Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

VULNERABILITIES IN FDA'S OVERSIGHT OF STATE FOOD FACILITY INSPECTIONS

Daniel R. Levinson
Inspector General

December 2011
OEI-02-09-00430

EXECUTIVE SUMMARY

OBJECTIVES

1. To determine the extent to which the Food and Drug Administration (FDA) enters into contracts with States to inspect food facilities.
2. To determine the extent to which FDA ensures that States complete the inspections required by their contracts.
3. To determine whether FDA ensures that State inspections are properly classified and violations are remedied.
4. To determine the extent to which FDA audits State inspections and addresses deficiencies identified by audits.

BACKGROUND

Each year, 128,000 Americans are hospitalized and 3,000 die after consuming contaminated foods and beverages. FDA is responsible for safeguarding the Nation's food supply and for routinely inspecting food facilities. In addition to conducting its own inspections, FDA relies on State agencies to conduct inspections on its behalf; however, in recent years, concerns have been raised about the rigor of these State inspections. For example, the peanut processing plant responsible for a 2009 salmonella outbreak was inspected multiple times by a State agency working on behalf of FDA. This outbreak resulted in one of the largest food recalls in U.S. history and has led to serious questions about the effectiveness of State food facility inspections. Because of concerns about food facility inspections conducted by State agencies, this review was requested by the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies.

FDA often enters into contracts with State agencies responsible for ensuring food safety. Each contract includes the number of food facility inspections the State will conduct for FDA and the amount the State will be paid for each inspection. During the 2009 contract year, FDA held contracts with 41 States to conduct FDA's inspections.

FDA oversees State inspections though its Contract Inspection Audit Program. The audit program is designed to verify that States conduct

inspections that satisfy the requirements of their contracts. FDA requires that a minimum of 7 percent of a State's contract inspections be audited each year. This minimum percentage—which is known as the minimum audit rate—ensures that States are conducting adequate inspections that meet the conditions of the contract.

We based this study on several sources of data: (1) FDA's inspection data, (2) FDA's documentation of contract inspections and payment data, (3) audit and corrective action documentation, and (4) structured interviews with FDA officials.

FINDINGS

FDA has increasingly relied on States to inspect food facilities. Although the number of food facilties inspected by FDA has decreased since 2004, the number of facilities inspected by States under contract to FDA has increased significantly. In fiscal year (FY) 2009, 59 percent of FDA's food inspections were conducted by State inspectors, compared to only 42 percent in FY 2004.

In eight States, FDA failed to ensure that the required number of inspections was completed; FDA paid for many inspections that were incomplete. These 8 States were responsible for completing a total of 2,170 inspections; however, these States failed to complete 10 percent of these inspections during the contract year. When States fail to complete the inspections required in their contracts, FDA's ability to identify facilities with potentially serious food safety violations is diminished. Also, FDA paid for 130 of the 221 inspections that were not completed. In four additional States, FDA paid for inspection visits, even though payment for such visits was not specified in the States' contracts.

FDA did not ensure that all State inspections were properly classified and that all violations were remedied. FDA officials responsible for 11 of 41 States were unclear about how to properly classify contract inspections. In these 11 States, FDA officials reported that they would not assign official action indicated classifications to State inspections under any circumstances, contrary to FDA guidance. If FDA does not correctly classify inspections that reveal serious violations, its ability to assess facilities' relative risk is impaired. Additionally, FDA officials responsible for another 11 States reported that when States were responsible for correcting violations, FDA was not always informed about actions taken by the States. As a result,

FDA was unable to ensure that serious violations had been adequately addressed.

FDA failed to complete the required number of audits for one-third of the States and did not always follow up on systemic problems identified. For 14 of 41 States with contracts, FDA did not complete the required number of audits and therefore failed to meet its minimum audit rate. Additionally, the audits in 10 States revealed systemic problems that needed to be corrected; however, FDA initiated corrective action in only 4 of the 10 States. If FDA does not follow its guidance and complete the required number of audits and address systemic problems, it cannot verify that States are conducting suitable inspections that satisfy the requirements of the contracts.

RECOMMENDATIONS

Our report identified significant weaknesses in FDA's oversight of food facility inspections conducted by States. Taken together, the findings demonstrate that more needs to be done to protect public health and to ensure that contract inspections are effective and prevent outbreaks of foodborne illness. Therefore, we recommend that FDA:

Ensure that all contract inspections are completed, properly documented, and appropriately paid for.

Ensure that contract inspections are properly classified in accordance with FDA guidance.

Ensure that all inspection violations are remedied by routinely tracking all actions taken to correct violations.

Ensure that the minimum audit rate is met in all States.

Address any systemic problems identified by audits.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA concurred with four of our recommendations and agreed in part with the fifth.

In response to our first recommendation, to ensure that all contract inspections are completed, properly documented, and appropriately paid for, FDA concurred, stating that it is conducting a systematic review of the State contracting program.

In response to our second recommendation, to ensure that contract inspections are properly classified, FDA concurred and noted that it is revising its directive to emphasize more clearly that classifications must be accurate, timely, and uniform.

In response to our third recommendation, to ensure that all inspection violations are remedied by routinely tracking all actions taken to correct violations, FDA agreed to track most violative inspections and the remedies taken by industry. However, FDA noted that certain violations may not be suitable for inspection followup and that other approaches may be used to track such violations. While we appreciate FDA's commitment to track certain violations, we encourage it to track all violations, even those that do not warrant followup inspections. FDA can use violation information to help establish the relative risk of facilities and determine how often they should be inspected.

In response to our fourth recommendation, to ensure that the minimum audit rate is met in all States, FDA concurred, noting that it is reviewing the current reporting requirements to ensure that audits are completed and tracked to verify compliance with FDA requirements.

Finally, in response to our fifth recommendation, to address any systemic problems identified by audits, FDA concurred and noted that it will continue to develop processes and procedures to ensure that systemic problems are identified and that corrective action plans are implemented.

We support FDA's efforts to strengthen State contract inspections and address the issues identified in the report. With the implementation of the Manufactured Food Regulatory Program Standards, FDA's oversight of State inspections is even more critical. As States adopt the standards, it is essential that FDA strengthen not only States' oversight but also its own oversight to ensure that States conduct high-quality food facility inspections.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVES

1. To determine the extent to which the Food and Drug Administration (FDA) enters into contracts with States to inspect food facilities.
2. To determine the extent to which FDA ensures that States complete the inspections required by their contracts.
3. To determine whether FDA ensures that State inspections are properly classified and violations are remedied.
4. To determine the extent to which FDA audits State inspections and addresses deficiencies identified by audits.

BACKGROUND

Each year, 128,000 Americans are hospitalized and 3,000 die after consuming contaminated foods and beverages.[1] FDA is responsible for safeguarding the Nation's food supply and for routinely inspecting food facilities. In addition to conducting its own inspections, FDA relies on State agencies to conduct inspections on its behalf; however, in recent years, concerns have been raised about the rigor of these State inspections. For example, the peanut processing plant responsible for a 2009 salmonella outbreak was inspected multiple times by a State agency working on behalf of FDA.[2] This outbreak resulted in one of the largest food recalls in U.S. history and has led to serious questions about the effectiveness of State food facility inspections.

