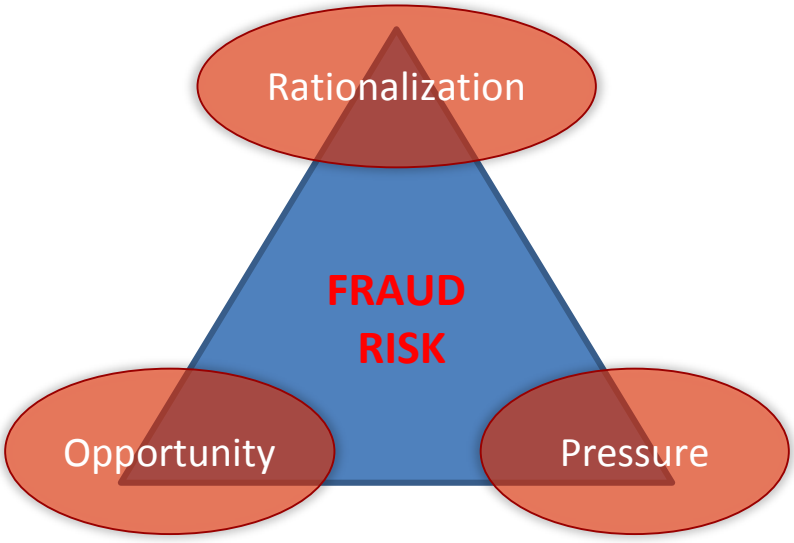
U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Science and Research

Fraud Controls for EPA's Contract Laboratory Program Are Adequate, but Can Be Strengthened With Formal Risk Assessment and Investigative Information Sharing

Report No. 17-P-0119 **March 6, 2017**



OIG Report No. 17-P-0119, *Fraud Controls for EPA's Contract Laboratory Program Are Adequate, but Can Be Strengthened With Formal Risk Assessment and Investigative Information Sharing*, was reissued on March 21, 2017. The At a Glance originally stated that the Contract Laboratory Program had demonstrated the effectiveness of four of five internal controls that provide reasonable assurance that the potential for laboratory fraud is minimized. Because we did not test the effectiveness of the individual controls—we tested to determine whether the controls were implemented—we revised that sentence, as well as a similar sentence in Chapter 2, to remove reference to the word "effectiveness." We also made minor edits to the report that did not change the findings or recommendations.

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Abbreviations

ASB	Analytical Services Branch
CID	Criminal Investigation Division
CLP	Contract Laboratory Program
COR	Contracting Officer's Representative
EPA	U.S. Environmental Protection Agency
EXES	Electronic Data Exchange and Evaluation System
FY	Fiscal Year
GAO	U.S. Government Accountability Office
OAM	Office of Acquisition Management
OCEFT	Office of Criminal Enforcement, Forensics and Training
OECA	Office of Enforcement and Compliance Assurance
OEI	Office of Environmental Information
OI	Office of Investigations
OIG	Office of Inspector General
OLEM	Office of Land and Emergency Management
OMB	Office of Management and Budget
OSRTI	Office of Superfund Remediation and Technology Innovation
QA	Quality Assurance
QATS	Quality Assurance Technical Support
QC	Quality Control
SMO	Sample Management Office

Cover image: EPA OIG graphic depicting the Fraud Triangle model.

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U.S. Environmental Protection Agency
Office of Inspector General

17-P-0119
March 6, 2017

At a Glance

Why We Did This Review

We conducted this review to determine whether the U.S. Environmental Protection Agency's (EPA's) Contract Laboratory Program (CLP) has the controls to detect or prevent fraudulent analytical services or data produced by CLP laboratories, and whether those controls provide reasonable assurance that the potential for fraud is minimized. We also sought to identify how the EPA monitors laboratory fraud cases across the agency to inform its system of controls.

The CLP is a national network which includes EPA-approved contract laboratories whose primary service is the provision of analytical data of known and documented quality. Since the 1980 inception of the CLP, 180 CLP labs have performed over 3.7 million analyses on samples from more than 20,900 sites, at an expense of approximately $431.5 million.

This report addresses the following EPA goals or cross-agency strategies:

- *Protecting human health and the environment by enforcing laws and assuring compliance.*
- *Embracing EPA as a high-performing organization.*

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Fraud Controls for EPA's Contract Laboratory Program Are Adequate, but Can Be Strengthened With Formal Risk Assessment and Investigative Information Sharing

What We Found

The impacts of lab fraud include risks to human health and the undermining of EPA regulatory programs.

