April 2012 through August 2014. We judgmentally selected 4 of 15 district offices, based on the number and types of establishments (i.e., slaughter, processing, and processing/slaughter) within the districts. In October 2012, FSIS consolidated districts, which dropped the total from 15 to 10,[52] but did not affect OIG's selection of district offices to visit. Eighteen of the 22 establishment visits were under the purview of the Alameda, Denver, and Philadelphia District Offices. As of January 2013, these 3 district offices were responsible for overseeing 2,385 out of 6,187 establishments nationwide. We selected the establishments to visit based on PHIS implementation dates,[53] types of establishments, establishment size, and inspection task information entered into PHIS. This information included the percentage of tasks completed and establishments with a high number of tasks that were not completed due to computer issues. We interviewed 25 FSIS inspectors assigned to the 22 establishments we visited. We also interviewed 11 front line supervisors, 11 supervisory and non-supervisory public health veterinarian personnel, 1 State inspector, and 1 State supervisor.

Subsequent to the completion of our fieldwork, and while in discussion with FSIS regarding our draft report, FSIS raised concerns and rebutted some of the report statements while providing a presentation showing its concerns and indicating that FSIS had taken major steps to improve PHIS since the completion of our audit coverage. Based on this, we requested additional

[52] FSIS closed the district offices in Lawrence, Kansas; Beltsville, Maryland; Minneapolis, Minnesota; Albany, New York; and Madison, Wisconsin. The establishments in these districts were reassigned to other district offices.
[53] Beginning in April 2011, FSIS implemented PHIS, by circuit, in three phases. After FSIS implemented PHIS in each establishment in the first phase, it began implementing PHIS in the next phase. Following the third phase, all FSIS inspection personnel had access to PHIS. Each phase included circuits from each district office.

information to substantiate the claims by FSIS, such as processes in place to effectively manage the cost, design, and implementation of PHIS; revised guidance provided to the employees related to the DCU; recommendations from the task force addressing connectivity issues; and documentation supporting that establishments were included in the correct pathogen sampling projects.

On February 6, 2015, FSIS began providing us with the requested documents relating to five of the six issues, and on February 18, 2015, we also had a subsequent meeting to discuss its criteria for including establishments in certain MT43 sampling projects and to discuss FSIS' calculation of incomplete inspection tasks. FSIS provided documents to show its processes to manage the cost, design, and implementation of PHIS. This included FY 2013 and 2014 documents showing the results of the USDA OCIO's annual review of PHIS (major IT systems), and its submission (to USDA) and the subsequent approvals of additional PHIS development services. FSIS also indicated that it established a Capital Planning and Cost Analysis Branch that will assist agency managers in cost estimation. We reviewed these documents and it appears that FSIS is taking steps to prevent the types of cost, design and implementation problems we noted during this audit; however, we did not assess the impact of these documents or the new Capital Planning and Cost Analysis Branch as it relates to the objective of this audit.

FSIS provided us with the revised DCU directive, communications with the staff (since our initial fieldwork) addressing connectivity, and narratives showing that they upgraded connectivity in some establishments in 2013 and 2014 and planned additional upgrades in 2015. We reviewed the documentation, but we did not conduct any additional site visits to verify that connectivity issues had improved, since it was provided after completion of fieldwork testing.

During our January meeting with FSIS, officials indicated concerns with our conclusions related to sampling projects. FSIS indicated that 1247, not 1502 establishments (as stated by OIG) should have been included in the sampling universe for MT43 sampling. FSIS also indicated that we included 11 ineligible product groups when determining whether all required establishments were in the sampling universe for MT43 and they provided a list of eligible and ineligible product groups. We reviewed the documentation provided and conducted a subsequent meeting with FSIS on February 18, 2015, to further discuss MT43 sampling projects and criteria available to support exclusions from the sampling universe. Based on these discussions, FSIS provided additional documentation on March 9, 2015. We reviewed the documentation and used it to re-compute the number of FSIS establishments that were not eligible for the MT43 sampling projects. On March 16, 2015, we also requested that FSIS provide the names and establishment numbers of the 1247 establishments it determined should be in the sampling universe. FSIS provided this documentation on March 25, 2015. The effect of this subsequent documentation is reported in the findings of this report.

FSIS also provided a listing of all assigned inspection tasks from April 2011 to January 1, 2013. This list included both performed and unperformed routine and directed tasks. We used this information to calculate the percentage of tasks completed during the time period mentioned above. The effect of this subsequent documentation is also reported in the findings of this report.

These additional interviews and documentation reviews were completed between January and March 2015.

In April 2015, FSIS provided additional documentation for our review and consideration. FSIS officials requested that this material be considered to present what the agency has done to improve PHIS implementation and operations since our field testing in establishments in 2012. Where appropriate, we included this information in the report for context. We did not perform tests to verify the information provided.

To accomplish our objectives, we:

- Interviewed FSIS headquarters, district office, and establishment personnel who were involved in the development, contracting, implementation, oversight, and management of PHIS.
- Interviewed FSIS establishment inspectors and front line supervisors responsible for the input and oversight of PHIS data, respectively.
- Interviewed FSIS personnel and Internal Revenue Service (IRS) officials[54] responsible for the award and oversight of contracts involving the development and implementation of PHIS.
- Reviewed agency policies and procedures relating to system security requirements and for using the system.
- Evaluated whether PHIS incorporated functions of systems it replaced, including: PBIS; Resource Information System; eADRS; Automated Import Information System; System Tracking *E. coli* O157:H7 Positive Suppliers; Pathogen Reduction and Enforcement Program; and eSample.
- Reviewed training material provided to in-plant personnel and determined the areas covered and whether inspectors attended PHIS training.
- Reviewed contract documentation to determine the overall cost of PHIS.
- Analyzed data relating to the completion of inspection tasks by in-plant personnel to determine whether adequate and accurate data are recorded within PHIS.
- Reviewed noncompliance records and PHIS establishment profile information to determine if serious food safety problems existed and whether they were recorded and addressed at the establishments we visited.
- Used ACL to analyze inspection task results by summarizing justifications for why tasks were not completed, summarizing completion rates for each specific task, and determining the number of inspection tasks assigned but not completed.

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

[54] FSIS contracted with the IRS Total Information Processing Support Services (TIPSS) program to obtain contracting services for the initial PHIS project. TIPSS is used by Federal agencies that lack resources (such as expertise) for large IT contracts.

Abbreviations

ACL.....Audit Control Language
AIIS.....Automated Import Information System
COTR.....Contracting Officer's Technical Representative
DCU.....Disconnected User Application
eADRS.....electronic Animal Disposition Reporting System
EIAO.....Enforcement, Investigations and Analysis Officer
EV-DO.....Enhanced Voice – Data Optimized
EVM.....Earned Value Management
FSIS.....Food Safety and Inspection Service
FY.....Fiscal Year
HACCP.....Hazard Analysis and Critical Control Points
HIMP.....HAACP Inspection Model Project
IPP.....In-Plant Personnel
IPPS.....In-Plant Performance System
IRS.....Internal Revenue Service
NFC.....National Finance Center
NIST.....National Institute of Standards and Technology
OCFO.....Office of the Chief Financial Officer
OIG.....Office of Inspector General
OMB.....Office of Management and Budget
PBIS.....Performance-Based Inspection System
PMB.....Performance Measurement Baseline
PHIS.....Public Health Information System
RIS.....Resource Information System
TIPSS.....Total Information Processing Support Services
USDA.....Department of Agriculture

Exhibit A: List of Establishments Visited

This table lists the establishments we visited, type of establishment and the type of products they produce.

District Office	Establishment Number	Type of Establishment	Product
Philadelphia District Office	1	Slaughter and Processing	Meat & Poultry
Philadelphia District Office	2	Slaughter and Processing	Meat & Poultry
Philadelphia District Office	3	Processing	Meat & Poultry
Philadelphia District Office	4	Slaughter and Processing	Meat & Poultry
Philadelphia District Office	5	Slaughter and Processing	Meat
Philadelphia District Office	6	Processing	Meat
Philadelphia District Office	7	Slaughter and Processing	Meat & Poultry
Philadelphia District Office	8	Slaughter and Processing	Poultry
Philadelphia District Office	9	Processing	Meat & Poultry
Philadelphia District Office	10	Slaughter and Processing	Poultry
Alameda District Office	11	Processing – HIMP[55]	Meat & Poultry
Alameda District Office	12	Processing	Meat & Poultry
Alameda District Office	13	Processing	Poultry
Alameda District Office	14	Processing	Meat & Poultry
Denver District Office	15	Slaughter and Processing	Meat
Denver District Office	16	Processing	Meat & Poultry
Denver District Office	17	Processing	Meat
Denver District Office	18	Processing	Meat & Poultry
Raleigh District Office	19	Slaughter and Processing	Meat
Raleigh District Office	20	Slaughter and Processing	Meat & Poultry
Raleigh District Office	21	Slaughter and Processing – HIMP	Poultry
Raleigh District Office	22[56]	Slaughter and Processing – HIMP	Poultry

[55] HIMP—HAACP Inspection Model Project.

[56] As part of FSIS' reorganization, FSIS consolidated establishments in the Beltsville District Office into the Raleigh, North Carolina District Office on October 1, 2012. This establishment was formerly under the Beltsville District Office.

Exhibit B: Connectivity and DCU Issues

This table describes the connectivity and DCU issues we identified during our establishment visits.

