OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

Overcoming Obstacles to Measuring Compliance: Practices in Selected Federal Agencies

Report No. 2007-P-00027

June 20, 2007

Report Contributors: Manju Gupta
Jeffrey Harris
Jeffrey S. Hart
Danielle Tesch

Abbreviations

APHIS	Animal and Plant Health Inspection Service
AQIM	Agricultural Quarantine Inspection Monitoring
BLS	Bureau of Labor Statistics
CFR	Code of Federal Regulations
DOL	Department of Labor
DOT	Department of Transportation
EPA	U.S. Environmental Protection Agency
ESA	Employment Standards Administration
FMCSA	Federal Motor Carrier Safety Administration
GAO	Government Accountability Office
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
ICR	Information Collection Request
ISS-2	Inspection Selection System
MCMIS	Motor Carrier Management Information System
OECA	Office of Enforcement and Compliance Assurance
OIG	Office of Inspector General
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
SAMHSA	Substance Abuse and Mental Health Services Administration
SafeStat	Motor Carrier Safety Status Measurement System
USDA	United States Department of Agriculture
WHD	Wage and Hour Division

Cover illustration: Various examples of graphs
(Source: National Center for Education Statistics)

U.S. Environmental Protection Agency
Office of Inspector General

2007-P-00027
June 20, 2007

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

The objective of this review was to collect successful practices from Federal agencies similar to the U.S. Environmental Protection Agency's (EPA's) Office of Enforcement and Compliance Assurance (OECA) that extensively use statistical methods, including random sampling, to measure and ensure compliance and to monitor regulatory programs.

Background

OECA faces many obstacles in measuring compliance across its regulated universe. These include limited knowledge of its large universe, limited resources, and difficulties in collecting data from States through random inspections and other means. These obstacles have prevented OECA from calculating compliance rates for the populations within its regulated universe and from demonstrating changes in compliance and trends.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:
www.epa.gov/oig/reports/2007/20070620-2007-P-00027.pdf

Overcoming Obstacles to Measuring Compliance: Practices in Selected Federal Agencies

What We Found

Federal regulatory agencies with missions and obstacles similar to EPA use statistical methods to generate compliance information. They use this information to monitor their enforcement and compliance programs and demonstrate program results. These Federal programs extensively use statistical methods to identify and analyze risk, set goals, develop strategies to manage the most significant risks, and report their accomplishments. While the programs we reviewed face similar obstacles as OECA, they use practical approaches to overcome these obstacles that OECA could potentially apply to its programs.

Other programs apply statistical methods, such as selective random inspections, to develop and publish compliance and other rates for their regulated populations. Some programs collect data through national surveys, while others require States to submit data as a condition of grant agreements. Programs leverage resources by working with statisticians from other offices within their agencies, as well as with statisticians from universities and external research centers. Programs found that having a champion in senior management within their agency is essential to overcome resistance to change and to adopt new methods.

Programs do not use statistical methods solely for reporting compliance rates. Programs reported that other benefits include identifying previously unknown risks, quantifying results, verifying the effectiveness of targeting schemes, and maximizing limited resources.

What We Recommend

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance establish a plan of action, with milestones, to incorporate using statistical methods to demonstrate the results of EPA's enforcement and compliance strategies. In addition, OECA can coordinate with the in-house statistical expertise available in EPA's Office of Research and Development and Office of Environmental Information to help develop statistical models and evaluate external proposals. The Agency accepted our recommendations.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

June 20, 2007

MEMORANDUM

SUBJECT: Overcoming Obstacles to Measuring Compliance:
Practices in Selected Federal Agencies
Report No. 2007-P-00027

FROM: Wade T. Najjum
Assistant Inspector General, Office of Program Evaluation

TO: Granta Y. Nakayama
Assistant Administrator, Office of Enforcement and Compliance Assurance

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. The report represents the opinion of the OIG and does not necessarily represent the final EPA position. EPA managers will make final determinations on matters in this report in accordance with established resolution procedures.

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $440,022.

Action Required

In accordance with EPA Manual 2750, you are required to provide a written response to this report within 90 calendar days. You should include a corrective actions plan for agreed upon actions, including milestone dates. We have no objections to the further release of this report to the public. This report will be available at http://www.epa.gov/oig.

If you or your staff have any questions, please contact me at (202) 566-0832 or najjum.wade@epa.gov; or Jeffrey Harris, Director for Program Evaluation, Cross-Media Issues, at (202) 566-0831 or harris.jeffrey@epa.gov.

Table of Contents

Chapters

Appendices

Chapter 1
Introduction

Purpose

The objective of this review was to collect successful practices from agencies similar to the U.S. Environmental Protection Agency's (EPA's) Office of Enforcement and Compliance Assurance (OECA) that extensively use statistical methods to measure, monitor, and report compliance levels. Specifically, we sought to answer the following questions:

- How have other Federal agencies used statistical methods to measure and ensure compliance?
- How did these other Federal agencies overcome the obstacles OECA currently faces to using statistical methods to measure compliance?

Background

OECA shares regulatory responsibilities with EPA regions and States. EPA's expenditures associated with improving compliance were $435 million, $437 million, and $489 million in fiscal years 2004, 2005, and 2006, respectively. OECA uses these funds for a variety of program activities, including categorical grants, civil and criminal enforcement, compliance incentives, and compliance monitoring.

Two recent Office of Inspector General (OIG) reports[1] found that OECA could not demonstrate changes in compliance levels of the diverse populations within its regulated universe,[2] and that OECA's publicly reported performance measures in fiscal year 2005 did not effectively characterize changes in compliance or other outcomes. OECA did not have current and complete data on either the regulated entities or changes in their compliance status. Also, OECA primarily reported completed activities (known as outputs or activity counts) rather than the results of the completed activities (known as outcomes). For example, OECA reported on the performance measure *Number of inspections/evaluations conducted by EPA*, but it could not determine the true state of compliance across programs in the regulated universe.

According to OECA, EPA and States do not have the resources to inspect every regulated entity for compliance with environmental statutes. States principally conduct targeted inspections at sites where they expect to find a violation

[1] EPA OIG Report No. 2005-P-00024, *Limited Knowledge of the Universe of Regulated Entities Impedes EPA's Ability to Demonstrate Changes in Regulatory Compliance*, September 19, 2005; and EPA OIG Report No. 2006-P-00006, *EPA Performance Measures Do Not Effectively Track Compliance Outcomes*, December 15, 2005.
[2] The term *universe* refers to the total number of facilities or entities subject to Federal statutes or regulations.

(facilities with a history of noncompliance). Compliance rates based solely on targeted inspections are biased and are likely not representative of the overall compliance in the regulated sector.

In contrast, compliance information derived from inspections based on random samples can help analyze the regulated community's overall compliance. Over time, this type of compliance information can also show trends and changes in noncompliance, which can help OECA identify emerging compliance problems that harm human health and the environment. Such data are central to making sound management decisions about strategic planning and resource allocation for regulatory programs.

The Office of Management and Budget (OMB) has directed OECA to develop performance metrics that measure compliance results, including statistically valid compliance rates based on random samples of regulated entities. At a minimum, OMB would like to see OECA make meaningful progress in expanding the use of statistical methods. OECA conducted several pilot studies between 2000 and 2004 to generate compliance rates for certain industries (e.g., petroleum refining, iron and steel manufacturing, and organic chemical manufacturing) and specific segments of regulated populations (e.g., combined sewer municipalities). OECA has not widely used compliance rates because of budget shortfalls and other resource, policy, and methodology obstacles.

In a September 2004 memorandum, OECA cited several obstacles to developing statistical methodologies that are applicable to larger segments of its regulated universe. OECA indicated in this memorandum that it:

- has limited knowledge about its large regulated universe;
- lacks in-house statistical expertise to develop statistical methods and resources to conduct nationwide inspections;
- experiences resistance from States to random inspections; and
- experiences challenges coordinating data collection from States.

We discuss OECA's obstacles and practices of other Federal regulatory programs that address these obstacles in detail in Chapter 2.