The FDA Food Safety Modernization Act was enacted in January 2011. This Act substantially increases the number of annual inspections that FDA will need to complete; it also authorizes FDA to continue its reliance upon State agencies to complete these additional inspections.[3]

---

[1] Elaine Scallan et al., "Foodborne Illness Acquired in the United States—Unspecified Agents," *Emerging Infectious Diseases*, Vol. 17, No. 1, January 2011. Accessed at http://www.cdc.gov on January 28, 2011.

[2] FDA, *Update on the Salmonella Typhimurium Investigation, FDA/CDC Joint Media Teleconference*, January 28, 2009. Accessed at http://www.fda.gov on January 28, 2011.

[3] P.L. 111-353.

Because of concerns about food facility inspections conducted by State agencies, the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies requested that the Office of Inspector General (OIG) review FDA's oversight of the program. Among other things, the Committee was concerned about State inspections conducted under contract with FDA, as well as FDA's audits of these inspections.

FDA's State Inspection Contracts

FDA often enters into contracts with State agencies responsible for ensuring food safety. Each contract specifies the number of food facility inspections the State will conduct for FDA; the amount the State will be paid for each inspection; and the extent to which the State will be paid for other activities, such as travel and training. In addition, each contract should specify whether the State will be compensated for inspection visits. An inspection visit occurs when an inspector visits a food facility in an attempt to conduct an inspection, but the inspection cannot be completed.[4]

During the 2009 contract year, FDA held contracts with 41 States to conduct FDA's inspections.[5] In the remaining States, FDA conducted all of its inspections without any State assistance. For the 2009 fiscal year (FY), FDA spent over $8 million for State contract inspections.

Officials from FDA's 19 district offices have the primary responsibility for overseeing contract inspections. These officials work with the States to determine which facilities will be inspected by FDA and which will be inspected by the States on FDA's behalf.[6] These officials, in conjunction with certain contracting officials in FDA headquarters, are also responsible for ensuring that States have completed the required number of

[4] This generally occurs when a facility is out of business or no longer subject to FDA inspection. A facility may no longer be subject to FDA inspection if, for example, it stops engaging in interstate commerce or if it is a seasonal facility that is not in operation at the time of the inspection visit.

[5] FDA has a contract with Puerto Rico to conduct food facility inspections. In this report, we refer to Puerto Rico as a State. In two instances, FDA had contracts with two agencies in a State (the Departments of Health and Agriculture). We used the information from both contracts in our analysis of these States.

[6] In some cases, both FDA and the State may inspect the same facility during the FY.

inspections, that all inspections are properly documented, and that States are appropriately paid for completed inspections.[7]

For each inspection, the State documents its findings in an inspection report and submits this report to FDA within 30 days of the inspection.[8] Each report is entered into a database that houses information about all FDA inspections. FDA then reviews and approves the information in this database. Additionally, States must submit a quarterly invoice that lists all inspections completed during the previous 90 days.[9]

Identifying Inspection Violations

During an inspection, State inspectors may identify potential violations of food safety laws and regulations. These violations are recorded in the inspection report. Based on the inspection report, FDA generally assigns one of three classifications: official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI).[10] An OAI classification signifies that the inspector found objectionable conditions in the food facility and that these violations potentially "warrant regulatory action."[11] This type of violation is the most significant identified by inspectors. A VAI classification signifies that the inspector found violations that are serious enough to record but do not cross "the threshold for regulatory action."[12] An NAI classification signifies that the inspector found either no violations of law and regulations or violations that were so insignificant that no action is warranted.[13]

In addition, under certain circumstances, FDA may also classify an inspection as "referred to State" (RTS). According to FDA guidance, an RTS classification signifies that there is either no

---

[7] FDA, *2009 Request for Proposals: Food*, § C-1(G)(6–8).

[8] Ibid., § C-1(G)(6).

[9] Ibid., § F-1(G)(5).

[10] FDA, Office of Regulatory Affairs, *Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (rev. June 7, 2007). Accessed at http://www.fda.gov on January 28, 2011.

[11] Ibid. Regulatory actions include warning letters, injunctions, and seizures.

[12] Ibid.

[13] More information about inspection violations can be found in OIG, *FDA Inspections of Domestic Food Facilities,* OEI-02-08-00080, April 2010.

Federal jurisdiction over the violation in question or that State action is the most efficient method of obtaining compliance.[14]

FDA's Contract Inspection Audit Program

FDA oversees State inspections though its Contract Inspection Audit Program, which is designed to verify that the State "conducts suitable inspections that satisfy the requirements contained in a contract."[15] FDA guidance requires that a minimum of 7 percent of a State's contract inspections be audited each year. This minimum percentage—which is known as the minimum audit rate—ensures that States are conducting adequate inspections that meet the conditions of the contract.[16]

To perform these audits, an auditor accompanies a State inspector who is conducting a contract inspection. Although most audits are conducted by FDA auditors, under certain circumstances, States may choose to assume responsibility for auditing their own inspectors. The auditor observes and assesses the inspector's performance according to at least 18 performance factors and rates each as either acceptable or needing improvement. See Appendix A for a description of these performance factors. Based on the total number of deficiencies, the inspector is assigned an overall rating of either acceptable or needing improvement. According to FDA guidance, State inspectors who receive an overall rating of needing improvement should receive remedial training from either FDA or the State to address the deficiencies prior to resuming their inspection duties.[17]

These audits are also used to identify systemic problems in States' inspection programs. According to FDA guidance, a systemic problem exists when audits identify the same deficiency in multiple audits during the same contract year.[18] FDA uses the

---

[14] FDA, Office of Regulatory Affairs, *Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (rev. June 7, 2007). Accessed at http://www.fda.gov on January 28, 2011.

[15] FDA, Office of Regulatory Affairs, *Field Management Directive No. 76:* § III.B. Accessed at http://www.fda.gov on January 28, 2011.

[16] According to its guidance, FDA may lower the minimum audit rate upon request from the district office. See *Field Management Directive No. 76:* § III.B. Accessed at http://www.fda.gov on January 28, 2011.

[17] Ibid., § III.F.

[18] Ibid.

threshold of four or more audits to determine whether a specific aspect of a State's inspection program needs improvement.[19] A systemic problem also exists when 20 percent of the performance factors in a State are rated as needing improvement.[20]

When systemic problems are identified, FDA and the State should determine the possible causes and solutions and agree on the type of corrective actions that may be needed. According to its guidance, FDA must monitor the effectiveness of the corrective actions.[21] If the deficiencies are not corrected in a reasonable amount of time or if they affect a substantial portion of the State's work, FDA may recommend probation, nonextension, or termination of the contract.[22]

During the 2009 contract year, FDA was responsible for conducting all of the audits in 27 States. Ten States were responsible for conducting all of their audits, and four States were in the process of assuming responsibility for conducting their audits.[23] See Appendix B for more detailed information about the States' role in conducting audits.