Establishment Number	Comments
Six Establishments Had Both DCU and Connectivity Issues	
1	• During our visit, we observed that PHIS operated very slowly on the inspector's computer. He stated that he does not get good reception for his EV-DO card inside the building. • The inspector also stated it takes a long time to upload the DCU back to PHIS because of the slow connection speed.
4	• During our visit, the inspector's EV-DO card was hanging out of the window to obtain better reception. However, we still observed PHIS operating very slowly at this establishment. For example, we witnessed PHIS close four times while the inspector attempted to open the task calendar. • The inspector stated that he attempted to install the DCU on his computer, however the installation failed and he was attempting to resolve this issue at the time of our visit, but to no avail. As a result of these issues, the inspector had difficulties accessing PHIS at this establishment, and he stated the nearest establishment with internet connection was 25 miles away.
6	• We observed the inspector hanging his EV-DO card outside of a window just to obtain minimal internet connection. The inspector stated if he attempted to record his tasks in PHIS at this establishment it takes approximately one hour. If he goes to another establishment in his assignment with better connection it takes him 10-20 minutes. • The inspector stated he does not use the DCU because it did not install properly on his computer.
13	• The inspector uses an EV-DO card to access the internet. He stated PHIS will stop working and he has to disconnect from the internet then restart PHIS. During our visit, it took him approximately eight minutes to access PHIS. • The inspector stated that the DCU does not work on his laptop.
16	• We observed the inspector trying to access PHIS at approximately 2 P.M. It took the inspector 15 minutes to gain access to PHIS. The system was extremely slow after connection. • The inspector stated he does not use the DCU because it is unreliable.
18	• During our visit, the inspector had difficulty maintaining internet connection while using his EV-DO card. This made it difficult to enter inspection results into PHIS. • The inspector stated he does not use the DCU because it is unreliable and does not allow him to complete his work.
Four Establishments Had DCU Issues Only	
7	• The inspector has to reset his database when he attempts to upload the DCU into the live version of PHIS.
12	• The inspector stated that the data he enters into the DCU disappears. He further stated that he had his laptop replaced five times but the DCU never worked properly on any of them so he no longer uses the DCU.
14	• During our visit an error message popped up on the inspector's screen when he was trying to access the DCU. The inspector confirmed that he cannot access the DCU on his laptop.
17	• The inspector stated he does not use the DCU because it is unreliable.
One Establishment Had Only Connectivity Issues	
22	• The inspector did not use the DCU, but stated that he occasionally loses connection to PHIS.

Exhibit C: Issues at Establishments Visited

This table shows the establishments we identified with product and volume discrepancies in the establishment profile.

Establishment Number	Slaughter (S); Processing (P); or Slaughter and Processing (SP)	Incorrect Products (Results in sampling project errors)	Incorrect Volume	Details
2	SP	X	X	This establishment was included in the wrong sampling project.
4	SP	X		The establishment was included in the wrong sampling project.
5	SP	X		The establishment was included in the wrong sampling project.
10	SP		X	
11	SP – HIMP		X	
12	P	X		The establishment was included in the wrong sampling project.
15	SP	X	X	The establishment was included in the wrong sampling project.
16	P	X		The establishment was included in the wrong sampling project.
19	SP		X	
20	SP – Tallmadge Aiken[57]	X	X	The establishment was included in the wrong sampling project. Also – only 1 out of 23 products had a volume listed. The inspector stated PHIS would not allow him to make the change in the system.

[57] The Federal-State Cooperative Act (Talmadge Aiken) (7 U.S.C. 450) authorizes the Secretary of Agriculture to enter into cooperative arrangements with State departments of agriculture and other State agencies to assist the Secretary in the administration and enforcement of relevant Federal laws and regulations. At the Talmadge Aiken establishments, State employees conduct the Federal inspection activities.

Exhibit D: Results of Prior Audit Recommendations

This exhibit lists the recommendations from audit reports 24601-07-Hy and 24601-07-KC[58] that we reviewed as part of the follow up work relating to PHIS.

Audit Number	Rec. No.	Prior Recommendation	Final Action Date[59]	Corrective Action Implemented?	Corrective Action Effective?
24601-7-Hy	1	Implement an action plan with specific milestone dates capturing results of food safety assessments in an appropriate configuration that allows for effective analysis	June 8, 2011	NO	N/A
24601-7-Hy	2	Perform FSA's using the new configuration, in all establishments that will be in the universe of establishments where risk-based inspection may be used. The FSA's should be comprehensive assessments of the establishments current operations	February 4, 2010	YES	YES
24601-7-Hy	3	Determine how the results of FSA's will be used by FSIS in estimating establishment risk.	April 2, 2009	NO	N/A
24601-7-Hy	6	Develop a process to obtain more accurate, verifiable production data (e.g. pounds produced by product type) and regularly update the data from FSIS-regulated establishments.	August 8, 2011	YES	NO
24601-7-Hy	7	Determine why Non Compliances (NR's) were not correctly accounted for (i.e. one counted twice and one omitted) when calculating an establishments level of inspection. Implement the necessary controls to ensure these types of errors do not occur and data are completed and accurately processed.	June 12, 2012	YES	YES
24601-7-Hy	8	Develop and implement at least an annual process to verify establishment control *Listeria Monocytogenes* in Ready-to-Eat product and establishments report when there is a significant change in the method they use to control Lm or	August 23, 2010	YES	YES

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

[59] The Office of Chief Financial Officer (OCFO) provides a final action date when agencies provide closing documents (i.e. corrective actions) to address recommendations.

Audit Number	Rec. No.	Prior Recommendation	Final Action Date[59]	Corrective Action Implemented?	Corrective Action Effective?
		volume of product they produced.			
24601-7-Hy	10	Prior to implementation, validate the accuracy of the risk-based inspection date (e.g. species, product type, public health NRs, and control of Lm in RTE product) used for calculating an establishments level of inspection.	June 26, 2012	YES	YES
24601-7-Hy	11	Institute the appropriate oversight and control during the development of critical IT systems needed to support risk-based inspection.	March 16, 2009	YES	[60]
24601-7-Hy	13	Develop and implement criteria for conducting periodic reevaluations of an establishment's food safety system to assess its progress after initial food safety assessment.	June 8, 2011	NO	N/A
24601-7-Hy	14	Develop and implement a system to track changes at an establishment over time and determine which changes would trigger FSIS to conduct food safety assessment at an establishment prior to its periodic reevaluation.	September 27, 2012	YES	YES
24601-7-Hy	16	Closely monitor the administration of the PHIS contract and the development, testing, and implementation of the new system to ensure it is progressing as intended to attain satisfactory assurance that it can support the operations necessary to carry out a complex, scientifically-based risk-based inspection program.	March 16, 2009	YES	NO
24601-7-Hy	17	Complete a comprehensive, agency-wide examination of national, divisional, and district level analytical and informational needs, and establish a process to periodically reassess needs. This should include implementing management controls to specifically define what analysis and information is needed, who should perform the analysis and collect the information, who needs to be provided the analysis or information (customers), how often the information needs to be collected and analyzed, what is	June 4, 2008	YES	YES

[60] We did not test corrective actions for recommendation 11 during this audit. We will conduct audit tests to determine if this corrective action was effective in another OIG audit that focuses on prior FSIS audit recommendations—Audit 24016-0001-23.

Audit Number	Rec. No.	Prior Recommendation	Final Action Date[59]	Corrective Action Implemented?	Corrective Action Effective?
		the most useful format to present the information or analysis to the final users, and, finally, who is responsible to ensure follow-up actions are taken to correct problems identified. The study should also include an action plan for making the necessary changes to the agency's operating procedures and the estimated timeframes for implementing these changes.			
24601-7-Hy	23	Provide pathogen test results data in a searchable format to the appropriate district office personnel	May 30, 2012	YES	YES
24601-7-KC	5	Develop a documented, supportable methodology for assigning in-plant inspection staff for offline inspection activities, including a basis for assignment at different types of plants.	August 8, 2011	YES	YES
24601-7-KC	18	Develop processes, as part of the new PHIS system, to verify inspectors are regularly performing SRM-related tasks as part of their inspection duties. Incorporate features in PHIS that will allow managers to track and evaluate the extent to which such tasks are being performed at the establishment, circuit, and district levels.	May 9, 2011	YES	YES
24601-7-KC	20	Add specific fields to both Assurance Net and IPPS for SRM-related activities and develop process to ensure these are adequately monitored both at the district and headquarter levels	February 1, 2012	YES	YES

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

United States Department of Agriculture

Food Safety and
Inspection Service

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

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

FROM: Alfred V. Almanza **/ s /** **July 27, 2015**
Deputy Under Secretary, Office of Food Safety
Acting Administrator, Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Implementation of the Public Health Information System (PHIS) for Domestic Inspection, Report Number 24601-0001-23

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

FSIS's General Comments

While the Agency appreciates the efforts made by OIG to assess the implementation of the Public Health Information System (PHIS) and report the observed findings, the delay in issuing the Discussion Draft report for 18 months following OIG's initial report of preliminary findings to FSIS management lessens its usefulness and highlights findings that result in a report that does not reflect the current state of PHIS.

Although the OIG states that fieldwork was performed through August 2014, the majority of OIG's Official Draft report is based upon data and on-site field observations made from 2012 and 2013. It is worth emphasizing that the version of PHIS audited by the OIG was 1.0, and that the current version in production is version 4.1 - three major and multiple minor releases later. These upgrades correct and address many of the conditions cited in the findings described in this report.