The CLP demonstrated four of five internal controls that provide reasonable assurance that the potential for laboratory fraud is minimized. One component—risk assessment—has not been formally documented. Rather, one CLP manager said they address fraud risks informally but on a continual basis, which results in the development of new tools and updated guidance documents. Formal risk assessment would provide the CLP assurance that its controls address risks, as well as provide a clear picture of efforts to address lab performance deficiencies.

Policies for EPA investigative offices do not require them to share information with program offices, or explain how or why lab fraud occurred. According to investigative units, there are additional reasons as to why they do not share information: a small caseload of lab fraud for them to data-mine trends; the inability to share sensitive information until a case closes; and resource limitations. Stakeholders we interviewed agreed with the merit of having investigative offices share relevant aspects of lab fraud findings, including methods and techniques used to commit the fraud. Stakeholders also agreed that investigative offices should share information to help program and regional offices strengthen and update their internal control systems for preventing and detecting lab fraud.

Recommendations and Planned Agency Corrective Actions

We recommend that the Assistant Administrator for the Office of Land and Emergency Management (OLEM) conduct and document a formal risk assessment of the CLP to determine whether additional internal controls are needed to mitigate detected risks. We also recommend that the Office of Enforcement and Compliance Assurance (OECA), and the Office of Inspector General (OIG) require investigative units to share pertinent information from laboratory fraud findings with relevant program and regional offices. Recommendations for OLEM and OECA are agreed-to with corrective actions pending. The OIG completed its corrective action.

Noteworthy Achievements

OLEM developed an electronic laboratory data validation package—the Electronic Data Exchange and Evaluation System (EXES)—that is being made available to other agency programs via pilot implementations. A new version of EXES is in the works, which will incorporate added controls based on a current CLP lab fraud case. This demonstrates OLEM's view of EXES as a dynamic system that will be periodically updated to reflect changes in the program.

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

OFFICE OF THE
INSPECTOR GENERAL

March 6, 2017

MEMORANDUM

SUBJECT: Fraud Controls for EPA's Contract Laboratory Program Are Adequate, but Can Be Strengthened With Formal Risk Assessment and Investigative Information Sharing
Report No. 17-P-0119

FROM: Charles J. Sheehan, Deputy Inspector General

TO: Barry Breen, Acting Assistant Administrator
Office of Land and Emergency Management

Lawrence Starfield, Acting Assistant Administrator
Office of Enforcement and Compliance Assurance

Arthur A. Elkins Jr., Inspector General

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). The project number for this evaluation was OPE-FY16-0022. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and does not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

Action Required

In accordance with EPA Manual 2750, your offices provided planned corrective actions in response to our recommendations. All recommendations are considered resolved. You are not required to provide a written response to this final report because you provided agreed-to corrective actions and planned completion dates for the report recommendations. Should you choose to provide a final response, we will post your response on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

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Chapter 1
Introduction

Purpose

We conducted this review to determine whether the U.S. Environmental Protection Agency's (EPA's) Contract Laboratory Program (CLP) has the controls to detect or prevent fraudulent analytical services or data produced by CLP laboratories, and whether those controls provide reasonable assurance that the potential for fraud is minimized. We also sought to identify how the EPA monitors laboratory fraud cases across the agency to inform its system of controls.

Background

Contract Laboratory Program

The CLP is located within the EPA's Office of Land and Emergency Management (OLEM). The CLP is a national network which includes EPA-approved contract laboratories whose primary service is the provision of analytical data of known and documented quality to support Superfund site decisions. All analytical services are performed by EPA-approved contract laboratories who meet stringent requirements and standards in order to be a part of the CLP. The reliability and accuracy of CLP lab data is important for monitoring environmental and public health issues.

Since the 1980 inception of the CLP, 180 CLP labs have performed over 3.7 million analyses from more than 20,900 sites, at an expense of approximately $431.5 million.

The Analytical Services Branch (ASB) within OLEM's Office of Superfund Remediation and Technology Innovation (OSRTI) manages and supports the CLP. There are 17 participant laboratories in the CLP (as of April 2016). The EPA has a four-tier strategy for acquiring laboratory analytical services for Superfund site sample analyses.[1]

Tier 1	EPA regional and state laboratories.
Tier 2	CLP and other national analytical services contracts.
Tier 3	Region-specific analytical services contracts.

[1] In March 1998, the Field and Analytical Services Teaming Advisory Committee (comprised of headquarters and regional Superfund program managers) was convened to promote coordination, enhance customer service and improve the quality assurance program with an emphasis on field activities. The committee recommended using a decision tree for selecting laboratory analytical service providers in order of preference, based on evaluating available analytical sources and considering the following parameters: quality, timeliness, cost, efficiency/availability (on-board resources), and potential vulnerabilities.