In the *2006-2011 EPA Strategic Plan*, OECA states that it plans to develop statistically valid noncompliance rates[3] for key populations within its national enforcement priority areas.[4]

[3] OECA defines *statistically valid noncompliance rates* as an estimate of the noncompliance for the entire population of regulated entities from a moderate-sized sample of inspections.

[4] OECA's national enforcement and compliance assurance program is responsible for maximizing compliance with 10 distinct Federal environmental statutes dealing with preventing and controlling air pollution, water pollution, hazardous waste, toxic substances, and pesticides. OECA organizes its work in two components: a limited number of national priorities that focus on significant environmental risks and noncompliance patterns, and core program activities that implement the requirements of all environmental laws and programs.

Scope and Methodology

OECA requested our assistance in developing statistically valid compliance rate methodologies for larger segments of its regulated universe. During preliminary research, we searched for compliance rates that States and other Federal agencies have calculated and reported. After preliminary analyses, we decided to focus only on Federal agencies because they are subject to similar challenges and reporting requirements as OECA. After talking with OECA officials, we decided to limit the scope of our evaluation to identifying Federal regulatory agencies that use statistical methodologies for implementing nationwide compliance monitoring and reporting. We conducted field work from June 2006 through August 2006, and performed our evaluation in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States.

We reviewed documents and interviewed program managers from selected health and safety compliance offices. While we initially identified more than five Federal agencies during preliminary research, we judgmentally limited our review to five programs that used statistical sampling methods to determine compliance levels, published compliance rates, and used the rates to manage their programs, and interviewed program managers from these programs (see Table 2-1 in Chapter 2).

We also reviewed documents provided by program managers in response to our questions. We analyzed information from the interviews and documents to identify practices that would be relevant and useful to OECA. We discuss these relevant practices in more detail in Chapter 2.

Appendix A provides more details on our scope and methodology, including the criteria used for selecting Federal agencies and the specific topics we discussed during the interviews. Appendices B and C provide detailed information about each program and selected bibliographic sources related to their programs, respectively.

Prior evaluations addressing OECA compliance measurement include the two EPA OIG reports cited in footnote 1, which outline OECA's difficulties in quantifying its regulated universe and demonstrating program outcomes with its current performance measures.

Chapter 2
How Federal Agencies Similar to OECA Measure Compliance Programs

Federal regulatory agencies that have similar missions and obstacles as OECA use statistical methods to generate compliance information. They use these methods to monitor their enforcement and compliance programs and demonstrate program results. Each Federal program regulates a large nationwide universe composed of diverse populations. Programs are subject to Federal budgetary constraints and share enforcement responsibilities with States and regions.

Other Federal Regulatory Programs with Missions Similar to OECA

OECA is responsible for enforcing compliance with regulations that support EPA's mission of protecting human health and the environment. To ensure compliance with environmental regulations, OECA conducts enforcement activities such as criminal and civil enforcement, compliance monitoring, compliance assistance, and providing compliance incentives. OECA monitors compliance by collecting information from States and regulated entities, as well as through inspections.

OECA and these other regulatory agency programs are subject to the Government Performance and Results Act (GPRA) of 1993, which requires Federal agencies to develop strategic plans, performance goals, performance measures, and report performance results. Federal agencies also submit their annual goals and report the outcomes of their program activities to OMB, emphasizing how program activities contribute to achieving performance goals.

We reviewed five Federal regulatory programs from four agencies with missions similar to EPA, e.g., protecting human health and/or safety, and safeguarding natural resources (see Table 2-1). Most programs we reviewed began incorporating statistical methods into their regulatory processes to report results in response to requirements of GPRA. Detailed descriptions of these programs are in Appendix B.

Table 2-1: Program Missions of the Five Federal Regulatory Agencies Reviewed

Agency – Program	Program Mission
United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS)	Safeguard agriculture and natural resources from risks associated with the entry, establishment, or spread of animal and plant pests and noxious weeds to ensure an abundant, high-quality, and varied food supply.
Department of Labor (DOL), Occupational Safety and Health Administration (OSHA)	Assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; and encouraging continual improvement in workplace safety and health.
DOL, Employment Standards Administration (ESA), Wage and Hour Division (WHD)	Administer and enforce several Federal labor laws, including minimum wage, overtime pay, recordkeeping, and child labor requirements of the Fair Labor Standards Act.
Department of Transportation (DOT), Federal Motor Carrier Safety Administration (FMCSA)	Reduce crashes, injuries, and fatalities involving large trucks and buses.
Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration (SAMHSA)	Build resilience and facilitate recovery for people with or at risk for substance abuse and mental illness.

Source: OIG summary of selected agency Websites and source material

OECA's Obstacles to Developing Compliance Rates

OECA identified several obstacles that inhibit its ability to measure and demonstrate changes in compliance. Some of the reasons OECA provides for not developing programmatic compliance rates are:

- OECA has limited knowledge of its large regulated universe, so it is difficult to select an accurate sample and develop a valid compliance rate;
- OECA finds national inspection-based rates for large populations cost prohibitive given its limited resources;
- OECA lacks internal statistical resources and expertise to develop sampling plans, identify sample sizes, and analyze results;
- States resist random inspections because they believe random inspections are not as effective as targeted inspections;
- OMB requires Federal agencies to file an Information Collection Request (ICR) to collect nationwide information from States, which delays and complicates collecting data from States; and
- Differences between EPA and State planning cycles make it difficult to schedule and complete the inspections needed for national compliance statistics.

Practices Other Federal Regulatory Programs Use to Overcome Similar Obstacles

The Federal regulatory programs we selected faced similar obstacles as OECA (see Table 2-2). Agencies, and States with delegated regulatory responsibilities, have integrated statistical methods into all phases of their program implementation and do not focus solely on producing and reporting compliance rates for individual projects. They use statistical models to stratify their large universes into risk groups and to evaluate the success of their targeting strategies. They selectively use random sampling to identify risks and to demonstrate program results.

Table 2-2: Other Federal Regulatory Agencies Have Faced Similar Obstacles

OECA's Obstacles	Did the Federal Regulatory Agency Face a Similar Obstacle?				
	APHIS	OSHA	WHD	FMCSA	SAMHSA
Limited Knowledge of Large Regulated Universe	Yes	Yes	Yes	Yes	Yes
Limited Resources					
• Inspection Resources	Yes	Yes	Yes	Yes	Yes
• Statistical Resources	Yes	Yes	Yes	Yes	Yes
States' Resistance to Random Inspections	N/A [a]	Yes	N/A [a]	Yes	Yes
Data Collection from States					
• OMB Information Collection Request (ICR) Restrictions	Yes	Yes	Yes	Yes	Yes
• Differences between EPA and State Planning Cycles	N/A	No [b]	N/A	No [b]	No [b]

[a] Federal agents conduct all of the inspections for APHIS and WHD. However, these programs also had to overcome resistance to including random inspections from management and agents.
[b] OHSA, FMCSA, and SAMHSA did not mention planning cycles as challenges to collecting data from States.

Source: OIG analysis of interviews with APHIS, OSHA, WHD, FMCSA, and SAMHSA

While we have not evaluated the validity of the statistical methods used by the other regulatory programs, the Government Accountability Office (GAO), OMB, and other external evaluators have reviewed these compliance programs and methods; they have taken no exceptions to using these statistical methods.

We discuss the practices the programs use to overcome obstacles cited by OECA (see Table 2-3 and following sections). We provide additional details about each

of the programs we reviewed in Appendix B. We also list selected sources for each of these programs in Appendix C.