The report makes alarming statements about the system but does not adequately take into account the numerous improvements that FSIS has made to PHIS since version 1.0. While the report acknowledges some of the actions FSIS has taken since the OIG performed the majority of its fieldwork, it does so with caveats and disclaimers. The OIG's explanation for including the caveats was that it decided not to invest the time or resources to validate FSIS's assertions. FSIS believes that the audit report would be materially different and more useful if the OIG had invested the resources necessary to verify our assertions relative to improvements made to PHIS since the initial audit fieldwork was conducted. We believe the report as written is not balanced because it minimizes the many PHIS improvements that have already been made

The narrative of OIG's report does acknowledge FSIS's efforts to control costs, improve connectivity, and use compensating controls, and it does reference documentation of improvements in PHIS that it received from FSIS after the release of the Discussion

draft report in December 2014, OIG minimizes the significance of these improvements by including statements that it was unable to verify the stated improvements since they did not conduct additional field work.

PHIS is a dynamic, comprehensive data analytic system that is critical to FSIS's effort to collect, consolidate, and analyze data in order to improve public health. It has allowed FSIS to enhance its mission critical functions in a way that was not possible with its legacy systems.

After initial difficulties in the implementation of the domestic function of PHIS in 2011, FSIS has dramatically improved and increased PHIS's functionality with the release of enhancements and new components. These enhancements have enabled PHIS to accommodate and stay current with developments in FSIS, such as the adoption of the New Poultry Inspection System (NPIS).

After the completion of the domestic inspection component, FSIS launched an industry component that allows industry members to use PHIS to conduct business with FSIS, such as to review reports on verification activities, receive sampling data, and respond to non-compliance records (NR). FSIS has also been able to enhance communication with State Meat and Poultry Inspection programs, with 23 States now using PHIS in many of the same ways as FSIS.

The OIG's report inappropriately may cause the reader to assume that food safety is being jeopardized. For example, the OIG incorrectly states that the domestic module in PHIS is designed to draw upon data "including products produced, production volume, and establishment size" when generating tasks for in plant personnel. In fact, PHIS inspection tasks generated by the domestic module are driven by different profile characteristics than those noted in OIG's statement. The PHIS scheduler uses an establishment's operation type and hazard analysis and critical control point (HACCP) categories to determine which tasks to assign, and uses the establishment's normal operating schedule to estimate the monthly number of tasks to perform. Products and volumes are generally used for sampling algorithms but, as will be discussed below, FSIS believes that OIG has significantly overstated issues with product data. No issues were identified with the PHIS slaughter data, which drives the agency's broiler and turkey testing for *Salmonella* and *Campylobacter* and its Residue testing program among other smaller sampling programs.

Furthermore, the routine tasks generated by PHIS, while sufficient for an inspector to schedule tasks throughout the month, do not represent the full scope of inspection tasks needed. Many tasks, such as sampling, follow-up tasks, or tasks to document unplanned findings, are scheduled in a more ad hoc manner that allows for inspectors to adjust their daily inspection activities as needed based on their experience and training. The primary advancement achieved with PHIS is not the automated scheduling of tasks (this was also done by the prior system, the Performance-based Inspection System (PBIS)), but the flexibility to make changes and adjustments to the standard set of tasks as circumstances warrant.

OIG notes that FSIS's policy places the responsibility of updating the establishment profile on inspectors. Establishment profile data includes information about what products an establishment chooses to produce, what days they choose to operate, what volumes of product they choose to produce, etc. This is information best collected and verified by FSIS personnel present in the facility. FSIS inspectors are conducting inspections in establishments daily, observing operations

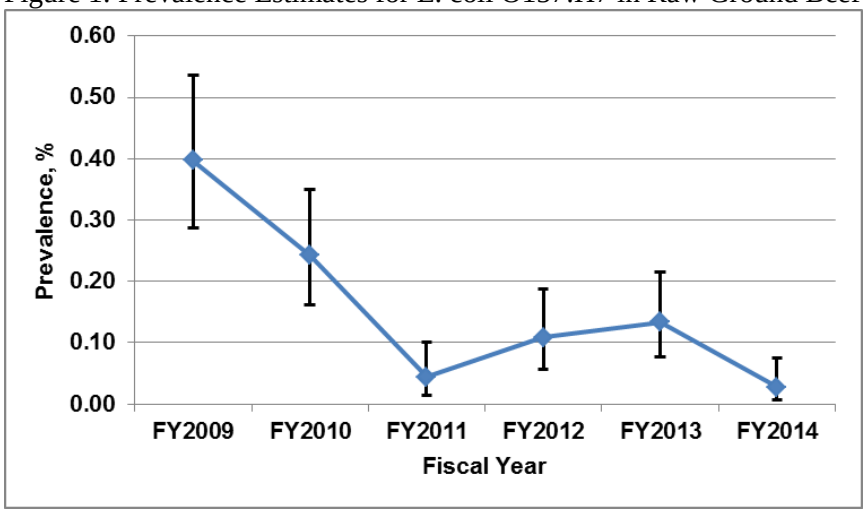
and reviewing records. Therefore, it is in the best interest of food safety that inspectors have primary responsibility for this activity. Through supervisory reviews and other activities, verification of data can be performed periodically and serve as an additional layer of review, but this occasional review would not replace the inspector's role.

The OIG noted that we did not implement sufficient internal controls to effectively monitor and evaluate the performance of PHIS. FSIS believes that it took appropriate action to implement controls. For example, FSIS developed improved instructions and reports within the first three months of implementation that enabled districts to successfully enter the critical establishment profile information necessary to conduct daily inspection. In addition, between 2011 and 2013 FSIS regularly analyzed data coming in from PHIS to assess whether the system was being utilized as expected. This analysis included evaluations of the number of establishments with inspection findings, the slaughter volume totals by species, sampling numbers by project code, non-compliance rates, amount of humane handling time documented, and rates of task performance. These evaluations were done to try to identify any major gaps in data reporting or inspection, and no major issues were identified. Examples of these evaluations were provided to OIG, but not mentioned in the Official Draft report.

OIG suggests that food safety could not be assured as a result of its findings. The major finding of the report states "FSIS Needs to Re-Assess PHIS to Ensure that the System Will Serve Food Safety Needs". While OIG identified areas for improvement with the FSIS information system, the audit did not disclose a single discrete example of a contaminated or uninspected product being released into commerce as a result of any failure of PHIS. In addition to FSIS's inspection data, FSIS also regularly monitors and evaluates other indicators of food safety, such as pathogen testing data and illness data. These data would be likely to signal an adverse trend in contaminated food if a systemic failure were occurring.

FSIS monitors and reports on its pathogen testing data on a regular basis and has not found evidence that food is less safe since the implementation of PHIS. For *E coli* O157:H7 in raw ground beef, FSIS finds that the prevalence has been consistently low since 2011 (see Fig 1, source: internal FSIS analysis).

Figure 1: Prevalence Estimates for E. coli O157:H7 in Raw Ground Beef



FSIS also regularly monitors case rates reported by CDC for indications of issues. The case rates for O157:H7 were significantly lower in 2014 and unchanged in 2013 compared to a 2006-2008 baseline period. (see CDC MMWR Reports, "Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food – Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006-2013" and "Preliminary Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food – Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006-2014"). While these case rates do not exclusively measure FSIS-regulated products, they represent a key metric on foodborne illness. FSIS collaborates with CDC and FDA to study and understand the food sources contributing to the overall case rates.

The findings OIG reported on the PHIS during the course of its audit and the actions FSIS has taken to address these findings since 2012, follow:

Cost, Design, and Implementation of PHIS

On July 11, 2012, the Government Accountability Office (GAO) issued GAO report GAO-12-629 on Information Technology Cost Estimation which found that PHIS program's cost estimations did not exhibit all of the qualities of a reliable cost estimate. In light of these findings, FSIS management immediately took steps to improve its cost estimations by establishing a Capital Planning and Cost Analysis Branch within the Office of the Chief Financial Officer. Further, the Agency later established a dedicated Program Management Division and Investment Planning and Control Branch within the Office of the Chief Information Officer and ensured that Federal and Department policies on Capital Planning and Investment Control were implemented and being appropriately followed. These practices have led to a comprehensive well-documented cost estimation approach for PHIS. Its accuracy and credibility for PHIS are proven by the Department's IT Portfolio Review assessment of PHIS showing FSIS' PHIS investment complies with OMB and Department reporting requirements.

In January 2010, the Office of Management and Budget (OMB) launched TechStat Accountability Sessions (TechStat). The TechStat is a face-to-face, evidence-based accountability review of an IT investment. It enables the Federal Government to intervene to turn around, halt, or terminate IT projects that are failing or are not producing results for the American people. In 2011, the Department conducted a TechStat on the Public Health Information Consolidation Projects (PHICP), which contained at that time PHIS. As part of its recommendations, in 2011, PHIS was separated out of PHICP and became its own major investment which required a rebaseline. On March 24, 2014, PHIS received an approved rebaseline as part of the Department's Integrated Baseline Review (IBR), per FAR Subpart 34.2 and OMB's Capital Programming Guide, supplement to Circular A-11, Part 7. For each rebaseline, FSIS has had to present a strong case to an independent review board to justify budgetary increases to PHIS and an establishment of new milestone timelines. The Agency not only justified its actions but has a more robust system protecting food safety today. FSIS also undergoes an annual PortfolioStat with USDA's Chief Information Officer (CIO) annually to ensure the health of its portfolio is independently assessed in depth. In fact, as recently as February 2015, the PHIS system was rated and reported to OMB as Green. The OIG finding is out-of-date because it has not assessed the improvements that FSIS has implemented to advance its efforts in designing, implementing, and costing out its software investments.