Manufactured Food Regulatory Program Standards

In May 2007, FDA implemented the Manufactured Food Regulatory Program Standards. These optional standards are designed to improve States' food safety programs and to develop greater consistency across State inspection programs. The standards address a wide range of initiatives designed to improve the overall quality of State inspection programs, such as developing appropriate protocols for food inspections and instituting a standard training curriculum for inspectors. These standards apply to a State's entire food safety program and are not limited to inspections conducted under contract with FDA. For the 2009 contract year, 21 States agreed to implement these

---

[19] FDA, *2009 Request for Proposals: Food*, § C-1(G)(5).

[20] See *Field Management Directive No. 76*, § III.E

[21] FDA Office of Regulatory Affairs, *Field Management Directive No. 76,* § II.F(6). Accessed at http://www.fda.gov on January 28, 2011.

[22] Ibid.

[23] Note that although these four States conducted some audits for training purposes, FDA was ultimately responsible for meeting the minimum audit rate in these States.

standards; all of these States were in the early stages of implementation.[24]

Related Work

This report builds upon a June 2000 OIG report that assessed FDA's oversight of State inspection contracts. That report found that FDA faced significant barriers in overseeing State inspections, including limited training provided by FDA to State inspectors and limited agency expertise in providing contract oversight.[25] In response to the report, FDA developed its Contract Inspection Audit Program.

OIG has also completed a number of other studies evaluating FDA's role in ensuring food safety. In a 2010 report evaluating FDA's inspections of domestic food facilities, OIG found that more than half of all food facilities have gone 5 or more years without an FDA inspection and that FDA does not always take swift and effective action to remedy violations found during inspections.[26] In a 2009 report on food traceability, OIG found that only 5 of 40 selected food products could be traced through each stage of the food supply chain.[27] It also found that 59 percent of selected food facilities did not comply with FDA's recordkeeping requirements and that these requirements were not sufficient to ensure the traceability of the food supply. OIG also issued a report that found that 5 percent of selected facilities failed to register with FDA as required and that almost half of the selected facilities failed to provide FDA with accurate information about their facilities.[28]

---

[24] An additional three States agreed to implement these standards, but not as part of their contracts with FDA.

[25] OIG, *FDA Oversight: A Call for Greater Accountability*, OEI-01-98-00400, June 2000.

[26] OIG, *FDA Inspections of Domestic Food Facilities*, OEI-02-08-00080, April 2010.

[27] OIG, *Traceability in the Food Supply Chain*, OEI-02-06-00210, March 2009.

[28] OIG, *FDA's Food Facility Registry,* OEI-02-08-00060, December 2009.

METHODOLOGY

Scope

This study assesses FDA's oversight of State food facility inspections. It focuses on contract inspections and audits completed during the 2009 contract year; it does not include inspections conducted by States on their own behalf.[29]

Analysis of FDA's Inspection Data

We requested and reviewed data from FDA on all food facility inspections for FYs 2004 through 2009 from its inspections database, called the Field Accomplishments and Compliance Tracking System (FACTS). FACTS includes information about all FDA inspections conducted by FDA and by States under contract with FDA, as well as the classifications of each inspection. We analyzed these data to determine the number of facilities inspected each year.

Analysis of State Contract Inspections and Payment Data

We requested from FDA all contracts for the 41 States conducting food facility inspections on FDA's behalf.[30] Specifically, we requested and reviewed the contracts for the 1-year contract period ending in 2009.[31] These contracts started at different times during 2008. In this study, we refer to this period as the 2009 contract year. We also requested and reviewed information about any changes made to the contracts, including any extensions.[32]

Based on our review of the contracts, we determined the total number of inspections that each State was required to conduct. We also determined whether inspection visits were allowable

[29] In addition to entering into contracts, FDA has partnership agreements with some States. These partnership agreements allow States and FDA to share information about inspections they conduct. We did not evaluate any partnership agreements, as these inspections are conducted by States on their own behalf.

[30] In two instances, FDA had contracts with two agencies in a State (the Departments of Health and Agriculture). We used the information from both contracts in our analysis of these States.

[31] We chose to use contracts ending in 2009 because it was the contract year most recently completed when we started this study.

[32] Three States' contracts were extended beyond the contract year through an agreement with FDA headquarters.

under the contract and, therefore, should have been counted toward the total number of required inspections.

To determine how many contract inspections were completed in the 2009 contract year, we obtained data from several sources. First, we analyzed FACTS to determine the total number of inspections recorded for each State. Next, we asked each FDA district office to provide us with documentation about any additional inspections or inspection visits completed by the State but not entered into FACTS. Using information in FACTS along with any additional FDA documentation provided, we determined how many inspections were completed by each State.

Lastly, we requested and reviewed information from FDA about the total number of inspections FDA paid for in each State. We used these data to determine whether FDA inappropriately paid for any inspections that were not completed.

Analysis of Audit and Corrective Action Documentation

We requested from FDA documentation of all audits conducted during the contract year. We analyzed this documentation to determine how many audits were conducted in each State and whether the required number of audits was completed.[33] To determine the required number of audits, we calculated the minimum audit rate.[34] We took into account any instances in which FDA had requested a lowered audit rate for a State.

We then reviewed the audits to determine the extent to which individual State inspectors had deficiencies and States had systemic problems. We considered an inspector to have a deficiency if he or she received a rating of needing improvement in at least one performance factor. We considered a State to have a systemic problem when the same performance factor was rated as needing improvement in four or more audits or when 20 percent or more of the performance factors in all audits in the State were rated as needing improvement. We then reviewed the audits to

[33] FDA provided joint inspection documentation as part of its audit documentation. A joint inspection by FDA and the State may count as an audit if it is used for training purposes. Joint inspections do not include inspector performance factors and generally do not include an overall rating.

[34] If the number of audits required was not a whole number, we rounded down to the nearest whole number.

determine the performance factors most frequently rated as needing improvement and the nature of these deficiencies.

We also requested and reviewed documentation from FDA on any actions taken by FDA or the States to correct deficiencies identified in the audits. We analyzed this information to determine the extent to which FDA followed up on problems identified by the audits.

Structured Interviews With FDA Officials

We conducted structured interviews with officials from each of FDA's 19 district offices. Our interview questions focused on how FDA oversees inspections conducted under contract with FDA. Specifically, we asked officials about how FDA tracks the completion of contract inspections, audits State inspectors and identifies deficiencies, and classifies contract inspections. We conducted these interviews with the district offices between March and April 2010. Additionally, we interviewed key FDA headquarters officials throughout the study. We asked these officials questions similar to those we asked in interviews with district officials, as well as additional questions to help clarify how they oversee contract inspections.

Limitations

We relied on FDA data to determine the extent to which States completed the inspections required by their contracts. We did not independently verify the accuracy of FDA's data.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FDA has increasingly relied on States to inspect food facilities

The overall number of facilities inspected has decreased from just over 17,000 facilities in FY 2004 to about 15,900 in FY 2009. Over this same period, the number—as well as the percentage—of facilities inspected by States under contract with FDA has increased significantly. In FY 2009, 59 percent of FDA's food inspections were conducted by State inspectors, compared to only 42 percent in FY 2004. (See Table 1.)