Table 2-3: Summary of Practices Used by Other Regulatory Agencies to Overcome OECA's Cited Obstacles

OECA's Obstacles	How Other Agencies Overcame Similar Obstacles
Limited Knowledge of Large Regulated Universe	• Supplemented knowledge of the regulated universe from external sources
Limited Resources: Inspection Resources and Statistical Resources	• Collaborated with States in sharing inspections responsibilities • Collaborated with statistical resources in other parts of the agency, as well as external sources for statistical expertise
States' Resistance to Random Inspections	• Demonstrated additional benefits of statistical methodologies to overcome resistance • Obtained support and a champion at agency leadership level
Data Collection from States: OMB ICR Restrictions and Differences in EPA and State Planning Cycles	• Collected data from States through grants, ICRs, and contractors • None of the agencies mentioned differences in planning cycles as a barrier to collecting data from States

Source: OIG analysis of interviews with APHIS, OSHA, WHD, FMCSA, and SAMHSA

Using External Sources to Supplement Limited Knowledge of Regulated Universe

Similar to OECA, the agencies we reviewed each regulates a large universe. Because these programs also regulate large numbers of industries and facilities that constantly change in size, the exact size of their universe is often unknown. They supplement knowledge of their universe by obtaining information from other parts of their agencies, as well as from States that share enforcement and compliance responsibilities, and other available reliable databases. Some agencies require this information from States as part of grant agreements. Some agencies use outside sources (e.g., Dun & Bradstreet) and external contractors (e.g., universities and research groups) to survey their regulated universe and develop a compliance baseline for each universe.

- OSHA uses DOL's Bureau of Labor Statistics (BLS) database, as well as Dun & Bradstreet, for information on its regulated universe. OSHA's universe consists of approximately 7 million private workplaces in the United States. OSHA sends out an annual survey to 80,000-100,000 work sites along with BLS' annual survey to collect site-specific information. The survey helps OSHA identify establishments that have a higher likelihood of noncompliance.

Every year OSHA submits an ICR to OMB to collect site-specific injury and illness data from regulated entities. OSHA uses its administrative recordkeeping rule as justification for OMB's approval of its ICR.

- FMCSA has information on most of its regulated universe of large trucking and carrier companies because Federal regulations require every interstate trucking company to obtain a DOT registration number. Approximately half of States' motor vehicles departments require a DOT registration number before issuing license plates to large trucks or carriers.

- SAMHSA identifies its universe of retail establishments selling tobacco products by requiring States to prepare lists of such retailers. SAMHSA requires this information as part of its grants to States for program implementation.

- APHIS collaborates with the Bureau of Customs and Border Protection to identify its universe of passengers and cargo entering the United States. APHIS also collaborates with field office staff to help identify all possible pathways and their respective sources of risk. APHIS defines *pathway* as a route through which agricultural risks enter into the United States, e.g., air carriers, trucks, cars, and ships.

- WHD uses several sources to identify the variety of populations within its universe that are subject to the Federal Fair Labor Standards Act regulations. WHD uses data from BLS, State licensing offices, and commercial databases, including Dun & Bradstreet, for conducting statistically valid, investigation-based compliance surveys to determine industry compliance rates.

Collaborating to Overcome Resource Limitations

Similar to OECA, the other Federal programs we reviewed have resource limitations, in terms of their Federal budgets, staff, and in-house statistical expertise. However, these agencies leverage their resources through collaboration with their State partners and other stakeholders to develop statistically valid compliance information. Four of the programs use statistical expertise found in other parts of their agencies, e.g., other programs within their agency, field offices, and research centers. Three programs also use external statisticians from universities and independent research centers.

- FMCSA provides current monthly compliance and safety data on its Website. It requires States to input inspection data into FMCSA's Motor Carrier Management Information System (MCMIS) database as a condition of the grants it provides to States. All States provide the data in accordance with uniform data standards for crash and accident data. FMCSA developed these standards in collaboration with the National Governors' Association and the Commercial Vehicle Safety Alliance. States conduct the majority of roadside

inspections and submit inspection data. FMCSA has also trained some State agents to conduct compliance reviews. FMCSA uses the statistical expertise of DOT's John A. Volpe Research Center for statistical models and data analyses.

- APHIS collaborated with the former U.S. Customs Service to develop and test the initial Agriculture Quarantine and Inspection Monitoring (AQIM) methodology. APHIS uses the statistical resources of the USDA National Agriculture Statistical Services to review agriculture inspection data. APHIS also works with its field personnel to enumerate risks to agricultural and natural resources from each pathway. Federal inspectors conduct all regularly scheduled and additional random inspections associated with AQIM activities.

- OSHA uses the resources of statisticians from BLS, in addition to the occupational injury and illness data submitted to BLS by regulated establishments. Further, with a few exceptions, OSHA uses its limited inspection resources to inspect only in those States without State Plan certification. OSHA relinquishes its inspection authority to the States that receive certification. The Directorate of Cooperative and State Programs (a separate group within OSHA) oversees the State Plan States. It has delegated the authority for monitoring State Plan States to OSHA's 10 regional offices. Although States are not subject to GPRA, OSHA works collaboratively with States to develop State-specific multi-year and annual strategic plans. OSHA requires submission of these plans by States as a part of their annual applications for OSHA's State Plan grants.

- WHD uses its resources to enforce regulations under the Federal Fair Labor Standards Act, whereas States enforce their individual State labor laws. Federal inspectors conduct all Federal inspections. WHD uses the University of Tennessee's Construction Industry Research and Policy Center to analyze compliance data and provide other statistical services. WHD conducts national surveys to develop a baseline of compliance information for selected industries. WHD publishes these compliance rates by region and industry.

- SAMHSA provides inspection resources to States to conduct random inspections and develop lists of retailers selling tobacco. SAMHSA develops and provides training and statistical models to States. SAMHSA requires States to use approved protocols for sample selection. States submit compliance data as a condition of the annual grant. SAMHSA collaborates with other stakeholders such as retailers, community groups, and parents by providing training materials, encouraging alertness during State inspections, and encouraging accuracy in State reporting.

Collaboration with States, internal agency departments, other Federal agencies, and external stakeholders helped the agencies we reviewed overcome multiple resource limitations. The programs we reviewed emphasize the need for

collaboration and cooperation with States in using uniform data standards and inspections protocols. Collaboration with States can also leverage resources for inspections. These programs also emphasize the need for collaboration with other agency offices in developing statistical methods and analyzing data.

Within EPA, we identified statistical resources from the Office of Research and Development and the Office of Environmental Information that can assist OECA in developing statistical models and in evaluating methods proposed by external statisticians.

Demonstrating Benefits of Statistical Methodologies to Overcome Resistance

According to OECA, States resist changing their methodologies from targeting facilities with known or suspected violations to including random selections of facilities for inspections. States anticipate that some randomly selected sites may not have violations, and that they use their limited resources more efficiently if they go after facilities with known or suspected problems.

All the programs we reviewed encountered initial resistance to random inspections from senior management, field staff, and/or States. Most programs mentioned two significant factors that helped in overcoming the resistance: (1) demonstrating the additional benefits of statistical methods, and (2) having a champion in the agency leadership ranks.

The programs overcame resistance to random sampling by demonstrating additional benefits of conducting random inspections. These benefits include identifying previously unknown risks, verifying sources of risk, showing differences in compliance among regions and industries, and quantifying program results.

- OSHA, WHD, FMCSA, SAMHSA, and APHIS quantified risks to human health, safety, and agricultural resources by including statistical methods, such as additional random inspections, in the inspection process. WHD, FMCSA, and APHIS mentioned that they overcame resistance, and won management support for random inspections, by demonstrating that random inspections can verify known risks, identify unknown risks, demonstrate the status of compliance for the regulated universe, and identify regional or industry differences in compliance levels. Recognizing that differences exist between regions and industries allows programs to develop management solutions to improve compliance specific to regions or industries. They were better able to identify the regional nature of certain problems, to focus limited resources on areas that need the most compliance monitoring and assistance. For example, WHD initially focused limited resources on three industries with the largest number of low-wage workers and a high incidence of noncompliance with minimum wage and overtime regulations. For these industries, WHD

identified the causes of noncompliance and developed strategies to address differences in regional compliance rates.

- APHIS and WHD demonstrated to inspectors (who target entities based on past compliance history and professional judgment), that statistical methods can confirm their "gut feelings" or suspicions. APHIS and WHD also showed inspectors that statistical methods help quantify the improvements in local compliance levels resulting from their enforcement activities.