Connectivity Problems Identified

Although FSIS acknowledges that there were limited instances of connectivity issues in certain geographically remote areas (such as the 22 plants that the OIG judgmentally selected to conduct site visits), at no time was food safety jeopardized because of PHIS connectivity issues. FSIS would like to emphasize that the 22 establishments visited were non-statistically selected, and they were not and are not representative of all 6,187 establishments nationwide. The OIG's findings about connectivity at 22 establishments suggest that the issues may be clustered to specific establishments or remote areas of the United States.

FSIS Inspectors enforce applicable statutes and regulations in accomplishing the Agency's mission. PHIS is a tool the inspectors use to assist them in managing and documenting their work. It is important to note that inspectors are also empowered to use their judgement in prioritizing and performing tasks to ensure the wholesomeness of the food supply as defined in FSIS Directive 13000.1 Although OIG states that in 11 of the 22 establishments (50 percent) visited, FSIS inspectors could not establish consistent access to PHIS in order to review scheduled tasks and record completion of tasks, this is belied by the fact that OIG asserts that only 2% of not-performed tasks were the result of computer or connectivity issues. Since this 2% figure does not take into account all the performed tasks, the impact of connectivity or computer issues is in fact very small and within an acceptable level of performance for a large, distributed information collection system.

Establishment Profiles Contained Inaccurate Information Which Was Then Used to Develop Sampling Projects

A critical FSIS function is to sample products in plant to determine whether they contain pathogens or illegal drug residues. FSIS's sampling capabilities have improved tremendously under PHIS. FSIS has increased the number of establishments sampled and is now conducting more robust and targeted sampling. In CY 2014, FSIS inspection program personnel (IPP) documented over 270,000 sampling tasks. The Agency staff uses data from PHIS to analyze the results of the inspection tasks and to make reports summarizing this data available to inspection personnel. In FY 2014, over 94,000 reports were generated by PHIS users.

OIG's claim about inaccurate information used to develop sampling projects is not supported by the information provided in the report. Depending on the sampling project and the nature of the inaccuracy (described in Exhibit C), there may be no impact at all on sampling. For example, a change in a raw ground beef production volume category from "1,001 to 3,000" to "6,001 to 50,000" would have no impact on sampling eligibility or frequency for the raw ground beef sampling program. As another example, a change in products produced from "Ground Beef Product from in-house source materials" to "Hamburger/Beef Patty combined with other species from purchased source materials" would also have no impact on sampling eligibility or frequency for the raw ground beef sampling program. FSIS is unable to determine the specifics of the inaccuracies that OIG mentions and does not agree that sampling projects were adversely impacted.

Furthermore, to ensure the adequacy of its sampling program, during PHIS implementation the FSIS employed compensating controls which would effectively mitigate the impact of possible

discrepancies in establishments profile data. It was FSIS's position to err on the side of over-inclusion rather than exclusion whenever there was a question about eligibility. One control FSIS employed was to consider prior sampling history in determining eligibility. For example, an establishment that had a history of submitting ground beef samples was kept in the sampling frame even if the PHIS profile did not indicate that the establishment still produced eligible ground beef product. This data was used as an input to the algorithm for ground beef until March 2012. Another control FSIS employed was to utilize past questionnaire data in determining eligibility. For example, prior to PHIS, FSIS used production information from a Raw Beef Checklist to develop sampling frames. FSIS continued using that Checklist data as an input for bench trim sampling for over a year after PHIS implementation began. An additional control FSIS employed when appropriate was to combine data over time from PBIS and PHIS to maintain consistent sampling eligibility criteria. For example, FSIS combined slaughter data from electronic animal disposition system (eADRS) and PHIS to compute annual slaughter activity at establishments. This is an input into the Residue sampling program. The algorithms include specific information about change history.

Further, from 2013 through 2015, FSIS has attempted to clarify OIG's misapplication of FSIS sampling eligibility criteria. OIG relied primarily on the FSIS Sampling Plan, posted on its website. But this document was intended to be a plain language explanation of the general characteristics of each sampling program, not a detailed technical document. FSIS explained to OIG that the agency directives and programming code for the algorithms were the primary ways to determine eligibility. OIG requested, and FSIS provided, the SAS code for several major sampling algorithms, including for raw ground beef. It was apparent in subsequent discussions about eligibility that OIG did not carefully review the sampling algorithms, nor did it request a meeting to discuss the algorithms as FSIS offered. Nevertheless, FSIS resubmitted to OIG the policies and programming code and met with OIG to explain how FSIS determines eligibility. This report does not provide sufficient information to evaluate how OIG determined that 10 of 22 establishments had inaccurate information.

In addition, in order to try to reconcile the differing assessments of sampling information, FSIS provided a detailed mapping of FSIS policies to the ground beef sampling algorithm, discussed in depth in the OIG audit. Both FSIS Directive 10,010.1 and the ground beef sampling algorithm were provided to OIG in 2013, during their audit, and again in 2015, during discussions of findings. FSIS provided information in response to OIG's analysis of the raw ground beef sampling program which is included in Exhibit 1.

OIG attempts to characterize FSIS's comments about additional documentation as confirmation that OIG's approach is valid, but this statement is in fact a mischaracterization of FSIS' position. FSIS agrees that further documentation of products mapping between policies and algorithms may provide additional clarity, but it does not agree that OIG's criteria would be in any way validated. Using the files provided to OIG in 2013, FSIS described how to correctly identify the eligible establishments, yielding 1,247 establishments, rather than 1,502 as OIG asserts.

FSIS was able to determine the products that OIG used to arrive at 1,502 eligible establishments and provided a detailed clarification of the eligible and ineligible products, including a table that showed whether the 1,502 establishments OIG identified were eligible for MT43 sampling (Exhibit 2). It's not clear why OIG insists on including products that are not eligible, and that FSIS explicitly clarified were ineligible.

By applying only the 8 eligible products for ground beef sampling, as described in Directive 10,010.1 and acknowledged by OIG in its report, FSIS finds that 97% of ground beef producers have been sampled. Thus, the error rate is at least half the 7%-10% error rate that OIG claims. There could be several reasons why this rate is not 100%, including that some establishments were intermittent producers and were not eligible the entire time.

OIG also asserts that 196 establishments "were included in the universe for MT43 sampling" but do not produce ground beef. FSIS believes that OIG arrived at this number by comparing historical sampling to a current list of ground beef producers. FSIS explained in 2015 the limits of this approach, including how establishments that had been producing ground beef, and sampled accordingly, might have stopped producing and appeared as ineligible. FSIS believes the universe of ground beef producers at the time of OIG's data request identifies establishments that are currently eligible, not establishments that have been historically eligible. Therefore FSIS does not agree that OIG's finding that 196 establishments were incorrectly sampled is a valid conclusion.

Based on an in depth assessment of one sampling algorithm, it is clear that OIG has not correctly assessed the algorithms and product information provided for the other 6 sampling projects that OIG evaluated. Therefore, OIG's estimate of a 40% error rate in sampling is incorrect.

FSIS also provided to OIG data about how sampling activity has actually increased for many of FSIS's major verification sampling algorithms. FSIS reviewed the numbers of establishments sampled under six major verification sampling algorithms (see table below). FSIS also analyzed the time these programs operated pre-PHIS and post-PHIS implementation. In every case, sampling coverage of the industry remained the same or increased. The reasons for the increases are varied, including improved sampling algorithms and policies that expanded eligibility.

	Numbers of distinct establishments sampled		
Sampling Projects	Pre-PHIS Jan '08- Apr '11	Post-PHIS May '11-Dec '14	Percent Growth
Broilers	170	197	16%
Ground Beef (Salmonella)	393	450	15%
Ground Beef (E coli)	1307	1321	1%
Ground Chicken	18	145	706%
Ground Turkey	24	65	171%
Turkeys	34	46	35%

FSIS Could Better Manage Access Privileges for Separated Employees

FSIS wants to ensure that OIG uses accurate language (pre-enrollment accounts vs access) when it comes to logical PHIS access. Significantly, OIG did not establish that the list of FSIS employees it cites actually had PHIS access. Rather, the OIG establishes that at one time there

was an account (enrolled or unenrolled) for the employee. While FSIS does not disagree with the notion that its off boarding process needs improvement. The fact is that the Agency has leveraged compensating controls that are entirely appropriate, and that OIG's conclusion is not correct, as explained.

FSIS employs several internal and external controls for securing PHIS. PHIS complies with applicable federal security requirements and has a layered security model to control access. The PHIS application access controls are in addition to the general controls that are in place to prevent unauthorized access to the Agency network. All layers must be in place and enabled for the user to access PHIS.

With the initial implementation of PHIS, FSIS employees were pre-enrolled in the system. To create the original accounts, data were used directly from the NFC data feed. This approach was the most efficient way to create the large number of PHIS accounts that were required at the initial deployment stage. Some employees in the NFC data feed never required access to PHIS and therefore never accessed the system. In those instances, the user never finished the creation of their account and did not have access to PHIS.