Table 1: Food Facilities Inspected by FDA and by States Under Contract With FDA, FYs 2004–2009

Fiscal Year	Total Number of Food Facilities Inspected	Number of Food Facilities Inspected by FDA	Number of Food Facilities Inspected by States Under FDA Contract	Percentage of Food Facilities Inspected by States
2004	17,032	10,354	7,073	42%
2005	15,773	8,247	7,828	50%
2006	14,547	7,065	7,695	53%
2007	14,418	6,118	8,506	59%
2008	15,055	6,209	9,050	60%
2009	15,920	6,796	9,430	59%

Note: The number of facilities inspected by FDA and the number of facilities inspected by States are not mutually exclusive and therefore do not sum to the total number of facilities inspected. On average, 271 facilities were inspected by both FDA and States in each FY.

Source: OIG analysis of FDA data, 2010.

According to FDA officials, one reason FDA relies on States is that these inspections are conducted under State regulatory authority, which often exceeds FDA's own authority. For example, several FDA officials noted that, under certain conditions, State inspectors can immediately shut down a facility or seize unsafe food products, whereas FDA would have to go through a lengthy legal process to achieve similar results.

FDA officials also noted that the Food Safety Modernization Act gives FDA additional inspection responsibilities and provides a mandate from Congress to continue to work closely with States to conduct these additional inspections. Officials reported that their goal is to establish an integrated, nationwide food-safety system with equivalent and coordinated inspections, inspection requirements, and training for inspectors.

In eight States, FDA failed to ensure that the required number of inspections was completed; FDA paid for many inspections that were incomplete

Each year, FDA enters into contracts with States. These contracts specify the total number of inspections that each State must complete during the contract year. FDA is responsible for ensuring that States conduct the required number of inspections and for appropriately paying the States for them.[35]

According to FDA data, inspections in 8 of the 41 States were not completed. As a part of completing inspections, each State must submit an inspection report that details the findings of the inspection. Each of these inspection reports is then required to be included in FDA's inspections database. For these eight States, the required reports were not contained in FDA's inspections database, nor could FDA locate paper copies of the reports. As a result, FDA's data indicate that the required inspections were not completed in accordance with FDA guidance.

Table 2: Number of Required Inspections Not Completed, Based on FDA Data, 2009

State	Number of Inspections in Contract	Number of Inspections Completed	Number of Inspections Not Completed
Nevada	153	59	94
California	335	248	87
West Virginia	125	102	23
Oklahoma	300	290	10
Connecticut	70	67	3
Texas	685	683	2
Maine	32	31	1
Virginia	470	469	1
Total	**2,170**	**1,949**	**221**

Source: OIG analysis of FDA data, 2010.

As shown in Table 2, these 8 States were responsible for completing a total of 2,170 inspections; however, FDA had no

[35] For detailed information about each State's contract and the number of required inspections, see Appendix C.

documentation indicating that 10 percent (or 221) of these inspections were conducted during the contract year.

FDA paid for most of these incomplete inspections without first verifying that the inspections had been completed and that the inspection reports were contained in FDA's database as required. Of the 221 inspections not completed, FDA paid for 130. FDA officials explained that they do not typically verify that inspections are contained in FDA's database prior to making payments to States. As a result, officials did not know whether the inspections they were paying for had been completed. When FDA does not verify that inspections are completed prior to payment, States may be paid inappropriately.

In four additional States, FDA paid for inspection visits, even though payment for such visits was not specified in the States' contracts

As noted earlier, an inspection visit occurs when an inspector visits a food facility but cannot complete the inspection. Each contract should specify whether the State will be compensated for inspection visits. However, a number of States had contracts that did not mention inspection visits or state whether these visits should be paid for by FDA. Officials noted that they do not routinely verify whether payments for inspection visits are allowable under the contracts prior to making payments to States. Several FDA officials have noted that this is because FDA has traditionally paid for inspection visits regardless of what was included in the contracts.

FDA did not ensure that all State inspections were properly classified and that all violations were remedied

FDA is responsible for classifying State inspections and for working with States to remedy violations. According to FDA guidance, uniform classification of State inspections is critical to the success of FDA's food safety program.[36] It is also critical that FDA ensure that all inspection violations are remedied, so that it may be assured of the safety of food produced by facilities that had serious violations.

[36] FDA, Office of Regulatory Affairs, *Field Management Directive No. 86: Establishment Inspection Report Conclusions and Decisions* (rev. June 7, 2007). Accessed at http://www.fda.gov on January 28, 2011.

FDA did not ensure that all contract inspections were properly classified; as a result, FDA was unable to assess the relative risk of facilities

In discussions with FDA officials, we learned that officials responsible for 11 of 41 States were unclear about how to properly classify contract inspections. As noted earlier, FDA assigns each inspection an OAI, VAI, NAI, or RTS classification; OAI classifications generally are assigned when the most serious violations are identified. In these 11 States, FDA officials reported that they would not assign OAI classifications to State inspections under any circumstances and instead assigned only VAI or RTS classifications for facilities with the most serious violations, contrary to FDA guidance. Several of the officials responsible for these 11 States noted that they believed that OAI classifications could not be used for State contract inspections.

In addition, despite that fact that FDA conducted fewer inspections than States, FDA inspections were much more likely to receive OAI classifications when compared to State contract inspections. Among all inspections conducted between FYs 2004 and 2009, those conducted by FDA inspectors received almost five times as many OAI classifications as those conducted by State inspectors. Although this disparity can be explained, in part, by the fact that FDA more frequently inspects high-risk facilities, this alone does not explain such a significant disparity between State and FDA inspections.[37]

If FDA does not correctly classify inspections with serious violations, its ability to assess facilities' relative risk is impaired. Beginning in FY 2011, FDA began assigning facilities numeric scores that were based partially on the number of past inspections that had been assigned OAI classifications. If FDA does not properly classify State contract inspections with the most serious violations, it cannot easily determine the facilities that pose greater risks for foodborne illness.

FDA did not know whether all inspection violations were remedied

FDA officials reported that depending on the State and the nature of the violations, FDA, the State, or both assume responsibility for

[37] See Appendix D for a comparison of the number of OAI classifications assigned for inspections conducted by States versus those conducted by FDA.

addressing any violations identified during State inspections. In all cases, FDA is responsible for ensuring that any State actions taken are adequate to ensure that the violations found during inspections are corrected. FDA officials responsible for 11 States reported that when States were responsible for ensuring that violations were corrected, FDA was not always informed about States' actions. As a result, FDA was unable to ensure that serious violations had been adequately addressed.

FDA failed to complete the required number of audits for one-third of the States and did not always follow up on systemic problems identified

FDA oversees State inspections through its Contract Inspection Audit Program. To perform an audit, an auditor accompanies a State inspector who is conducting a contract inspection. FDA guidance requires that a minimum of 7 percent of its contract inspections be audited each year. This minimum—which is known as the minimum audit rate—ensures that the quality of the inspections conducted by States is adequate and that States are satisfying the requirements of their contracts. In addition to conducting these audits, FDA is also responsible for following up on any systemic problems identified.