Championship and commitment from agency leaders also helped the agency programs overcome the initial resistance to incorporating random inspections into the inspection process. A champion in senior management can advocate using statistical methods to States and other program offices, reallocate existing resources for developing and implementing statistical methods, create opportunities for collaboration with internal and external stakeholders, and facilitate data collection efforts.

All five of these programs conduct randomly sampled inspections in conjunction with complaint-based inspections and inspections of known noncompliers. The programs mentioned that combining targeted inspections with randomly sampled inspections helped them use limited enforcement resources more effectively. For example, OSHA allocates 55 percent of its resources to conducting inspections from statistical samples, and the other 45 percent to conducting inspections based on complaints and prior knowledge of violations. All the programs generate the rates that are most significant to meet their program mission and goals. They do not develop compliance rates for all of the populations within their universe. They develop a limited number of rates for populations that they select based on risk assessment.

Programs we reviewed stress the need to set realistic goals when applying statistical methods to populations within their large universes governed by complex regulations. The programs initially conducted random samples or national surveys on a few areas that had high risk, or widespread incidence of noncompliance. After building national baselines, these agencies selected additional industries or sectors for which to conduct random inspections and surveys, and to develop statistically valid compliance rates. WHD found that annual surveys do not allow sufficient time to analyze the results of surveys, determine the causes for noncompliance, develop and implement interventions to improve compliance. As a result, WHD changed its survey strategy to conduct followup reviews in 5-year intervals.

Using Grants, ICRs, and Contractors to Collect Data from States

OECA needs the compliance data collected by States to create nationwide compliance statistics. According to OECA, States conduct most of the inspections at regulated facilities for EPA's delegated programs, but the applicable

statutes do not require States to submit data from all inspections to OECA. The data OCEA receives from States are also of an inconsistent quality. Specifically, OECA listed two obstacles related to collecting inspection and compliance data from States:

- The need to file an ICR with OMB delays and complicates coordination with States; and
- Differences in EPA and State planning cycles make it difficult to schedule and complete the inspections needed for a national compliance rate within a year.

The agencies we reviewed had a number of ways of gathering the data needed to produce compliance rates.

- OSHA uses an administrative record-keeping rule that justifies the need for OSHA to gather injury and accident data from establishments. OSHA submits an ICR to OMB annually to collect such site-specific data from regulated entities for managing its compliance program. OSHA also requires annual goals and performance reports from States as a part of the States' grant applications. FMCSA and SAMHSA require States to submit data and/or compliance rates as part of grant agreements. WHD does not need an OMB-approved ICR to conduct investigation-based surveys because the statute authorizes WHD to conduct such investigations. WHD uses a university research center to conduct the surveys to collect and analyze data.

- None of the agencies mentioned differences between Federal and State planning cycles as a challenge to scheduling or completing inspections needed for compliance statistics. These agencies emphasized that cooperation and collaboration with States and grant agreements are effective ways to obtain State compliance data.

Using record-keeping rules, data-reporting requirements in grant agreements, ICRs, and outside contractors allows agencies to obtain the data needed for calculating rates (including compliance rates) that identify risks and demonstrate program outcomes. Agencies that collect data through grant agreements can also require that the data meet certain standards, which can help to build a reliable database. Most programs provide funding to States through grants to implement compliance and enforcement programs. They utilize the grants agreements as instruments to obtain compliance data from States.

Conclusion

Based on our review of five comparable Federal regulatory programs, we believe that OECA can overcome its stated obstacles to develop statistical estimates of compliance. Other agencies have encountered similar obstacles, but have adopted statistical methods to manage and monitor their compliance programs. Use of random samples can assist OECA in risk assessment by identifying previously

unknown sources of risk, as well as help in evaluating the effectiveness of its inspections targeting. OECA can use the results of statistical methods to monitor and demonstrate the results of compliance and enforcement strategies.

OECA needs to commit to a practical approach and develop a plan of action with milestones. OECA can begin by establishing a set of incremental goals for a few areas of high environmental risk. Steps can include updating the knowledge of the populations in its universe, developing statistical samples for the selected areas, collaborating with and overcoming resistance from States, developing tools to collect data from States (e.g., grant requirements, ICRs), and requiring reliable compliance data from States. OECA can obtain in-house statistical support from EPA's statisticians in the Office of Research and Development and the Office of Environmental Information in developing statistical models and evaluating methods proposed by external statisticians.

Recommendations

We recommend that the Assistant Administrator for Enforcement and Compliance Assurance:

2-1 Establish a plan of action with milestones to incorporate using statistical methods to demonstrate the results of EPA's enforcement and compliance strategies.

2-2 Coordinate with the in-house statistical expertise available in EPA's Office of Research and Development and Office of Environmental Information to help develop statistical models and evaluate external proposals.

Agency Comments and OIG Evaluation

OECA accepted both of our recommendations; we have included their comments in Appendix D. Based on OECA's comments, we made changes to the report as appropriate.

In response to the first recommendation, OECA stated that it has committed to OMB to expanding the use of statistical methods for specific national priority and problem areas. OECA is currently conducting two related reviews in order to develop an action plan for OMB. The reviews relate to strategies for national priorities and problem areas for the fiscal years 2008-2010 planning cycle and revision of compliance objectives to focus on national priority and problem areas rather than on program tools. In response to the second recommendation, OECA agreed to examine the level of expertise and the types of services that EPA's in-house statisticians from the Office of Research and Development and the Office of Environmental Information can provide.

OECA's commitment to expand the use of statistical methods to focus on national priority areas is an encouraging first step. We have provided examples of approaches other agencies have taken to overcome similar difficulties as OECA has faced. OECA can obtain more details from these sources and potentially apply these approaches to its programs. OECA should incrementally develop a strategy for expanding the use of statistical methods for management of the core program activities where feasible. In OECA's written response to this report, we will be looking for (1) a Corrective Action Plan with milestones—potentially a reiteration of actions previously committed to OMB, and (2) information regarding the status of compliance in core program activities.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
2-1	13	Establish a plan of action with milestones to incorporate using statistical methods to demonstrate the results of EPA's enforcement and compliance strategies.	O	Assistant Administrator for Enforcement and Compliance Assurance			
2-2	13	Coordinate with the in-house statistical expertise available in EPA's Office of Research and Development and Office of Environmental Information to help develop statistical models and evaluate external proposals.	O	Assistant Administrator for Enforcement and Compliance Assurance			

[1] O = recommendation is open with agreed-to corrective actions pending;
C = recommendation is closed with all agreed-to actions completed;
U = recommendation is undecided with resolution efforts in progress

Appendix A

Details on Scope and Methodology

Criteria Used to Select Federal Regulatory Agencies

During preliminary research, we searched for compliance rates reported by State and Federal agencies. We identified 18 States that reported compliance rates. We surveyed seven of these States to determine if State agencies use statistical methods to measure compliance. We found that few States use statistical methods for measuring compliance and therefore did not include States in our evaluation. Additionally, we found that OECA was already collecting such information from States. After talking with OECA officials, we limited the scope of the evaluation to identifying successful practices from other Federal agencies.

While we initially identified more than five Federal agencies during preliminary research, we used the following criteria to limit our scope to those Federal regulatory agencies or programs that are most applicable to OECA's enforcement situation:

- The agency/program has **regulatory responsibilities** for enforcing/assuring compliance with statutes/regulations (can be within a single program area or multiple program areas);
- The agency/program has a **mission related to human health, safety, or the environment**;
- The agency/program has a **large regulated universe**;
- The agency/program has a **national scope focused across States and/or regions**;
- The agency/program **uses (or has used) statistical sampling methods** for determining compliance with statutes/regulations;
- The agency/program has **developed/published compliance rates**; and
- The agency/program **uses compliance rates as an outcome measure** to manage the agency/program.

We judgmentally selected five Federal regulatory agencies for further review (see Table 2-1).