OIG was provided a list of all PHIS inactive accounts. The list of the separated users provided by OIG was compared to the historical database of all PHIS application users. Out of the listing of separated users provided by OIG (which included 604 records), only 206 names were found in the PHIS database. Of the 206 names, only 3 of those employees ever completed the activation process and had a PHIS active account with assigned roles. FSIS knows that this is the case because when a user first enters PHIS, the system captures his or her eAuth ID under the "eAuthID" field. If a user never logs into the system, this field reads "NULL." Only 3 users from the OIG list had their eAuth ID captured, and the system shows these three accounts as inactive. The Agency does not remove accounts that have not been activated since the accounts are inactive, preventing users from accessing the system. If a user has not activated his or her account during the pre-enrollment process, he or she would be required to begin the registration process over by getting his or her Administrator's approval to get an account.

Lastly, PHIS requires Government-issued equipment for access, including an active network account and a computer with an approved image (including the Agency's Virtual Private Network software) or access to the Local Area Network.

PHIS meets both NIST and USDA security standards as shown by its annual security assessments and its Authorization to Operate from USDA. OIG's assumption that FSIS runs the risk of unauthorized users altering data and jeopardizing the integrity of the data in PHIS is without basis and highly unlikely. The assertion OIG makes in its draft report is based on a misunderstanding of the data provided that OIG made no effort to understand or correct. The layered approach to PHIS's security provides an extremely low risk of unauthorized users gaining access to PHIS.

Tasks Not Performed

OIG reports findings on the number of routine tasks not performed by inspectors but is silent on the number of directed tasks, not generated by PHIS routinely, that were also performed by inspectors. Further, there are several reasons why tasks may not be performed. The majority of the time (68%) justified inspection tasks are not completed in a given day because the plant is not

operating that day or not producing eligible product. These reasons are a consequence of plant operations and are not related to connectivity, inspector workload, or incorrect task assignments. When the not-performed inspection task rates are discounted to exclude these establishment-related reasons, the percent of tasks not performed because of any other reason drop to 10.1% between 4/1/2011 and 12/31/2012 and 5.6% for CY2014."

The ability to issue directed tasks is critical functionality that helps ensure that key food safety issues are identified and documented. For example, if an inspector has completed all of the routine tasks assigned by PHIS for a particular sanitation task but happens to identify a noncompliance, that inspector can create an additional task to document the non-compliance. The inspector might very well do that in lieu of some other task that is determined to be less important. Furthermore, FSIS's review of the reasons why inspection tasks were not performed shows that about two-thirds of the time that a task was not performed it was because the task did not apply because the plant was not producing the product in question or not operating at all. Oftentimes this situation results from the nature of the establishment's operations. For example, in a situation where an establishment produces products under the 03D, 03E, 03F, 03G and 03H HACCP categories, PHIS cannot predict which products will be produced throughout the month, so it assigns tasks for all 5 HACCP categories for all operating days. If that establishment only produces product under one category on any given day, then 4 out of those 5 tasks will not be performed that day. These kinds of scenarios explain approximately two-thirds of the not performed tasks.

It is not clear to FSIS how tasks not performed, and their nonperformance not justified, when a plant is not operating constitutes a food safety issue. FSIS acknowledges that in a minority of instances the fact that nonperformance of tasks was not unjustified does merit attention, but it is clear that OIG's findings significantly overstate the nature of the problem.

Additionally, OIG's analysis misinterprets the data that are available and covers a timeframe when many in-plant personnel were still under PBIS. OIG's misperception stems from the fact that when FSIS transitioned from PBIS to PHIS, many of the tasks performed after PHIS was implemented continued to be documented in PBIS. Moreover, it is true that PHIS over-schedules inspection tasks. FSIS does this intentionally because it cannot predict what special problems may arise during the course of the month. The Agency does not expect IPP to perform 100 percent of the tasks. Rather, IPP have the flexibility to prioritize the tasks they perform based on public health. With that said, IPP performed over 80 percent of the tasks generated by PHIS.

FSIS has also looked at the relationship between inspection tasks and Salmonella levels in chicken and turkey ("FSIS Risk Assessment for Guiding Public Health - Based Poultry Slaughter Inspection: An Implementation Scenario - Based Approach", FSIS, 2014). In that risk assessment, FSIS found that increased unscheduled tasks were significantly associated with reduced pathogen levels. This finding supports that the performance of unscheduled (aka "Directed" in PHIS) tasks is important in controlling pathogen levels, and that an inspector's decision to perform and document these tasks in lieu of routine tasks assigned by PHIS is generally the correct decision. The ability of inspectors to perform directed tasks, sometimes in lieu of routine ones, is an important aspect of conducting inspection. OIG's criticism that inspectors should spend more of their time justifying why they did not perform a routine task seems counter-productive to the Agency's mission.

Analysis of Assigned Tasks

OIG states that it could not verify that directed tasks adequately replaced the functions of the routine tasks. Directed tasks are not intended to be a replacement for the same functionality of the routine tasks. For example, all PHIS sampling tasks are considered directed tasks. There are no routine tasks that serve the same function. As a result, there is no expectation on the part of FSIS that a sampling task is meant to replace a routine task of the same function. In fact, FSIS instruction is that the directed task should replace a lower priority task. The task that is replaced could be a completely *different task, such as an administrative or non- food safety related task.*

As FSIS explained to OIG in preliminary discussions, routine tasks are scheduled by the system based on the operating days of the week and the lengths of shifts, in addition to other factors, in order to provide tasks for 100% of the operating time of the month. Scheduling cannot take into account various factors such as the unplanned need to document non-compliances, complete questionnaires to support agency initiatives, perform randomly assigned sampling tasks, or adjust to changing production practices by establishments. For these reasons, there are circumstances where routine tasks cannot all be performed or directed tasks should be substituted for routine tasks. These sections in Directive 13000.1 support this assertion:

> I. "IPP are to use their knowledge of the specific operations in their assigned establishments to schedule their inspection tasks in the most efficient and effective manner."
> V. "FSIS recognizes that IPP have constraints on their time because of the individual operational characteristics of their assigned establishments, necessary travel for patrol assignments, unforeseen issues that arise, and other factors."
> V. "IPP are to use this information to decide what and when to schedule the necessary inspection tasks."
> IX.H. "Planned frequencies of PHIS tasks do not always reflect actual establishment operations."
> IX.H. "In cases where establishment operations require additional instances of a task, IPP are to initiate directed instances of the appropriate tasks in accordance with applicable policies"
> VI.B.4. "IPP are also able to initiate directed instances of routine tasks based on conditions they observe in establishments."
> X.B.3. "Therefore, in establishments with multiple slaughter lines, IPP are to schedule additional instances of this task as directed tasks to meet the instruction in the directive"
> X.B.5. "IPP can also schedule as many directed instances of a task by using the same method as described for routine tasks."

Directed tasks are set-up to allow flexibility in scheduling. They include sampling tasks, follow-up sampling, follow-up inspection tasks in response to non-compliances, questionnaires that the Agency may decide to schedule, and issues that an inspector may see on a given day and need to document. Directed tasks replace routine tasks and therefore should be counted in the total number of tasks performed. Using the total of routine and directed tasks performed, divided by the number of routine tasks planned by PHIS, the percent of tasks performed was 68.3% for the period 4/1/2011 to 12/31/2012. As inspectors have acclimated to the system, the rates of tasks

performed have improved. The percent of tasks performed increased to 82.6% for the period 1/1/2014 to 12/31/2014, as shown in Table 2.

The routine tasks are scheduled by the system using information about a plant's operating days and shift length. PHIS schedules routine tasks to essentially fill that plant's operating time, but there are limits in how well this can be done.

For example, in a scenario where a plant conducts slaughter and processing operations and is operating 5 days a week, approximately 22 days per month on average, PHIS will schedule tasks for both slaughter and processing for 22 operating days. The plant may in fact only slaughter 1 day a week and process the other 4. The inspector needs to schedule the appropriate tasks. This information cannot be programmed into PHIS because establishments change the days of production frequently to respond to market needs. Routine task are scheduled monthly in PHIS. Daily changes must be managed by FSIS in-plant personnel. (See Directive 13,000.1 for more details.)

FSIS raised a number of concerns, but these issues are not addressed in OIG's analysis of inspection task data. OIG's finding does not account for the need to perform tasks not generated by PHIS. Some PHIS tasks are product specific, and OIG makes the incorrect assumption that FSIS, via PHIS, knows up to a month in advance what an establishment will be producing each day of the month (see the example above regarding a plant that produces products in the 03D-03H HACCP categories). By FSIS's calculations, shared with OIG during discussions in 2015, 83% of tasks were performed in CY2014, compared to 68% between 4/1/2011 and 12/31/2012. Data used from OIG visits to four FSIS districts from April 2011 to October 2012 cover the phasing-in of PHIS, when some establishments were still using the PBIS, but the PHIS system was assigning inspection tasks to these establishments.

Scope and Methodology

OIG states that one of the factors used in selecting establishments is the number of tasks not performed because of computer issues. FSIS believes that this biases OIG's audit toward the most challenging establishments in terms of connectivity and other issues. FSIS questions whether such biased sampling is an appropriate context to make broad claims about the 6,100 other establishments and several thousand other inspectors.

Exhibit C

Exhibit C, while likely presented in the manner it was for brevity, exaggerates the scope of data errors found by OIG. OIG states in the report that four data variables were assessed: location, contacts, products, and volumes and references Exhibit C in that discussion. But Exhibit C only presents findings from two of the four variables. Furthermore, OIG only presents data for the 10 establishments that it identified with data issues. The result of omitting two, presumably clean, variables and 12 of 22 establishments leaves a false representation of the data. Without careful scrutiny of what was omitted from the table, a reader might conclude from Exhibit C that nearly 100% of the establishments and variables had some degree of data issue. In reality, only 50% of the variables and 45% of the establishments had data issues identified. When considering the full assessment that OIG performed, FSIS observes that OIG reviewed 88 data points (4 variables across 22 establishments) and found 13 errors or approximately a 15% error rate. While this rate is concerning to FSIS, and merits further attention, placing findings in their appropriate context helps avoid mis-interpretation, over-reaction, and inappropriate allocation of resources toward

this issue. FSIS believes a more representative summary for Exhibit C would look like the figure below, assuming FSIS has drawn the correct conclusions about the omitted data.