FDA failed to complete the required number of audits in 14 of 41 States

For one-third of the States with contracts, FDA did not complete the required number of audits and therefore failed to meet its minimum audit rate. Specifically, in these States, FDA failed to complete 38 percent (85 of 222) of the required audits.[38] For each of these 14 States, FDA was responsible for conducting the required audits and for meeting the minimum audit rate. For the 2009 contract year, 553 required audits were completed for all States under contract.[39]

FDA officials generally attributed their inability to complete the required number of audits to a lack of resources. For example, one

[38] Note that four States met their minimum audit rate because FDA lowered the rate and audited a reduced number of inspections.

[39] See Appendix E for the total number of audits completed for each State during the 2009 contract year.

official noted that his district ran out of the travel funds needed to complete the audits; another official noted a lack of trained FDA auditors available to conduct the audits. Without conducting the minimum number of required audits, FDA cannot effectively ensure that State inspectors are following proper procedures and adequately identifying violations during inspections.

When audits were conducted, they most commonly found problems with inspectors' ability to identify violations

Of the 419 inspectors audited in the 2009 contract year, 32 percent had at least 1 deficiency. Of the inspectors with deficiencies, over half failed to properly identify violations in food facilities. Specifically, these inspectors had at least one of the following deficiencies:

- failure to properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded;
- failure to assess employee practices critical to the safe production and storage of food; and
- failure to recognize violative conditions or practices (if present) and record findings consistent with State procedures.

Examples of these deficiencies include instances in which the auditors noted that the inspectors did not write up evidence of rodents, did not notice a leaky roof above exposed food, or did not notice broken glass that could find its way into a food product.

The audits in 10 States revealed systemic problems that needed to be corrected; FDA often failed to correct them

According to FDA guidance, a systemic problem exists when audits identify the same deficiency in four or more audits during the same contract year or when 20 percent of the performance factors in a State are rated as needing improvement.

The audits in 10 States revealed systemic problems that needed to be corrected. Of the 10 States with systemic problems, 9 had audits that identified the same deficiency in 4 or more audits. The most common systemic problem was the inspectors' failure to identify violations. For example, four of these States had systemic problems because four or more inspectors did not properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or

misbranded. The 10th State had more than 20 percent of its performance factors rated as needing improvement.

FDA officials initiated corrective action in 4 of the 10 States with systemic problems.[40] In another 5 of these 10 States, FDA did not analyze the audit data and was, therefore, unaware of the systemic problems in those States. For the remaining State, FDA knew about the problem but did not take any corrective action. If FDA does not follow its own guidance and address systemic problems found during its audits, it cannot verify that States are conducting suitable inspections that satisfy the requirements of the contracts, nor can it be assured of the safety of food facilities inspected by those States.

In addition to revealing these systemic problems, several audits identified problems with the performance of individual inspectors whose overall ratings indicated that their performance needed improvement. Specifically, 3 of the 419 inspectors received overall ratings of needing improvement, and 1 of those inspectors received an overall rating of needing improvement in 2 separate audits. State inspectors who receive overall ratings of needing improvement are supposed to receive remedial training from either FDA or the State prior to resuming inspection duties. For two of these three inspectors, the State arranged remedial training; for the remaining inspector, FDA failed to take any corrective action.

[40] In one of these four States, FDA initiated corrective action as a result of our inquiry.

RECOMMENDATIONS

FDA has increasingly relied on States to conduct food facility inspections. Further, the FDA Food Safety Modernization Act substantially increased the number of inspections that FDA needs to complete annually, and FDA has indicated that it will continue to rely on States to help conduct these additional inspections. As a result, it is critical that the agency monitor and oversee these inspections.

Our report identified significant weaknesses in FDA's oversight of State food facility inspections. Notably, in eight States, FDA failed to ensure that the required number of inspections was completed and paid for many inspections that were incomplete. If States fail to complete the number of inspections required in their contracts, FDA's ability to identify facilities with potentially serious food safety violations is diminished.

Also, FDA did not ensure that all contract inspections were properly classified or that all inspection violations were remedied. Finally, FDA failed to complete the required number of audits for one-third of the States, and when audits were performed, FDA often failed to address the systemic problems identified. If FDA does not conduct the required number of audits and fails to address systemic problems, it cannot verify that States are conducting suitable inspections that satisfy the requirements of the contracts, nor can it assure the safety of food facilities inspected by those States.

Taken together, the findings demonstrate that more needs to be done to protect public health and to ensure that contract inspections are effective and prevent outbreaks of foodborne illness. Therefore, we recommend that FDA:

Ensure that all contract inspections are completed, properly documented, and appropriately paid for

FDA should ensure that all inspections required by the contracts are completed and properly documented in its inspections database prior to making payments to States. FDA should also verify that inspection visits are allowable under the contracts prior to making such payments. At a minimum, FDA should annually review its data to ensure that all inspections are completed and documented in its database. By putting these controls in place,

FDA would ensure that it pays appropriately for contract inspections.

Ensure that contract inspections are properly classified in accordance with FDA guidance

FDA should properly classify all contract inspections, especially those in which the most serious violations are found. FDA may need to revise its guidance to clarify the circumstances under which OAIs should be given for contract inspections. FDA may also need to conduct training for district office officials to ensure that the guidance is consistently applied. Appropriate classification of inspections will improve FDA's ability to assess the relative risk of facilities.

Ensure that all inspection violations are remedied by routinely tracking all actions taken to correct violations

FDA should ensure that violations identified during contract inspections have been corrected. If FDA determines that States are responsible for correcting food facility violations, it should require that the States notify FDA of all actions taken. FDA may also consider expanding the capability of its inspections database or consider developing a tracking system to monitor the corrective actions taken by States as well as facilities' responses.

Ensure that the minimum audit rate is met in all States

Audits ensure that States conduct suitable inspections that satisfy contract requirements. FDA should ensure that 7 percent of State contract inspections are audited each year. If FDA reduces a State's minimum audit rate, it should ensure that the lowered rate is sufficient to determine whether the State is conducting suitable inspections.

Address any systemic problems identified by audits

FDA should analyze all audit deficiencies to determine when corrective action is necessary. FDA should review deficiency data for the entire State to identify any systemic problems. When problems are identified, FDA should ensure that corrective action is taken and that all problems have been addressed. FDA should also review deficiency data on individual State inspectors and ensure that they receive the required remedial training, or other actions as necessary, and that deficiencies are addressed. FDA should also work with States to ensure that inspectors receive additional training in areas where a significant number of them are deficient.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its response to the draft report, FDA concurred with four of our recommendations and agreed in part with the fifth. It noted that collaboration with its State partners is critical to an integrated national food safety system. FDA also noted that the current oversight program is in transition and that although FDA continues its longstanding program audits of State inspections, it is moving forward to fully implement its Manufactured Food Regulatory Program Standards.

In response to our first recommendation, to ensure that all contract inspections are completed, properly documented, and appropriately paid for, FDA concurred, stating that it is conducting a systematic review of the State contracting program. FDA further stated that it will ensure that processes are established to periodically review contract data. In addition, FDA noted that it has instituted practices to ensure that it reviews all contracts before they are issued to confirm that the contractors have elected to either include or exclude inspection visits.