Interviews with Program Managers

We interviewed program managers from five Federal agency programs to gain a better understanding of the statistical methods they use, the purpose for which they use the methods, and how they use statistics for measuring and reporting on compliance, including developing compliance rates. We requested information on the following topics from all of the agencies/programs:

- **Background Information:** Background on what initiated the need for developing statistically valid rates, knowledge of the composition and size of the regulated universe, and shared enforcement/ inspection responsibilities with States.
- **Resources Used:** Resources used in the development of the statistical methodology; statistical expertise used (in-house or external contractors); full-time equivalents, money, time, etc.; and resources needed to calculate the rate on a continuous basis.

- **Description:** Description of the methodology, data sources, and data quality.
- **Benefits and Uses:** How does the agency use the statistically valid rates, what benefits has the agency experienced using the methodology, and what lessons have been learned from using the methodology.
- **Opportunity Costs:** How does the agency balance the need for targeted sampling with the need for statistically valid sampling.
- **External reviews (or related reports):** Have the agency's methodologies been reviewed.

We also reviewed documents that the program managers provided in response to our questions. We analyzed information from the interviews and documents to identify practices that would be relevant and useful to OECA. We discuss these relevant practices in Chapter 2.

Analysis of Interview Responses

We prepared a table that compared interview responses for 17 variables among the five Federal regulatory agencies we interviewed. We shared our analysis of interview responses with Federal agencies and requested that they verify the information we are including in this report. This information is available in Appendix B.

Scope Limitations

The purpose of this project was to focus on the statistical methods other regulatory agencies use for monitoring and reporting compliance. We did not review the management controls of OECA or the other agencies. We relied on information from interviews with program managers, documents provided by the managers, and other resources available on the identified Federal agencies' Websites. While we confirmed the accuracy of our information with each individual agency, we did not independently verify this information or evaluate the validity of their selected statistical methods. However, GAO, OMB, and other external evaluators have reviewed these compliance programs and methods; they have taken no exceptions to the use of these statistical methods.

As coordinated with OECA, we did not evaluate OECA's current methodology for developing compliance rates; therefore, we also did not compare its methodology with methodologies from other agencies. We selected regulatory agencies with missions related to human health, safety, and the environment, but did not determine which statistical methods for measuring compliance might be most suitable for OECA.

Appendix B

Federal Regulatory Agency Programs Reviewed by OIG

We provide below brief descriptions of the Federal regulatory agency programs we reviewed. Table B-1 provides more details on each program.

United States Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine

APHIS calculates two compliance rates: the "actual" and the "predicted" entry rates of pests and diseases through a pathway. APHIS bases the actual entry rate on programmed inspections and the predicted entry rate on additional random inspections conducted through APHIS' AQIM activities. APHIS initiated its effort to use statistical methodologies after Congress passed GPRA in 1993. The purpose of conducting AQIM activities is to identify the pathways that pose the most risk of introducing pests or disease to U.S. agricultural resources. APHIS works with field personnel in performing the risk assessments

Department of Labor, Occupational Safety and Health Administration

OSHA calculates and publishes national injury and illness rates. OSHA requires regulated establishments with more than 40 employees to submit injury and illness rates annually; OSHA conducts random inspections or compliance reviews of regulated establishments with rates higher than two times the national average. OSHA also provides compliance assistance to establishments out of compliance with regulations. OSHA monitors the progress of 10,000–11,000 core establishments to measure injury and illness rates over time. OSHA selects establishments with injury and illness rates higher than two times the national average for random inspections.

Department of Labor, Employment Standards Administration, Wage and Hour Division

WHD measures compliance of establishments with Federal labor laws in order to ensure workers receive the wages due to them. For over a decade, WHD has used investigation-based surveys to accurately project compliance rates in a number of low-wage industries affecting a range of employees. Statistically valid investigation-based surveys (i.e., investigations of establishments that are not identified by employee complaint, anecdotal evidence, or investigator experience) provide an unbiased assessment of compliance.

The knowledge gained through statistically valid surveys helps WHD leadership make informed decisions, in particular, in determining priority areas for directed enforcement and in gaining insight into effective intervention tools. Survey findings resulted in national attention to specific industries and particular vulnerable employees within those industries (e.g., youth workers, low-

wage workers in particular industries). WHD also uses statistically valid surveys for reporting purposes to demonstrate the program's impact on compliance.

Department of Transportation, Federal Motor Carrier Safety Administration

FMCSA uses a number of performance measures for compliance reviews, roadside inspections, and traffic enforcement. In addition to measuring a large truck-related fatality rate, FMCSA determines compliance with individual Federal Motor Carrier Safety Regulations and individual Hazardous Waste Regulations with randomly selected roadside inspections. Data and information from these inspections assist FMCSA in selecting companies for on-site compliance reviews.

FMCSA selects for inspections companies that are most likely to have crashes, based on statistical analyses of performance statistics. It also selects companies for other reasons such as complaints, carrier requests, etc. FMCSA quantifies risks to human safety by including statistical methods and using the SafeStat Inspection Selection System (ISS-2). The ISS-2 is an automated, data-driven system that measures the relative safety fitness of interstate motor carriers using on-the-road safety, enforcement, and compliance review data. It provides relative ranking of motor carriers based on performance. The SafeStat system analyzes the prior 30-month history of State reported crashes, roadside inspections, compliance reviews, enforcement cases, and census data in the Motor Carrier Management Information System database. The data is time and severity weighted. FMCSA uses the results of these analyses as a tool in prioritizing motor carriers for compliance reviews and increased roadside inspections.

Department of Health and Human Services, Substance Abuse and Mental Health Administration

SAMHSA requires States to conduct unannounced random inspections of tobacco retailers to determine compliance with regulations prohibiting the sale of tobacco products to individuals under the age of 18. States report to SAMHSA the noncompliance rates, i.e., retailers that sell tobacco to minors. The Synar Amendment requires that compliance rates be statistically valid. SAMHSA then calculates a national noncompliance rate by assigning weights, based on State population, to the State noncompliance rates. Random inspections and reporting of the results is a grant requirement under the Substance Abuse Prevention and Treatment block grants States receive.

SAMHSA has an administrative record-keeping rule that outlines its need for data to manage its programs. SAMHSA analyzes the data in order to measure results and adjust compliance strategies.

Table B-1: Summary of Federal Regulatory Agency Programs Reviewed by OIG Evaluation Team

	USDA APHIS	DOL OSHA	DOL ESA WHD	DOT FMCSA	HHS SAMHSA
Agency Performance Goal(s)	• Mitigate and reduce agricultural risk entering into the United States	• Prevent job-related illnesses, injuries, and fatalities	• Ensure workers receive the wages due them according to Federal laws	• Reduce large truck-related fatality rate by 41% from 1996 to 2008, resulting in a 2008 rate of 1.65 fatalities per 100 million truck vehicle miles traveled	• Restrict sale of tobacco products to minors • Goal: Attain compliance by 80% of tobacco retailers, by reducing non-compliance below 20%
Agency Performance Measure(s)	• Actual entry rate of pests and diseases through a pathway • Predicted entry rate of pests and diseases through a pathway	• Injury rate • Illness rate	• Compliance rates of establishments withholding fair wages due to employees	• Large truck-related fatality rate • Compliance of individual commercial motor vehicles and drivers with Federal Motor Carrier Safety Regulations and Hazardous Materials Regulations	• Noncompliance rate of retailers who sell tobacco to minors
Who Conducts Inspections	• In 2003, inspection responsibilities were transferred to the Department of Homeland Security's Bureau of Customs and Border Protection	• State inspectors in States with approved State Plans; Federal inspectors in all other States	• Federal investigators conduct the investigation-based statistical surveys to determine compliance with Federal labor laws	• FMCSA provides funds to States through grants and requires States to enter safety and crash data from inspections into the MCMIS database • FMCSA conducts most of the compliance reviews of trucking companies, but some State officials are trained to conduct compliance reviews	• States conduct inspections of retailers selling tobacco that are also accessible to minors • SAMHSA provides funds for inspections through Substance Abuse Prevention and Treatment block grants
Role of the States	• No State involvement in the AQIM inspection or inspection monitoring processes	• Conduct inspections in States with approved State Plans • Feed inspection data into Federal data collection system • Develop strategic plans and present annual plans, as part of grant applications to OSHA	• States enforce their individual State labor laws; WHD may refer complaints to state labor agencies if appropriate.	• States conduct most of the approximately 3 million yearly roadside inspections • FMCSA provides funds to States through grants and requires States to enter safety and crash data from inspections into the MCMIS database	• States implement the program, report data and results to SAMHSA • States develop rates for known universe of tobacco retailers and submit them to SAMHSA annually • States compile the universe of retailers for their respective States