Establishment Number	Slaughter (S); Processing (P); or Slaughter and Processing (SP)	Incorrect Location Information	Incorrect Contact Information	Incorrect Products (Results in sampling project errors)	Incorrect Volume	Details
1	SP					
2	SP			X	X	This establishment was included in the wrong sampling project.
3	P					
4	SP			X		The establishment was included in the wrong sampling project.
5	SP			X		The establishment was included in the wrong sampling project.
6	P					
7	SP					
8	SP					
9	P					
10	SP				X	
11	SP – HIMP				X	
12	P			X		The establishment was included in the wrong sampling project.
13	P					
14	P					
15	SP			X	X	The establishment was included in the wrong sampling project.
16	P			X		The establishment was included in the wrong sampling project.
17	P					
18	P					
19	SP				X	
20	SP – Tallmadge Aiken57			X	X	The establishment was included in the wrong sampling project. Also – only 1 out of 23 products had a volume listed. The inspector stated PHIS would not allow him to make the change in the system.
21	SP – HIMP					
22	SP – HIMP					

As demonstrated on the previous page, PHIS is not the same system as it was when first implemented, and it is not the same system that it was when OIG reviewed it almost two years ago. It does more and functions significantly better than its predecessor, PBIS, and it is enabling FSIS to better protect public health.

As is pointed out repeatedly in this response, there are numerous errors and inappropriate assumptions made by OIG. Their number, and OIG's insistence on making them in the face of the corrective explanations provided by FSIS, raises significant questions about the fairness and objectivity of the audit team that prepared this report, and whether this report should be issued at all. Nonetheless, FSIS will respond to the eight recommendations made in the report.

Recommendation 1

Complete a written assessment of the current status of the Public Health Information System (PHIS) implementation that includes prioritized corrective actions with specific timeframes for completion. Also, implement a process to verify that the corrective actions are completed within the established timeframes

FSIS Response:

Among the numerous steps FSIS has taken to improve PHIS since its implementation, the Agency, on its own initiative, brought in a third-party to conduct a top-to-bottom assessment of PHIS. To complete this assessement, FSIS entered into an agreement with MITRE, a not-for-profit organization operating Federally Funded Research and Development Centers (FFRDC). In June 2014, MITRE completed a two-phased assessment of the current status of the system and made several recommendations of areas where FSIS can improve the system and its related infrastructure and processes. In its written assessment, MITRE also included an action plan for the Agency to consider in moving forward with recommendations. FSIS believes MITRE's written assessment of the current status of PHIS fulfills OIG's recommendation. Since the conclusion of the assessment, FSIS has been in the process of implementing MITRE's recommendations.

MITRE's assessment focused on the five following areas: (1) Architecture and Design; (2) Processing Layers; (3) Shared Infrastructure; (4) User Experience; and (5) Governance. As part of the assessment, MITRE conducted 22 site visits, approximately conducted 40 interviews, and utilized a number of tools to gather data. In addition, FSIS gave MITRE full access to PHIS project management documents. In its assessment, MITRE found that to improve the system and the end-user experience, FSIS needs to make improvements to its end-user client systems, connectivity in remote locations, shared infrastructure in enterprise data centers, software development life cycle (SDLC) processes, IT service management processes, and training and education of end-users.

Since the assessment, FSIS has upgraded its personnel to Window 7 laptops with a more optimal performance capacity to operate PHIS. In addition, FSIS has made significant connectivity improvements in the field, and has been in the process of upgrading hundreds of sites to T1 connections,and as recommended by MITRE, is replacing EVDO cards with MiFi devices for our field personnel to achieve better connectivity when using PHIS. In addition, the Agency is working to formalize a structure and operation for the Change Control Board (CCB), the body

that manages and priortizes changes in PHIS, by enhancing and documenting its processes and incorporating it into the Agency's already rigorous governance process. PHIS releases are required to follow the agency's System Development Life Cycle (SDLC). Prior to each software release, PHIS is required to go through the 8 different phase gates which are composed of technical subject matter experts and business area representatives. As for PHIS testing and release quality management, FSIS has instituted a more robust user acceptance testing process for each release with more testers, impact testing, and an enhanced testing schedule. In regards to MITRE's recommendation to improve training and keep it up-to-date, FSIS recently launched a PHIS Help Button, a training resource accessible from within the system. With the Help Button, personnel can receive help on PHIS functionality by reading step-by-step instruction, watching a video, and by practicing performing the steps within the help feature.

FSIS has identified short-term and long-term actions for each area of emphasis in MITRE's assessment and incorporated these actions into ongoing PHIS application development and infrastructure development and maintainence.

Estimated Completion Date:
FSIS believes the Agency has fully responded to recommendation 1.

Recommendation 2:
Enhance internal controls by ensuring management oversight of PHIS encompasses ongoing monitoring and periodic evaluation of PHIS to ensure the system is accessible, operating as designed, and includes both complete and accurate information.

FSIS Response:
Over the last couple of years, FSIS has instituted enhanced internal controls through implementation of investment planning and controls. FSIS implemented the following management controls for the PHIS Investment:

- FSIS oversight of the PHIS investment includes review as part of FSIS' Annual PortfolioStat. The review is briefed to the FSIS Management Council, which consists of the Agency's senior leadership as part of the Agency's Enterprise Governance process. It is also reviewed by the Under Secretary for Food Safety and briefed to the USDA CIO.
- Quarterly Investment Reviews are conducted in collaboration with FSIS Office of the Chief Information Officer (OCIO), FSIS OCFO, FSIS Stakeholders, and USDA OCIO to review the PHIS Investment including project activities, Earned Value Management (EVM), issues, and risks.
- FSIS, in conjunction with USDA, performs monthly investment reviews for PHIS. Monthly investment reviews are posted on the Office of Management and Budget (OMB) Federal IT Dashboard.
- On a weekly basis, OCIO's PHIS Program Manager provides a detailed status briefing of PHIS to the senior OCIO staff. The briefing reports on the health and status of the system.
- In addition, PHIS software releases follow the Agency's SDLC. PHIS releases go through 8 different phase gates which are comprised of technical subject matter experts and business area representatives.
- Each year, following the Enterprise Governance (EG) process, the Management Council

(MC) functions as the Agency's IT Investment Review Board (ITIRB) for approval of major development, modernization or enhancement (DME) work.

- The PHIS investment program is managed by a Federal Acquisition Certification for Program and Project Managers (FAC P/PM) level 3 certified program manager. The development contract is managed by a certified Contracting Officer's Representative.

In 2014, a rebaseline of the PHIS investment was reviewed and approved by the USDA Executive Information Technology Investment Review Board as part of USDA's Integrated Information Technology Governance Framework.

Estimated Completion Date:
FSIS has completed all the aforementioned corrective actions and believes it has addressed this recommendation.

Recommendation 3:
Develop and implement a plan to review and correct the data in PHIS' establishment profiles. This should include procedures for FSIS supervisors to conduct ongoing reviews of data in establishment profiles.

FSIS Response:
FSIS has implemented a process through targeted FSIS policy issuances to utilize directed PHIS task functionality to target updates of specific profile elements, such as a specific task to update poultry products profiles and another separate task to specifically update pork products. FSIS intends to continue using this approach to update specific data elements under a systematic scheduled timeline culminating in July 2016.

Estimated Completion Date:
By July 31, 2016, FSIS will develop and begin the implementation of a plan that will continually maintain updated establishment profiles and develop a process for periodic reviews of establishment profile data for completeness and accuracy by supervisors.

Recommendation 4:
Develop instructions that define the specific data fields, such as product produced, that are required for an establishment to be included in a sampling project.

FSIS Response:
FSIS instructions to IPP adequately define the eligibility criteria for various sampling programs, and AskFSIS provides a mechanism for IPP to clarify any questions they might have. To address this recommendation, FSIS will, by July 31, 2016, develop a reference document that defines the PHIS data elements used in sampling algorithms. This reference guide will describe how sampling algorithms are implemented in terms of PHIS data elements on products produced, volumes, intended uses, exclusion criteria, and other relevant parameters.

Estimated Completion Date:
FSIS will develop a reference document by July 31, 2016.

Recommendation 5:
FSIS needs to strengthen its procedures to ensure that a separated employee's user role, user account, and system access is promptly disabled and/or removed, in accordance with Federal guidance.

FSIS Response:
As indicated in our general comments, OIG has not demonstrated that the cited list of PHIS employees actually had PHIS access, just that at some time there was an account (enrolled or unenrolled). FSIS has leveraged compensating controls that are entirely appropriate, and its approach to PHIS' security provides a very low risk of unauthorized users gaining access to PHIS. However, FSIS is working to strengthen its off-boarding notification procedures and to ensure that there is timely notification to the accounts operation team of user departures for account disabling. FSIS will issue a policy on on-boarding and off-boarding procedures. In addition, FSIS performs a daily scan of Active Directory to identify inactive accounts and disable them.

Estimated Completion Date:
FSIS will issue a policy on on-boarding and off-boarding procedures by June 2016.