In response to our second recommendation, to ensure that contract inspections are properly classified, FDA concurred and noted that it is revising its directive to emphasize more clearly that classifications must be accurate, timely, and uniform. FDA stated that it will issue the revisions, post them on its Web site, and establish an outreach schedule to explain the revisions to all key stakeholders within its district offices.

In response to our third recommendation, to ensure that all inspection violations are remedied by routinely tracking all actions taken to correct violations, FDA agreed to track most violative inspections and the remedies taken by industry. However, FDA noted that certain violations may not be suitable for inspection followup and that other approaches may be used to track such violations. FDA noted that it is evaluating and modifying its existing procedures to incorporate requirements for tracking State followup and actions to correct violations. While we appreciate FDA's commitment to track certain violations, we encourage it to track all violations, even those that do not warrant followup inspections. FDA can use violation information to help establish the relative risk of facilities and determine how often they should be inspected.

In response to our fourth recommendation, to ensure that the minimum audit rate is met in all States, FDA concurred, noting that it is reviewing the current reporting requirements to ensure that audits are completed and tracked to verify compliance with FDA requirements.

Finally, in response to our fifth recommendation, to address any systemic problems identified by audits, FDA concurred and noted that it will continue to develop processes and procedures to ensure that systemic problems are identified and that corrective action plans are implemented.

We support FDA's efforts to strengthen State contract inspections and address the issues identified in this report. With the implementation of the Manufactured Food Regulatory Program Standards, FDA's oversight of State inspections is even more critical. As States adopt the standards, it is essential that FDA strengthen not only States' oversight but also its own oversight to ensure that States conduct high-quality food facility inspections.

For the full text of FDA's comments, see Appendix F. We made minor changes to the report based on technical comments.

APPENDIX A

Table A-1: Performance Factors of the Contract Audit

Audit element*
1. Did the inspector review the State's establishment file for the previous inspection report and possible complaints or access other available resources in preparation for the inspection?
2. Did the inspector have the appropriate equipment and forms to properly conduct the inspection?
3. Was FDA jurisdiction established?
4. Did the inspector select an appropriate product for the inspection and, if necessary, make appropriate adjustments based on what the firm was producing?
5. Did the inspector assess the employee practices critical to the safe production and storage of food?
6. Did the inspector properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?
7. Did the inspector recognize significant violative conditions or practices (if present) and record findings consistent with State procedures?
8. Did the inspector demonstrate the ability to distinguish between significant verses insignificant observations and isolated incidents versus trends?
9. Did the inspector review and evaluate the appropriate records and procedures for this establishment's operations and effectively apply the information obtained from this review?
10. Did the inspector collect adequate evidence and documentation in accordance with State procedures given the nature of the inspection findings?
11. Did the inspector verify correction of deficiencies identified during the previous State inspection?
12. Did the inspector act in a professional manner and demonstrate proper sanitary practices during the inspection?
13. Did the inspector identify himself/herself and make appropriate introductions, which include explaining the purpose and scope of the inspection?
14. Did the inspector use suitable interviewing techniques?
15. Did the inspector explain the findings clearly and adequately throughout the inspection?
16. Did the inspector alert the firm's appropriate management when an immediate corrective action was necessary?
17. Did the inspector answer questions and provide information in an appropriate manner?
18. Did the inspector write his/her findings accurately, clearly, and concisely on the State form/document left with the firm?
Performance factors specific to inspections of certain high-risk facilities
1. Did the inspector use the "Fish and Fishery Products Hazards and Controls Guide" or the "Juice HACCP Hazards and Controls Guide," as appropriate, to identify and evaluate the hazards associated with the product and the process?**
2. Did the inspector assess the firm's implementation of sanitation monitoring for the applicable eight key areas of sanitation?
3. Did the inspector review the firm's HACCP plan (or necessary process controls in the absence of a HACCP plan) and applicable monitoring, verification, and corrective action records, including those related to sanitation?
4. Did the inspector recognize deficiencies in the firm's monitoring and sanitation procedures through in-plant observations?

*Taken from the Food and Drug Administration (FDA) Contract Audit Form 3610.

**HACCP refers to Hazard Analysis and Critical Control Points, a food safety management system for foods or processes considered high risk by FDA.

Source: Office of Inspector General review of the FDA Contract Audit Form 3610, 2010.

APPENDIX B

States' Role in Conducting Audits as Part of the Food and Drug Administration's Contract Inspection Audit Program

The Food and Drug Administration's (FDA) audit program allows States to assume responsibility for conducting their own audits of State inspectors. If FDA and a State agree, the States assume responsibility for some or all of the audits. The terms of these additional responsibilities—as well as the amount of additional compensation received by the States—are specified in the States' contracts. The audit program is made up of three successive phases of increasing responsibility assumed by the States:

Phase 1. In the first phase, trained FDA auditors conduct all of the audits of State inspectors. In this phase, FDA must meet the 7-percent minimum audit rate.[41]

Phase 2. In the second phase, both FDA and State auditors conduct the audits of State inspectors. Before he or she is allowed to conduct audits independently, a State auditor trainee must have the appropriate qualifications. The trainee must then observe an FDA auditor performing an audit of a State inspector. Finally, an FDA auditor must verify that the trainee's performance is acceptable by observing an audit. Once State auditors are deemed qualified, the State can work with FDA to meet the 7-percent minimum audit rate; however, FDA is ultimately responsible for ensuring that the minimum audit rate is met.

Phase 3. In the third phase, State auditors conduct all audits of State inspectors, and State auditors are solely responsible for meeting the 7-percent minimum audit rate.

In this phase, FDA oversees State audits by auditing the performance of the State auditors. These FDA verification audits are conducted during a State audit of a State inspection. To perform these audits, FDA selects a representative sample of State audits. An FDA auditor then observes and assesses the State auditor and produces a memorandum with the results of the audit.

See Table B-1 for the phase of the contract audit program for each State in the 2009 contract year.

[41] FDA, Office of Regulatory Affairs, *Field Management Directive No. 76:* § III.B. Accessed at http://www.fda.gov on January 28, 2011. Although each contract is for 1 year, timeframes for auditing inspectors are based on the length of time since an inspector was last audited.

Table B-1: Phases of the Contract Audit Program for the 2009 Contract Year

States in Phase 1	States in Phase 2	States in Phase 3
Alabama, California, Connecticut, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Minnesota, Montana, Nebraska, Nevada, New Jersey, Ohio, Oklahoma, Pennsylvania, Puerto Rico, Rhode Island, South Carolina,* Texas, Virginia, Vermont, Washington, West Virginia,* Wyoming	Colorado, North Carolina, South Carolina,* Tennessee	Arkansas, Alaska, Maryland, Michigan, Mississippi, Missouri, New York, Oregon, West Virginia,* Wisconsin,

*FDA had two contracts with two different State agencies in West Virginia and South Carolina; in both States, these two agencies were in different phases of the audit program.

Source: Office of Inspector General analysis of FDA State contracts, 2010.