	USDA APHIS	DOL OSHA	DOL ESA WHD	DOT FMCSA	HHS SAMHSA
Oversight of States	• Not applicable - only Federal agents enforce these laws	• Three meetings per year between Federal OSHA and State Plan States	• Not applicable - only Federal agents enforce Federal laws	• The National Governors Association and Commercial Vehicle Safety Alliance developed uniform data standards • States use standardized computer software • Provides training to State inspectors	• SAMHSA monitors State inspections • Reduction in grant funds is the penalty for not meeting goals • Center for Substance Abuse and Prevention has an internal policy to monitor the States once every 3 years for onsite inspections
Regulated Universe	• Pathways through which risk can enter into the agriculture in the United States • Consists of 10 major pathways, i.e., ways passengers and cargo enter into the United States: air carriers, trucks, cars, ships, etc.	• Approximately 7 million private workplaces in the United States	• Universe includes a variety of industries with low-wage hourly workers such as agriculture, healthcare, garment manufacturing, grocery stores, nursing homes, and restaurants	• Approximately 685,000 to 700,000 interstate trucking companies	• States and territories compile lists of "eligible outlets," i.e., retailers that sell tobacco and are accessible to minors • Full universe may be unknown. Rates represent the universe of known eligible outlets • In response to the GAO review, Center for Substance Abuse and Prevention now requires States to conduct a study to validate their retailer lists for coverage and accuracy
Types of Inspections	• AQIM is an inspectional process where random samples are customized for each of the pathways • AQIM is conducted in addition to regular inspection activities	• Conducts safety and health inspections • Targeted inspections limited to establishments with more than 40 employees • By law OSHA must have administratively neutral selection criteria • 45% of inspections are unprogrammed (from complaints, referrals, fatalities, etc.) • 55% of inspections are programmed	• Conducts national investigation-based statistical surveys to monitor national, regional and local progress with labor regulations • Conducts directed and complaint-driven investigations • Approximately 75% of investigations are complaint-driven, 21% focus on low-wage industries, and 8-19% focus on recidivism	• FMCSA conducts roadside inspections and compliance reviews • FMCSA stratifies interstate trucking companies based on the data on safety records into four groups • The companies most likely to have crashes are selected for inspections and compliance reviews	• SAMHSA requires States to conduct inspections from random samples throughout the year • Inspections use minors that attempt to buy tobacco without any identification or without valid identification • States may conduct additional targeted inspections for improving compliance

	USDA APHIS	DOL OSHA	DOL ESA WHD	DOT FMCSA	HHS SAMHSA
Targeted Population	• Customized random samples for each of the pathways posing agricultural risk • AQIM Handbook outlines how to develop targeting plans for each of the pathways	• Establishments in selected industries with more than 40 employees • Industries targeted based on injury and illness rates reported by BLS • OMB limits OSHA's data collection to establishments with more than 40 employees • Excludes construction industry	• WHD develops targeting strategies for industries/ companies with high levels of noncompliance based on information from surveys • Industries that employ a large number of low wage hourly workers and low compliance rates (as suggested by WHD enforcement statistics) • Businesses that employ child labor	• Interstate trucking companies most likely to be involved in future crashes based on their safety statistics in the SafeStat database. • Companies with no data in the MCMIS database	• Retail establishments are selected from random samples • States may target retailers suspected of noncompliance in addition to the random inspections required by SAMHSA
How Establishments are Selected for Inspection	• Pathways prioritized based on risk after initial random samples help develop a first level of agricultural risk • Conduct additional AQIM inspections through statistical random sampling	• OSHA collects Injury and Illness Logs from all establishments in the targeted population • Establishments are required to keep Injury and Illness Logs by law • Establishments with Injury/Illness rates 2 to 3 times the national average receive letters encouraging them to use OSHA's free compliance assistance services (approximately 13,000-14,000 establishments) • Inspections conducted at 175 randomly selected establish-ments with low rates in industries with high rates • Inspections conducted at a random number of establishments that do not submit the required Injury and Illness Log *(continued)*	• WHD analyzes information from directed and complaint-driven investigations to identify potential areas of noncompliance • Statistically valid investigation-based surveys help identify noncompliance in populations that may not complain when there are violations • National survey findings show that particular sources of noncompliance may be more prevalent in some geographic locations • Surveys help develop future targeting strategies	• FMCSA ranks companies according to prior 30-month compliance history and severity of data • SafeStat, a computer algorithm, uses the compliance data collected by Federal and State agents and the crash/inspection data State agencies collect to create compliance percentile rankings of trucking companies • SafeStat stratifies companies according to safety records; the companies most likely to have crashes are selected for inspections and compliance reviews • Category A and Category B are the highest priorities (represent high risk); these companies become priorities for full onsite compliance reviews and inspections *(continued)*	• SAMHSA requires each State to prepare its own sampling plan that must meet 10 standards/ components before SAMHSA approves it • States can have separate plans to inspect known violators in addition to the SAMHSA required random inspections

	USDA APHIS	DOL OSHA	DOL ESA WHD	DOT FMCSA	HHS SAMHSA
How Establishments are Selected for Inspection ***(continued)***		• Inspections conducted at those establishments with a history of the most severe safety and health violations		• The Inspection Selection System (ISS-2) uses SafeStat results to generate red, yellow, or green light recommendations to assist States in selecting trucks for roadside inspections • Companies with no data in the SafeStat database receive a high risk rating, "red," rating from the ISS-2 that recommends State agents conduct a roadside inspection	
Collaboration	• Piggy-backed on a former Customs Service contract, utilizing the contracted statistician from George Mason University to review early sampling protocols • Assistance from USDA statisticians at the National Agricultural Statistics Service in developing and reviewing the methodology • Used external statisticians for developing the sampling frames for each pathway	• OSHA works collaboratively with States to develop annual and multi-year strategic plans • Works with BLS for data collection and annual estimation of rates • OSHA annually receives OMB approval to collect site specific information on injuries and accidents from establishments	• WHD works with approximately 750 investigators from five regions and 48 district offices • Federal investigators conduct the investigation-based statistical surveys • External statisticians develop a statistical methodology, draw a representative sample, and conduct in-depth analysis of statistically valid surveys	• FMCSA coordinates with State licensing agencies, who can require a U.S. DOT registration number from a company before licensing its trucks (Approximately half the States do this now) • States conduct the majority of roadside inspections conducted a year • John A. Volpe Center National Transportation Systems Center (Volpe Center), a DOT independent research center, was the primary contractor for the SafeStat system	• Consulted with external statisticians to develop the statistical sampling frame • SAMHSA provided guidance documents and training materials to States, community groups, and merchants • SAMHSA collaborates with community groups and parents by providing training to be alert and report violators