Recommendation 6:
Review and evaluate the tasks PHIS currently generates for inspectors, as well as the inspectors' workload. Develop and begin implementing a plan that ensures the inspectors are assigned a manageable number of tasks and that the most important tasks are routinely performed at each establishment. The plan should require the front-line supervisors to: monitor the inspectors' completion of the tasks and to document the results of this review; take corrective actions needed to ensure compliance; and monitor the status of those corrective actions.

FSIS Response:
FSIS is committed to providing a system that is inherently flexible and allows for inspectors to make decisions about the most important tasks to perform on any given day based on their knowledge of day-to-day plant operations and in response to additional directed tasks that may be assigned. Furthermore, FSIS provides data to supervisors to review task completion data and effectively manage work performed by inspectors. Although PHIS schedules a full workload of "routine" tasks, additional "directed" tasks may be added based on specific, unforeseen needs, such as 1) randomized sampling, 2) additional tasks that the inspector determines are needed based on observations in the plant and 3) follow-up tasks after a non-compliance is identified. FSIS has instructed inspectors to perform certain directed tasks "in lieu" of other tasks (for example, see Directive 5420.1, Part XII.D.6) and more generally has instructed inspectors to use their knowledge of plant operations and task priorities to prioritize which tasks to perform. FSIS has calculated that 80% of routine tasks are either performed or replaced by a directed task. FSIS also believes that the majority of tasks that are not performed are not performed because the establishment is not producing applicable product for the specific tasks. It is important to note that there is now a higher level of task performance than OIG calculated during its audit in 2012 and 2013 while PHIS was being implemented. Yet FSIS supports the concept of continuous improvement and sees task assignment as an area for potential improvement. By July 31, 2016, FSIS will develop and begin implementing a plan to address inspection task assignment. This plan will include an assessment of the current task scheduling and task completion data to

identify specific areas for improvement, as well as a focus on potentially developing new methodologies for assigning tasks. FSIS will also review its instructions to supervisors for conducting reviews of inspection task performance and make updates as appropriate.

Estimated Completion Date:
By July 31, 2016, FSIS will develop and begin implementing a plan to address inspection task assignment.

Recommendation 7:
Develop an action plan with specific timeframes for implementing the actions agreed to in Recommendations 1, 3, and 13 of Audit Report 24601-0007-Hy.

FSIS Response:
Recommendation 1 (Audit Report 24601-0007-Hy)-Implement an action plan with specific milestone dates for capturing results of food safety assessments in an appropriate configuration that allows for effective analysis.

FSIS began a phased implementation of the PHIS food safety assessment (FSA) reporting system in fall 2013, and by February 2014, the system was being used by all districts. PHIS implementation allows for the FSAs to be available for PHIS reports and other data analysis. FSIS began implementation by deploying PHIS testing of FSAs in 2011 and 2012, and based on PHIS testing, additional work was needed to fully implement the FSA reporting system. FSIS determined that the FSA component did not need to be immediately implemented in PHIS because food safety assessment information was already being collected and stored in AssuranceNet[2]. FSAs continued to be collected in AssuranceNet until 2014, when the FSA reporting system was fully implemented in PHIS. In addition, FSIS contracted data analysis work in 2012 to analyze FSA data housed in non-PHIS systems such as pdf formats. The Agency conducted analysis for its ongoing accomplishment reports, research for policy or to revise the questions EIAOs use to document the FSA. After the implementation of FSAs in PHIS, all FSAs are now in a configuration that allows for effective analysis, and AssuranceNet is no longer used for FSA reports.

Recommendation 3 (Audit Report 24601-0007-Hy)-Determine how the results of food safety assessments will be used by FSIS in estimating establishment risk.

FSIS revised how it uses inspection history criteria for prioritized scheduling of FSAs to take advantage of new data collected through PHIS by identifying public health regulations (PHRs) and included instructions on prioritizing FSAs in response to whether establishments had received PHR NRs in Directive 5100.4, *Prioritized Scheduling of FSAs*. The criteria FSIS used to identify the PHRs include whether noncompliance specific regulations are associated with positive pathogen test results or enforcement actions. These criteria are described in detail in FSIS' Public Health Decision Criteria Report. FSIS started using the PHR criterion to schedule FSAs in May2013. FSIS reviews the PHR list annually, as recommended by the National Advisory Committee on Meat and Poultry Inspection (NACMPI), and makes updates as needed. Updates are announced around July 1 each year with a targeted implementation month of October. If an establishment meets the PHR criteria or any other triggers for scheduling an FSA listed in 5100.4, EIAOs are provided with a copy of the previous FSA, along with inspection and sampling history

and information from the inspector-in-charge (IIC) or front line supervisor (FLS) to determine whether to conduct an FSA.

In addition, FSIS began conducting FSAs using a new methodology in June 2015, as described in FSIS Directive 5100.1, *FSA Methodology*. This new methodology includes public health risk evaluations (PHRE), as described in FSIS Directive 5100.4. PHREs utilize a risk-based decision making process to determine whether to conduct an FSA or to take immediate enforcement action based on establishment risk. In addition, FSIS uses FSA results to determine whether no action at an establishment is necessary, that the in-plant team is to issue NRs, that the district office is to issue a Notice of Intended Enforcement (NOIE) with or without NRs, or that the district office is to issue a Notice of Suspension (NOS).

According to FSIS Directive 5100.1 NRs can be issued to the establishment as a result of FSA findings. The EIAO is to work with the FLS to determine whether there are public health-related or complex HACCP system design noncompliances that would require a follow up once the establishment has provided corrective actions.

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

The OIG found that the FSIS response in 2011 to generate an inspection task to review the FSA as part of the annual reassessment was inadequate because results of the inspection tasks did not contain alerts in PHIS to trigger inspection program personnel to conduct an FSA based on results of such inspection tasks. Since 2011, FSIS began working to implement new triggers based on inspection results across all PHIS inspection tasks that are analyzed monthly for FSA scheduling. Therefore, FSIS decided that an alert to trigger the FSA was no longer necessary. As is discussed above, FSIS currently uses PHR decision criteria and other criteria included in Directive 5100.4 for scheduling FSAs. Furthermore, FSIS district office personnel can also schedule FSAs based on FLS or IIC input when IPP find changes to the establishment's HACCP system that warrant an FSA. According to FSIS Directive 5100.1 NRs can be issued to the establishment as a result of FSA findings. The EIAO is to work with the FLS to determine whether there are public health-related or complex HACCP system design noncompliances that would require a follow up once the establishment has provided corrective actions.

As is also discussed above, FSIS began conducting FSAs using a new methodology in June 2015. The new methodology includes a step before the FSA called PHREs. PHREs use a risk-based decision making process to determine whether to conduct an FSA or take enforcement action. During the PHRE, the EIAO will review the PHRE report, which includes inspection results, and follow-up with IPP and the FLS to gain a better understanding of issues that triggered the FSA.

<u>Estimated Completion Date</u>:
FSIS believes the Agency has fully responded to recommendation 7.

Recommendation 8:
Develop an action plan with specific timeframes to ensure the effective implementation of the corrective actions put in place to address Recommendations 6 and 16 of Audit Report 24601-0007-Hy.

FSIS Response:
Recommendation 6 (Audit Report 24601-0007-Hy)—Develop a process to obtain more accurate, verifiable production data (e.g., pounds produced by product type) and regularly update the data from FSIS-regulated establishments.

FSIS acknowledges the importance of accurate product type and product volume information for the successful implementation of FSIS' sampling programs. Inspection program personnel verify the accuracy of the product type and product volume data and make the necessary corrections in the establishment profile in PHIS. AskFSIS provides a mechanism for IPP to request clarification on any questions they might have.

During this fiscal year, FSIS provided instructions to personnel regarding updating establishment profiles for product type and product volumes on three occasions. FSIS Notice 39-14 *Clarification and Expansion of Sampling Eligibility Criteria for the Routine Beef Manufacturing Trimmings (MT60) and Bench Trim (MT55) Sampling Programs*, FSIS Notice 33-15 *Updating the Public Health Information System (PHIS) Profile for Raw Pork Products* and FSIS Notice 12-15 *Updating the PHIS Profile for Raw Chicken and Turkey Products* instructed inspection program personnel at beef slaughter and processing establishments, pork slaughter and processing establishments, and personnel at establishments slaughtering or producing raw intact or raw non-intact chicken and turkey products, respectively, to update the PHIS establishment profile for the products subject to the Notice. FSIS has found that IPP effectively updated profile data following the instructions in these notices.

In Directive 5100.4 *Enforcement, Investigations and Analysis Officer (EIAO) Food Safety Assessments (FSA)* published on June 10, 2015, FSIS added instructions to the general FSA tool. It advises that while performing an FSA, the EIAO observes the establishment is not within a correct sampling frame, the EIAO will communicate with the FLS for follow up with in-plant inspection personnel.

By the end of September 2015, FSIS will issue FSIS Directive 10,010.1, *Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli (STEC) in Raw Beef Products*. This directive instructs personnel to update establishment profiles for raw beef products. Additionally, this directive will include instructions for IPP to discuss changes made to the establishment's profile during the weekly meeting with establishment management and to provide the establishment the opportunity to provide product and product volume information.

The need for the instruction in Directive 10,010.1 arose from agency reviews of reasons samples were not collected. By October 31, all establishments that produce raw beef products will have had their establishment profiles updated. The directive also instructs IPP on how to enter the days of production and instructs supervisors to verify the profile updates and to review the profile for product and product volume accuracy.