APPENDIX C

Table C-1: Description of Services in State Contracts for the 2009 Contract Year

State	Total Food Inspections Required	Inspection Visits Included in Contract	Implementing Manufactured Food Regulatory Program Standards	Other Services Listed in the Contract
Alabama	175	Yes	Yes	Training and travel
Alaska	292	Yes	Yes	Training and travel
Arkansas	200	Yes	No	None
California	335	No	No	Training and travel
Colorado	207	Yes	Yes	Training, travel, and samples
Connecticut	70	Yes	No	Training and travel
Florida	490	No	No*	Training, travel, and samples
Georgia	225	Yes	Yes	Training and travel
Illinois	390	Yes	No	None
Iowa	150	No	No	None
Kansas	125	Yes	Yes	Training and travel
Kentucky	136	Yes	No	Training and travel
Louisiana	200	No	No	Training and travel
Maine	32	Yes	No	None
Maryland	180	No	Yes	Training, travel, and samples
Massachusetts	275	Yes	Yes	Training and travel
Michigan	410	No	Yes	Training, travel, and samples
Minnesota	282	Yes	No*	Training and travel
Mississippi	100	No	Yes	Training and travel
Missouri	450	Yes	Yes	Training and travel
Montana	90	No	No	Training and travel
Nebraska	130	Yes	No	Training and travel
Nevada	153	Yes	No	Training and travel
New Jersey	411	Yes	No	Training and travel
New York	378	Yes	Yes	Training and travel
North Carolina	254	Yes	Yes	Training and travel
Ohio	500	Yes	No	Training, travel, and samples
Oklahoma	300	Yes	Yes	Training and travel
Oregon	750	No	Yes	Training and travel
Pennsylvania	100	No	No	None
Puerto Rico	90	No	No	None
Rhode Island	150	Yes	Yes	Training and travel
South Carolina Department of Agriculture	115	Yes		Training and travel
South Carolina Department of Health	33	Yes	Yes	Training, travel, and samples
Tennessee	185	No	No	Training and travel
Texas	685	Yes	No	Training and travel
Vermont	8	No	Yes	Training and travel
Virginia	470	Yes	No*	Training and travel
Washington	550	Yes	Yes	Training and travel
West Virginia Department of Agriculture	45	Yes	No	None
West Virginia Department of Health	80	Yes	Yes	Training and travel
Wisconsin	289	Yes	Yes	Training and travel
Wyoming	35	No	Yes	Training and travel
Total	**10,525**			

*State has agreed to implement the Manufactured Food Regulatory Program Standards, but not as part of its contract with the Food and Drug Administration (FDA).

Source: Office of Inspector General analysis of FDA's State contracts and documentation, 2010.

APPENDIX D

Table D-1: Number of Inspections Classified as Official Action Indicated Conducted by FDA* and by States, FYs 2004–2009

Fiscal Year	Number of FDA Inspections Classified as Official Action Indicated	Number of State Inspections Classified as Official Action Indicated
2004	540	118
2005	425	113
2006	323	124
2007	244	32
2008	266	12
2009	371	47
Average from 2004 to 2009	**362**	**74**

*Food and Drug Administration.

Source: Office of Inspector General analysis of FDA data, 2010.

APPENDIX E

Table E-1: Audits Completed for the 2009 Contract Year, by State

State	Minimum Number of Audits Required	Number of Required Audits Completed	Additional Audits Completed	Met the Minimum Audit Rate?
Alabama	12	5	0	No
Alaska	20	20	0	Yes
Arkansas	4*	4	10	Yes
California	23	18	0	No
Colorado	14	14	0	Yes
Connecticut	4	4	0	Yes
Florida	34	34	0	Yes
Georgia	15	15	4	Yes
Illinois	27	18	0	No
Iowa	10	3	0	No
Kansas	8	4	0	No
Kentucky	9	9	1	Yes
Louisiana	14	14	0	Yes
Maine	2	2	0	Yes
Maryland	12	12	2	Yes
Massachusetts	10*	10	2	Yes
Michigan	28	28	1	Yes
Minnesota	7*	7	16	Yes
Mississippi	7	7	2	Yes
Missouri	6*	6	0	Yes
Montana	1*	1	2	Yes
Nebraska	9	3	0	No
Nevada	10	0	0	No
New Jersey	20*	20	0	Yes
New York	26	26	1	Yes
North Carolina	17	17	1	Yes
Ohio	35	35	0	Yes
Oklahoma	21	4	0	No
Oregon	52	52	0	Yes
Pennsylvania	7	6	0	No
Puerto Rico	6	6	0	Yes
Rhode Island	10	6	0	No
South Carolina Department of Agriculture	8	6	0	No
South Carolina Department of Health	2	2	2	Yes
Tennessee	12	12	1	Yes
Texas	35*	34	0	No
Vermont	1	1	0	Yes
Virginia	32	23	0	No
Washington	38	38	3	Yes
West Virginia Department of Agriculture	3	0	0	No
West Virginia Department of Health	5	5	1	Yes
Wisconsin	20	20	0	Yes
Wyoming	2	2	0	Yes
Total	**638**	**553**	**49**	

One of the two agencies in South Carolina and in West Virginia failed to meet the audit rate; in these instances, we counted the State as having failed to meet the audit rate.

*The Food and Drug Administration (FDA) lowered the minimum audit rate for this State.

Source: Office of Inspector General analysis of FDA's audit forms and documentation, 2010.

APPENDIX F

Agency Comments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

DATE: October 28, 2011

TO: Deputy Inspector General for Evaluations and Inspections, OIG

FROM: Acting Associate Commissioner for Policy and Planning, FDA

SUBJECT: FDA's Response to OIG's draft report entitled, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections,* OEI-02-09-00430

FDA is providing the attached response to the Office of Inspector General's draft report entitled, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections,* OEI-02-09-00430.

FDA appreciates the opportunity to comment on this draft report.

/S/

David Dorsey, J.D.

Attachment

The Food and Drug Administration's General Comments to the Office of Inspector General's Draft Report Entitled, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections (OEI-02-09-00430)*

The Food and Drug Administration (FDA or the agency) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections*. Collaboration with our state partners is critical to an integrated national food safety system and also is mandated under the FDA Food Safety Modernization Act (FSMA). FDA has worked since 2006 to develop and implement state inspection standards and more recently to help strengthen states' infrastructures. FDA oversight of state inspection programs also is critical, and the agency is strengthening its oversight to ensure that state regulatory programs are able to verify that the food industry is complying with food safety requirements.

Building an integrated national food safety system based on both collaboration and leveraging of federal and state information and regulatory findings has long been a foundational element of FDA's strategy for supporting an effective and efficient food safety program. Building that food safety system, which is one of the key mandates of FSMA, is premised on full strategic and operational partnerships with state and local food safety agencies – an effort in which FDA has been engaged for the last decade, most recently through the Partnership for Food Protection and the development and implementation of the Manufactured Food Regulatory Program Standards (MFRPS). The MFRPS establishes a uniform foundation for the design and management of state programs responsible for the regulation of food plants and is comprised of 10 critical standards, including staff training, quality assurance, laboratory resources and program assessment. FDA's oversight of state regulatory programs, including the state inspection contracts and the inspection information that FDA receives through these contracts, enables FDA and the states to leverage knowledge, outcomes and successes to strengthen the nation's regulatory system and maximize the safety of the foods consumed by the American public.