	USDA APHIS	DOL OSHA	DOL ESA WHD	DOT FMCSA	HHS SAMHSA
Benchmarking	• APHIS focuses on analyzing the reason(s) for the differences between two rates: - Actual rate that pests and diseases enter through a pathway, from regularly scheduled inspections - Predicted rate, from additional AQIM random inspections	• OSHA benchmarks the Federal States' progress against Federal OSHA's progress • OSHA tracks a core group of 10,000-11,000 establishments to measure injury and illness rates over time	• Uses national investigation-based statistical surveys to monitor national, regional, and local progress with labor regulations • WHD prepared baselines for targeted industries, and develops trends to show changes in compliance	• Goal to reduce large truck-related fatality rate by 41% from 1996 to 2008, resulting in a 2008 rate of 1.65 fatalities per 100 million truck vehicle miles traveled • Publishes rates on its Website, where the public, industry, and insurance companies can access performance information	• The goal of the program is to ensure nation-wide noncompliance no higher than 20% by 2000, from a baseline national rate of 42% noncompliance in 1996 • SAMHSA monitors a State's performance against the State's own benchmark
Other Inspection Program Components	• AQIM is an inspectional process conducted in addition to regular inspection activities • APHIS conducted AQIM activities with available resources • Identifying agricultural risks is statistically valid rather than risk known from previous experience • APHIS can objectively target the pathways posing the highest risk to agriculture; may include previously unknown risks • Develops rates quarterly	• Five national emphasis programs: exposure to lead, exposure to silica, amputations, trenching in construction, and the ship-breaking industry • Approximately 145 local emphasis programs	• Initially identified three industries and used national surveys to develop a compliance baseline: agriculture, the garment industry, and health care industry • The statistically valid surveys supplement targeted enforcement programs • Uses various sources to identify its universe: Dun & Bradstreet and State licensing agencies are used most frequently	• Maintained and used compliance rates internally since the 1980s • Publishes monthly updates of percentile compliance rates on its Website • Additional weight is not added for the size of the company; an internal process adds "a little more weight" for companies that haul hazardous waste and passengers • Roadside inspection data are very accurate because of conditions in the Motor Carrier Safety Assistance Program grant agreements • FMCSA provided approximately $185 million in 2005 to States to conduct roadside inspections	• SAMHSA also requires States to annually input the coded inspection data into SAMHSA's statistical package • From 1996 to 2000, the national average of retailer non-compliance decreased from 42% to approximately 19% • For 2006, the national weighted non-compliance rate was 10.9% • SAMHSA annually publishes noncompliance rates for each State in its Website
Statutory/ Regulatory Authority to Collect Data	• Supports the mission to mitigate and reduce agricultural risk entering into the United States	• Occupational Safety and Health Act of 1970 • Title 29 Code of Federal Regulations (CFR) 1904, Recording and Reporting Occupational Injuries and Illnesses	• Title 29 CFR 516, Records to be Kept by Employers (under the Fair Labor Standards Act)	• Title 49 CFR 350, Commercial Motor Carrier Safety Assistance Program • Data submission part of grants agreements	• Section 1926 of Public Health Service Act (Synar Amendment) • Title 45 CFR 96, Tobacco Regulation for the Substance Abuse Prevention and Treatment Block Grant

	USDA APHIS	DOL OSHA	DOL ESA WHD	DOT FMCSA	HHS SAMHSA
Analyses	• Uses data to identify the pathways that pose the highest risk • Uses data to verify that previously identified pathways posing risks to agriculture are still valid	• OSHA analyzes the data from BLS database • Collects information from sites • Uses statistical samples to select sites for inspections • Used external consultants for evaluating results of Site specific targeting methodology	• Federal investigators conduct surveys • External statisticians develop the statistical methodology, draw a representative sample, and conduct in depth analysis of statistically valid surveys • Independent analyses by: - University of Tennessee - Mathematica - Boston University	• Volpe Research Center analyzes data and conducts studies to assess the success of the compliance strategy	• SAMHSA reviews the inspection and compliance data States report. They analyze data and investigate the reasons for discrepancies or suspected problems with data accuracy
Benefits	• Evaluate intermediate results and improve the resources allocated to pathways • Identify high risk pathways that require additional resources • Identify unknown risks to agricultural resources • APHIS can plan for situations of current funding and reduced funding	• OSHA can quantify its program results, e.g., a 13% decrease in injury rates when OSHA used a combination of letters and inspections	• Can objectively demonstrate the results of enforcement and compliance assistance strategies • Can identify and pinpoint types and areas of noncompliance • Identify certain populations of workers who may not complain when their employers are noncompliant • Provide unbiased assessment of compliance	• FMCSA provides access to current safety data and crash statistics monthly on its Website • FMCSA uses SafeStat results to establish Federal priorities for on-site compliance reviews • Because FMCSA publishes compliance rates on its Website, and updates them monthly, companies have to stay diligent • Compliance Review Assessment Model and Compliance Review Effectiveness Study	• SAMHSA can quantify results of enforcement strategies • From 1996 to 2000, the national weighted average of retailer non-compliance decreased from 42% to approximately 19% • For 2006, the national weighted non-compliance rate is 10.9%
External Reviews	• A contracted statistician reviewed the AQIM methodology; says the concept is good • USDA OIG	• OSHA (in general) reviewed by GAO four to five times a year • DOL OIG once or twice • Received all green ratings from OMB's Program Assessment Rating Tool	• OMB's Program Assessment Rating Tool reviewed WHD's methodologies to ensure valid and dependable results • OMB was concerned that WHD only focused on three industries; WHD has since expanded their methods into other industry areas	• DOT OIG • GAO • Volpe Center	• HHS OIG (once shortly before and once shortly after the Synar amendment was implemented) • GAO in 2001

	USDA APHIS	DOL OSHA	DOL ESA WHD	DOT FMCSA	HHS SAMHSA
Lessons Learned	• Need for a champion in top management that accepts/supports the activity • Need for local managerial support (day-to-day champion) • If another agency becomes involved in the process, learn its culture and adapt • Data quality is vital • The planning is never entirely complete • Documentation of the process/steps is key so the methodology is defensible to outsiders • Private companies may be able to help with logic models and outcome measurement activities • Random sampling methodologies were verified with different levels of staff to assess ability for complete inspections • EPA's media programs sound like "pathways" • Top management can help obtain State data	• Compliance assistance combined with inspections was more effective in reducing noncompliance. Establishments were not asking for assistance when OSHA decreased the number of inspections in 1994-1995 • For maximizing its impact, OSHA enters into settlement agreements with companies that have more than one establishment in violation	• WHD secured support from top leadership and demonstrated improvements in compliance, to address initial internal resistance to using random samples • Using an external third party for sampling and analysis can remove the perception of bias • Set realistic goals to achieve compliance; e.g., WHD learned that annual industry surveys do not allow time to determine the full impact of intervention, and improvement. WHD changed to doing surveys at 5-year intervals • Causes for violations are different in different industries. The same approach is not effective for everyone • Recognize different levels of noncompliance, based on number of affected workers and the extent of the noncompliance	• Work collaboratively with States to collect data • Require data and statistics from States as part of grant agreements • Accountability and accuracy of data increased because external stakeholders use data, e.g., industry, insurance companies, and the public • FMCSA used statistical methods to maximize the limited resources to bring into compliance companies most likely to be involved in future crashes	• Fourteen local studies showed that direct enforcement activities with penalties drastically reduce retailer noncompliance • Perception of enforcement activities is a big component of the Synar program • Analyze data and verify results to check that they are realistic and accurate. Analyze the data and adjust strategy based on the cause of the problem

Source: OIG analysis of interviews with, and documents from, APHIS, OSHA, WHD, FMCSA, and SAMHSA

Appendix C

Selected Sources

United States Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine

USDA APHIS. 2006. Plant Protection and Quarantine Home Page. Available at: http://www.aphis.usda.gov/ppq/

USDA. 2002. *Agricultural Quarantine Inspection Monitoring (AQIM) Handbook*, 10/2006-02 Edition. Marketing and Regulatory Programs, Animal and Plant Health Inspection Service, Plant Protection and Quarantine. Available at: http://www.aphis.usda.gov/ppq/manuals/port/AQIM_Chapters.htm

USDA APHIS. 2005. *Plant Protection and Quarantine Strategic Plan FY 2006-2009*. Available at: http://www.aphis.usda.gov/ppq/strategic-plan.html

USDA OIG. 2005. Animal and Plant Health Inspection Service: *Transition and Coordination of Border Inspection Activities Between USDA and DHS*. Report No. 33601-0005-Ch. Available at: http://www.usda.gov/oig/webdocs/33601-05-CH.pdf

Department of Labor, Occupational Safety and Health Administration

OSHA. 2006. OSHA Home Page. Available at: http://www.osha.gov/

ERG. 2004. *Evaluation of OSHA's Impact on Workplace Injuries and Illnesses in Manufacturing Using Establishment-Specific Targeting of Interventions*. ERG: Lexington, MA.