As noted in response to recommendation 4, by July 31, 2016, FSIS will develop a reference document that defines the PHIS data elements used in sampling algorithms. This reference guide will describe how sampling algorithms are implemented in terms of PHIS data elements on products produced, volumes, intended uses, exclusion criteria and other relevant parameters.

Recommendation 16 (Audit Report 24601-0007-Hy)—Closely monitor the administration of the PHIS contract and the development, testing, and implementation of the new system to ensure it is progressing as intended to attain satisfactory assurance that it can support the operations necessary to carry out a complex, scientifically-based risk-based inspection program.

As noted in response to recommendation 1, the Agency is working to formalize a structure and operation for the CCB, the body that manages and prioritizes changes in PHIS, by enhancing and documenting it processes and incorporating it into the Agency's already rigorous governance process. PHIS releases are required to follow the Agency's SDLC. Prior to each software release, PHIS is required to go through the 8 different phase gates which are composed of technical subject matter experts and business area representatives. As for PHIS testing and release quality management, FSIS has instituted a more robust user acceptance testing process for each release with more testers, impact testing and an enhanced testing schedule.

Estimated Completion Date:
FSIS believes the Agency has fully responded to recommendation 8.

EXHIBIT 1

Issue of Data Mapping of Directive 10010.1 to sampling algorithms for Ground Beef

Below are sections of Directive 10010.1 rev 3 that describe eligibility or ineligibility requirements for ground beef sampling. FSIS has added remarks, in bold italics and tables, to explain the connection to PHIS data.

Directive 10,010.1 rev3, Chapter I, Part VI.A:

Raw Ground Beef Products: FSIS samples raw beef food products that meet the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c)). In addition, FSIS will begin sampling product that contains a mixture of ground beef and non-beef species, unless the establishment labels the product in a manner to show that beef is not the predominant species in the product.

1. Raw ground beef products include:
    a. raw ground or chopped beef;
    b. hamburger;
    c. ground or chopped veal;

NOTE: For purposes of this directive, when the directive references beef, veal is included.

    d. veal or beef patties;
    e. veal or beef patty mix; and
    f. ground veal or beef product with added seasonings.

PHIS PRODUCT GROUPS SUBJECT TO MT43 SAMPLING AS PER THE ABOVE INFORMATION:

ID	*Description*
16	*Ground Beef Product from in-house source materials*
17	*Ground Product*
18	*Hamburger/Beef Patty Product*
73	*Ground Beef Product from purchased source materials*
74	*Ground Beef combined with other species from in-house source materials*
75	*Ground Beef combined with other species from purchased source materials*
85	*Hamburger/Beef Patty combined with other species from in-house source materials*
86	*Hamburger/Beef Patty combined with other species from purchased source materials*
*92**	*Hamburger/Beef Patty combined with other species from purchased source materials*

** ID #92 is currently inactive*

Directive 10,010.1 rev3, Chapter I, Part VI.A, Second Note:

NOTE: A raw ground beef product formulated with any amount of beef product derived from Advanced Meat Recovery (AMR) systems is considered "ground beef." Raw product comprised only of beef from AMR systems is not sampled as a raw ground beef product. Raw product comprised only of beef from AMR systems is considered a raw ground beef component or raw beef patty component (see VI, B., 3. of this section for a description of AMR systems).

PHIS PRODUCT GROUP EXCLUDED FROM MT43 SAMPLING AS AMR AS PER THE ABOVE INFORMATION:

Id	***Description***
1	*Advanced Meat Recovery (AMR)*

Directive 10,010.1 rev3, Chapter I, Part VI.C:

Products Not Subject To FSIS Sampling

Fabricated steaks and finely sliced beef (9 CFR 319.15(d)) do not meet the standard of identity for ground or chopped beef product and, therefore, would not be subject to *E. coli* O157:H7 sampling. Raw beef sausage products are not subject to FSIS' *E. coli* O157:H7 sampling and testing. Ground buffalo or bison is also not a raw ground beef product subject to this FSIS verification sampling.

PHIS PRODUCT GROUPS EXCLUDED FROM MT43 SAMPLING AS PER THE ABOVE INFORMATION:

Id	***Description***
83	*Fabricated Steaks and other Non-Intact Subprimals*
34	*Other Non-Intact Product (fresh sausage, meat loaf, gyros, meat balls, etc.)*
14	*Formed Steaks*

Directive 10,010.1 rev3, Chapter II, Part I.A.9:

IPP are not to sample product that the establishment **intends for use in intact product, or ready-to-eat products,** provided the establishment's hazard analysis and flow chart show that the product is intended for one of these uses and identify establishment controls that ensure that the product is used as intended. IPP are to verify that there are measures in place to ensure that the product is used as intended. Such controls may include letters to receiving establishments; P. 15; Ch. II, I, A, 9.

IF ALL PRODUCTS IN PHIS ARE DESIGNATED WITH THIS INTENDED USE, THE ESTABLISHMENT IS EXCLUDED FROM SAMPLING. A CHECK-BOX EXISTS FOR THE RTE INDICATION:

ESTABPRODUCTSXREFHACCPINTENDEDUSES.HACCPINTENDEDUSEID MUST = 1 TO EXCLUDE THAT PRODUCT.

In addition, the MT43 SAS program provided to OIG in early 2013 included the SQL to extract the necessary data. Below is the primary SQL query in the MT43 Sampling Algorithm submitted to OIG in 2013. Annotations have been added to describe the data criteria/filters used to determine eligible establishments.

```
select distinct
   EP.EstablishmentId as 'EstID',
   EN.PrimaryEstablishmentNumber as 'EstNbr',
   case
    when sum(V.minimumvolume) between 1 and 4 then 4
    when sum(V.meanvalue) between 1001 and 50000 then 3
    when sum(V.meanvalue) between 50001 and 250000 then 2
    when SUM(v.meanvalue) > 250000 then 1
    else null
   end as 'VValue'
from EstablishmentProducts EP
 join EstablishmentNumberOrgLevel EN on EN.EstablishmentID = EP.EstablishmentId
        and EstablishmentStatus = 'A' [1]/* Active Establishments */
 join DomesticEstablishments de on EN.EstablishmentID = de.EstablishmentId
 join DomesticEstablishmentNumbers DEN on de.Id = DEN.DomesticEstablishmentId
        and GOITypeId = 1 [2]/* Grant is Meat */
        and (GOIStatusId not in (11, 12, 13, 15) [3]
         OR GOIStatusId is null[4])
        /* Status is not withdrawn or suspended */
 left join RefLMVolumes V on V.Id = EP.LMVolumeId and V.IsActive=1
 left join EstabProductsXRefHACCPIntendedUses x on x.ProductId = EP.Id and
x.HACCPIntendedUseId = 1
where EP.FinishedProductId in (7)  [5]/* Beef */
 and EP.ProductGroupId in (16, 17, 18, 73, 74, 75, 85, 86, 91, 92)[6]  /* Patties and RGB */
 and (x.HACCPIntendedUseId is null or x.HACCPIntendedUseId != 1[7]) /* Removes Product
intended for cooking */
```

---

[1] Includes establishments whose status is currently “Active”

[2] This limits establishments to ones with a Grant of “Meat”

[3] Excludes establishments whose grant status is “Voluntarily Withdrawn”, “Withdrawn by FSIS”, “Voluntarily Suspended”, “Suspended by FSIS”

[4] Includes establishments whose grant status is unknown

[5] Includes establishments whose FinishedProductId is “Beef”

[6] Includes establishments whose Product Groups are “Ground Beef Product from in-house source materials”, “Ground Product”, “Hamburger/Beef Patty Product”, “Ground Beef Product from purchased source materials”, “Ground Beef combined with other species from in-house source materials”, “Ground Beef combined with other species from purchased source materials”, “Hamburger/Beef Patty combined with other species from in-house source materials”, “Hamburger/Beef Patty combined with other species from purchased source materials”, “Hamburger/Beef Patty combined with other species from purchased source materials”

[7] Includes establishments whose product has no intended use or the intended use is not “For RTE Cooking Only”

```
group by EP.EstablishmentId, EN.PrimaryEstablishmentNumber
order by EP.EstablishmentId
```

EXHIBIT 2

Products Included in OIG's 1,502 eligible establishments:

ID	Product Group	MT43 Eligible Product?
1	Advanced Meat Recovery (AMR)	**No**
87	Ammoniated Beef	**No**
4	Beef Trimming from non-intact beef	**No**
84	Bench Trim (derived from non-intact beef not slaughter at the est.)	**No**
83	Fabricated Steaks and other Non-Intact Subprimals	**No**
14	Formed Steaks	**No**
74	Ground Beef combined with other species from in-house source materials	Yes
75	Ground Beef combined with other species from purchased source materials	Yes
16	Ground Beef Product from in-house source materials	Yes
73	Ground Beef Product from purchased source materials	Yes
85	Hamburger/Beef Patty combined with other species from in-house source materials	Yes
86	Hamburger/Beef Patty combined with other species from purchased source materials	Yes
18	Hamburger/Beef Patty Product	Yes
22	Low Temperature Rendered Product - Finely Textured Beef (FTB)	**No**
23	Low Temperature Rendered Product - Partially Defatted Beef Fatty Tissue (PDBFT)	**No**
27	Non-Intact Cuts (including Bone in and Boneless Meats)	**No**
33	Other Non-Intact	**No**
34	Other Non-Intact Product (fresh sausage, meat loaf, gyros, meat balls, etc)	**No**

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