The current oversight program is in transition, and although FDA continues its long-standing program audits of state inspections, the agency is moving forward to fully implement MFRPS. MFRPS also promotes the development of a high-quality state manufactured food regulatory program and includes a process for continuous improvement based upon quality management systems. As part of its work to implement MFRPS, FDA is staffing an auditing group that will provide independent assessment and verification of compliance with the program standards by state agencies. To evaluate the state programs' progress, FDA will conduct program assessment validation audits at 18 and 36 months and a comprehensive audit at 60 months after the state programs have initiated implementation of the standards. As part of these audits, FDA will review the records and supporting documents to determine if the state programs have achieved the applicable standards.

In 2011, FDA provided additional financial resources to state programs implementing MFRPS to assist them in their efforts to comply with the standards. FDA provided this funding both to enhance MFRPS implementation in general and to specifically support laboratory accreditation. Currently, 38 manufactured food regulatory programs in 37states are implementing MFRPS.

FDA continues to rely on state-developed information and evidence to inform FDA operations and decisions and to support the collective public health food safety mission. Although the history of relying on state-developed information and evidence spans many years, FDA updated the Regulatory Procedures Manual in 2010 to reflect the agency's position that FDA can rely on state evidence to support administrative regulatory actions, and this new procedure now ensures that state data used to support such actions appropriately meet all agency regulatory standards. In fiscal year 2011, FDA developed more than 50 cases, ranging from an advisory letter to an injunction, using state evidence as the sole or supportive source of evidence. In addition, FDA has issued three warning letters this year by FDA based solely on state-developed evidence. These actions demonstrate FDA's commitment to leverage state inspections while ensuring appropriate oversight to meet regulatory requirements.

Recommendation 1: Ensure that all contract inspections are completed, properly documented, and appropriately paid for.

FDA concurs with this recommendation and is committed to ensuring that all state contract inspections are properly issued, completed, reviewed, documented, and paid for. FDA is conducting a systematic review of the overall state contracting program to ensure that expectations, roles, responsibilities, and process steps are clearly defined. FDA will also ensure that processes are established to periodically review contract data. Additionally, the contract language will be reviewed and modified as necessary to ensure an accurate definition of the contracted work product.

The review of the contracting process will include steps for tracking receipt and review of inspection reports received from state contractors, assuring that report data are entered into the appropriate FDA databases, and verifying that the contract work is completed before FDA makes payments. To further enhance FDA's management of the state contracting process, FDA is implementing new components of an information technology system that will integrate regulatory data across FDA and state programs and improve the process for managing such data.

In addition, FDA has instituted practices to ensure that it reviews all contracts before they are issued to confirm that the contractor has made an election to either include or exclude inspection visits in the number of inspection units included in the contract cost proposals. This change will provide clarity about whether the contractor can invoice and receive compensation for inspection visits.

Recommendation 2: Ensure that contract inspections are properly classified in accordance with FDA Guidance.

FDA concurs with this recommendation. Proper classification of contract inspections is a key component to oversight of state inspections, and FDA has increased internal communications to clarify the existing guidelines for FDA district office classification of state contract inspections found in FDA's Field Management Directive (FMD) 86, "Establishment Inspection Report Conclusions and Decisions." FDA is currently revising the directive to emphasize more clearly that classifications must be accurate, timely and uniform. Once they are completed, FDA will issue these revisions to all FDA district offices and post them on FDA's web site to ensure that

FDA staff is aware of the updated guidelines. FDA will also establish an outreach schedule to explain the revisions to all key stakeholders within FDA district offices.

Recommendation 3: Ensure that all inspection violations are remedied by routinely tracking all actions taken to correct violations.

FDA agrees with this recommendation to track most violative inspections and the remedies taken by industry to correct the violations. However, FDA notes that certain violations may not be suitable for inspection follow-up, and other approaches may be used to track such violations.

To improve tracking of violative inspections, FDA is evaluating and modifying existing procedures to incorporate requirements for tracking state follow-up and actions to correct violations; establishing timeframes for review and follow-up; establishing an alert system framework to notify FDA if timeframes are exceeded; and developing systems and processes to help the agency effectively monitor the status of state actions.

Standard 6 of the MFRPS sets forth the compliance and enforcement foundation for the state programs implementing the standards. The programs must establish and manage strategies, procedures and actions to enforce the laws and regulations for compliance and enforcement programs. These procedures and actions include developing and implementing written enforcement strategies; tracking critical and chronic violations and violators; using a risk-based system to determine when a directed investigation, follow-up, or re-inspection is needed; and establishing a timeline for progressive actions. These procedures and actions also include a system to communicate verbal and written policy and guidance to staff and to conduct an annual review of enforcement actions to identify improvements, modify procedures, and develop enforcement strategies. FDA audit staff will assess the states' adherence to their established compliance policies and procedures during program assessments, which will provide FDA with additional mechanisms to ensure facilities have implemented appropriate corrective actions.

Recommendation 4: Ensure that the minimum audit rate is met in all states.

FDA concurs with this recommendation to ensure audit rates are met under the current performance audit system and guidance in FMD 76. Conducting audits of state contract inspections are an important component of the existing oversight system and serve to assess their quality and further develop and maintain alignment between federal and state inspection programs.

Contracted inspections are subject to performance audits through FMD 76. Trained FDA or state personnel perform the audits and tabulate the results on an annual basis. FDA establishes minimum audit rates necessary to provide the appropriate level of oversight for each state program. FDA is reviewing the current reporting requirements to ensure that audits are completed and tracked to verify compliance with the requirements of FMD 76.

In addition, MFRPS provides a framework for FDA to ensure a larger foundation of quality attributes in the development of regulatory policies, training, inspection, program audit, food borne illness outbreak response, compliance and enforcement, industry and community relations,

program resources, laboratory support and program assessment. Each standard includes self assessment worksheets and forms to determine the level of conformance with each standard. A state program is required to develop an improvement plan that identifies gaps and details strategies to advance conformance with the standard for any program element that fails to meet the requirements of the standard. The state programs' periodic self assessments and program assessment validation audits, together with the comprehensive audits conducted by FDA, will determine if the self-assessment and improvement plans accurately reflect the state programs' level of conformance with each of the standards.

Recommendation 5: Address any systemic problems identified by audits.

FDA concurs with the recommendation to address systemic problems identified by audits, either under the current system or under the MFRPS, and is committed to improving the process related to the remediation of these issues. FDA will continue to develop processes and procedures to ensure that systemic problems are identified and the agency or the implicated state program establishes and implements corrective action plans to remediate the concerns identified. FDA acknowledges that results of audits may reveal a systemic problem in a single state or could be indicative of a systemic problem across the program. Toward this end, FDA will continue to review the results of individual and program audits to identify specific trends and implement the appropriate corrective action plan to address individual program problems as well as those at a national level. In addition, FDA will continue to evaluate existing business processes and procedures to ensure that they are clear, concise, and comprehensive, and that training, tracking and reporting requirements are fulfilled.

ACKNOWLEDGMENTS

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meridith Seife, Deputy Regional Inspector General.

Vincent Greiber served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to the report include Levita Lowe, and Bailey G. Orshan; central office staff who contributed include Kevin Farber and Sandy Khoury.

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.