OSHA. 2005. *OSHA Strategic Management Plan 2003-2008*. Available at: http://www.osha.gov/StratPlanPublic/index.html

Department of Labor, Employment Standards Administration, Wage and Hour Division

WHD. 2006. WHD Home Page. Available at: http://www.dol.gov/esa/whd/

DOL. 2006. *U.S. Department of Labor Strategic Plan FY 2006-2011*. Available at: http://www.dol.gov/_sec/stratplan/main.htm

WHD. 2005. 2005 Statistics Fact Sheet: *Wage and Hour Collects $166 Million in Back Wages for 241,000 Employees in FY 2005*. Available at: http://www.dol.gov/esa/whd/statistics/200531.htm

Department of Transportation,
Federal Motor Carrier Safety Administration

FMCSA. 2006. FMCSA Home Page. Available at: http://www.fmcsa.dot.gov/

FMCSA. 2005. *FMCSA Safety Program Effectiveness Measurement: Compliance Review Effectiveness Model—Results for Carriers with Compliance Reviews in 2002*. FMCSA-RI-05-036. Available at: http://ai.fmcsa.dot.gov/CarrierResearchResults/PDFs/CREMMay2005.pdf

FMCSA. 2005. *Research and Technology 5-Year Strategic Plan (2005-2009)*. Available at: http://www.fmcsa.dot.gov/facts-research/research-technology/rt-5year-strategicplan.pdf

FMCSA. 2006. *Summary of Program Measures Activity*. Available at: http://ai.fmcsa.dot.gov/ProgramMeasures/Intro/ProgramMeasuresMain.asp

FMCSA. 2006. *FMCSA 2006-2011 Strategic Plan, Draft*. Available at: http://www.fmcsa.dot.gov/about/what-we-do/strategy/strategic-plan.htm

GAO. 2005. *Large Truck Safety: Federal Enforcement Efforts Have Been Stronger Since 2000, but Oversight of State Grants Needs Improvement*. GAO-06-156. Available at: http://www.gao.gov/new.items/d06156.pdf

John A. Volpe Center. 2006. *Measuring the FMCSA's Safety Objectives from March 2000 to September 2004. FMCSA-RI-06-038*. Prepared for FMCSA. Available at: http://ai.fmcsa.dot.gov/CarrierResearchResults/PDFs/StrategicPlan_2006.pdf

Department of Health and Human Services,
Substance Abuse and Mental Health Administration

SAMHSA. 2006. *Synar Amendment: Protecting the Nation's Youth from Nicotine Addiction*. HHS SAMHSA Center for Substance Abuse Prevention. Available at: http://prevention.samhsa.gov/tobacco/default.aspx

SAMHSA. 2003. *Synar Regulation: Sample Design Guidance*. HHS SAMHSA Center for Substance Abuse Prevention.

SAMHSA. 2006. *Guide for a Synar Sampling Frame Coverage Study*. HHS SAMHSA Center for Substance Abuse Prevention. Available at: http://download.ncadi.samhsa.gov/csap/CSAPCoverageStudyGuide-2006.pdf

Appendix D

Agency Response

May 22, 2007

MEMORANDUM

SUBJECT: The Office of Enforcement and Compliance Assurance's Agency Response to the Draft Evaluation Report: Overcoming Obstacles to Measuring Compliance: Practices in Selected Federal Agencies; Report No. 2006-00378

FROM: Granta Y. Nakayama (/s/ by Catherine McCabe for Granta Y. Nakayama)

TO: Jeffrey K. Harris
Director for Program Evaluation, Cross-Media Issues
Office of Inspector General

The purpose of this memorandum is to provide the Office of Enforcement and Compliance Assurance (OECA) response to your April 5, 2007 memorandum which transmitted the draft version of the evaluation report entitled: *Overcoming Obstacles to Measuring Compliance: Practices in Selected Federal Agencies*. We appreciate the opportunity to comment on the draft evaluation report.

OECA recognizes the value of examining the measurement practices of other agencies in order to learn about approaches that might be useful to EPA's national enforcement and compliance assurance program. In fact, several years ago OECA outreach to other regulatory agencies resulted in identification of an approach to developing statistically-valid compliance rates used by the U.S. Customs Service. That approach provided a methodology that combined targeted inspections and random inspections to produce statistically-valid compliance rates. OECA retained the consultant used by the Customs Service to develop the methodology that OECA continues to use to produce statistically-valid rates for specific segments of the regulated universe.

While the current draft report identifies five other federal programs that may have similarities to EPA's compliance programs, OECA is unable to fully assess, from the information provided in the draft report, the applicability of these practices to OECA's needs and requirements for producing statistically-valid compliance rates. As we have discussed, EPA's national compliance and enforcement program is responsible, along with the states, for maximizing compliance with 12 environmental statutes, 28 distinct programs under those statutes, and dozens of regulatory requirements under those programs which apply in various combinations to a universe containing millions of regulated entities.

While the draft report acknowledges many obstacles OECA faces in measuring compliance across the regulated universe, we do take issue with the characterization of OECA "as resistant to conducting random inspections." OECA has in fact made conscious management

choices on how best to use enforcement resources. The current methodology used for producing statistically-valid rates combines inspections targeted at facilities likely to be in violation with inspections conducted at randomly-selected facilities to produce a representative sample of the regulated population. Because inspection resources are finite, every random inspection conducted means sacrificing a targeted inspection likely to identify violations. This, OECA's challenge has and will continue to be to carefully and effectively balance its measurement approaches with its mission of protecting public health and the environment.

OECA acknowledges the information provided in the draft report and accepts the report recommendations.

Recommendation 1 directs the Assistant Administrator for OECA to "establish a plan of action with milestones to incorporate using statistical methods to demonstrate the results of EPA's enforcement." OECA has previously accepted this recommendation.

In OECA's July 31, 2006 report to OMB entitled *Expanding the Use of Outcome Measurement for EPA's Office of Enforcement and Compliance Assurance*, OECA made a commitment to expand the use of statistically-valid compliance rates for specific noncompliance patterns focused on national priorities or other important problem areas. This commitment will entail development of an action plan.

The plan can be completed after two distinct but related reviews already underway are completed by OECA. The first of these is a review of the strategies for the national priorities chosen for the FY2008-2010 planning cycle. This review is designed to make the strategies more performance-based by establishing clear goals and performance measures to guide the management and oversight of the national priorities. The second review is designed to revise the current compliance objective and sub-objectives in the EPA Strategic Plan so they are focused on national priorities and problem areas, rather than their current orientation toward program tools such as assistance, incentives, inspections, and enforcement. A commitment to make these revisions was made as part of OECA's July 2006 report to OMB. This plan of action will be completed by the end of calendar year 2007.

Recommendation 2 directs the Assistant Administrator for OECA to "coordinate with the in-house statistical expertise available in EPA's Office of Research and Development and Office of Environmental Information to help develop statistical models and evaluate external proposals." OECA accepts this recommendation.

OECA has in place a contract and funding for statistical support that we believe will be sufficient to perform the primary tasks associated with expanding the use of statistically-valid compliance rates. However, we will examine the level of statistical expertise and the types of statistical services that could be provided by staff in the Office of Research and Development and the Office of Environmental Information in order to support our efforts to develop meaningful compliance rates.

Thank you for the opportunity to comment. If you have any questions, you may contact OECA's Audit Follow-up Coordinator, Gwendolyn Spriggs, on 202 564-2439.

Appendix E

Distribution

Office of the Administrator
Office of General Counsel
Assistant Administrator for Enforcement and Compliance Assurance
Assistant Administrator for Environmental Information
Assistant Administrator for Research and Development
Agency Followup Official (CFO)
Agency Followup Coordinator
Associate Administrator for Congressional and Intergovernmental Affairs
Associate Administrator for Public Affairs
Senior Advisor to the Assistant Administrator for Enforcement and Compliance Assurance
Audit Followup Coordinator, Office of Enforcement and Compliance Assurance
Audit Followup Coordinator, Office of Environmental Information
Audit Followup Coordinator, Office of Research and Development
Acting Inspector General