Tier 4 Analytical services interagency agreements and regional field contracts/subcontracts.

In general, there is increased cost for analyses and quality reviews when using a higher tier. Tiers 1 and 2 are considered the most preferred; Tier 4 the least preferred.

Quality Assurance/Quality Control Processes

The quality assurance (QA) process consists of management review and oversight at the three stages of the environmental data collection: planning, implementation and completion. This process is intended to ensure that the data provided are of known and documented quality. The quality control (QC) process includes those activities required during data collection to produce data suitable for decision-making. Each contract lab has a Quality Management Plan and a Quality Assurance Project Plan. Some labs combine these two documents into one. Each lab must also include the QA/QC activities designed to achieve the data quality requirements in the contract.

Additionally, each CLP analytical method, identified by its respective statement of work, has a corresponding set of guidelines (called the National Functional Guidelines) for the review and evaluation of the data. The National Functional Guidelines are intended to assist in the technical review of analytical data generated by the respective CLP statement of work. The National Functional Guidelines are not intended to be used alone in determining the ultimate usability of the data; rather, the guidelines are intended to aid in the formal data review process, along with other sources of guidance, information and professional judgment.

Laboratories are used to analyze soil, water, and other media to determine their chemical composition, to assess whether such chemicals pose human health risks, and to determine whether such media are contaminated and in need of remedial treatment. In light of this role, maintenance of the integrity of laboratory sample tests, results and reports is critical.

The ASB and EPA regions conduct primary lab performance monitoring activities to ensure that contract labs produce appropriate, quality data. Monitoring activities include the following: on-site lab evaluations, electronic data audits, data package audits, and lab evaluations through the use of blind performance evaluation samples. Additionally, “proficiency testing” audits are used to evaluate a laboratory’s ability to identify and quantify target analytes in performance evaluation samples provided by the EPA. The agency then uses the results to assess and verify a CLP laboratory’s continuing ability to produce acceptable analytical data in accordance with contractual requirements. CLP laboratories analyze proficiency testing audit samples

several times per year under direction from the ASB. The CLP laboratory is not informed of either the analytes or sample concentrations.

Quality staff in the Office of Environmental Information (OEI) are responsible for issuing agencywide QA/QC policies and procedures. Quality staff have liaisons in every EPA program office and region, although titles may vary by location (e.g., QA Managers, Directors or Coordinators).

CLP Key Entities

Personnel from all 10 EPA regions play a vital role in CLP activities as the primary users of the CLP and as a key part of analytical program management. The regional CLP Contracting Officer's Representative (COR) serves as the primary coordinator for CLP activities within each region; provides feedback on data quality, usability and CLP laboratory performance to ASB; and contacts the laboratory if there are questions or issues that arise during data validation. The regional CLP COR leads on-site laboratory audits and may visit the CLP laboratory if there are serious performance problems.

The Office of Acquisition Management (OAM) is responsible for all contracting-related activities. OAM's Laboratory Analysis Service Center manages CLP contracts. OAM's Contracting Officer is the only person with the authority to enter into, administer and terminate contracts. The Contracting Officer has the authority to approve CLP laboratories exceeding their monthly capacity and place CLP laboratories on "suspension of work" status.

As noted earlier, CLP labs fall under Tier 2 in the EPA's decision tree when selecting analytical service providers. CLP labs are supported by two support contracts: the Sample Management Office (SMO) contract, and the Quality Assurance Technical Support (QATS) contract.

- **SMO**—The contractor-operated SMO provides management, operations and administrative support to the CLP. The SMO receives regional analytical requests, coordinates and schedules sample analyses, and tracks sample shipments. The SMO also receives and checks data for completeness and compliance, performs automated data assessment, processes laboratory invoices, and maintains a repository of sampling records and program data. The SMO's online portal offers CLP users one central location for available tools that support the CLP.

- **QATS**—This is the CLP support contractor directed and tasked by the ASB on behalf of OAM. The QATS provides QA and audit support, as well as technical expertise to assist in evaluating CLP data quality. The primary objective of QATS is to provide a data package and

electronic, on-site and special investigative audit[2] support; develop, maintain, distribute and scope proficiency testing samples; and provide technical feedback to ASB on required CLP deliverables and data quality. The ASB's QATS contracting officer's representative schedules on-site audits, initiates routing and special investigative audits, oversees the proficiency testing audit program, and gives final approval to all reports produced by QATS in support of the CLP.

Key entities in the CLP are shown in Figure 1.

Figure 1: Major entities in the CLP

Source: OLEM-OSRTI-ASB presentation to the EPA's Office of Inspector General (OIG) on 06/22/16.

CLP Resources

Table 1 presents the headquarters-level CLP budget and full-time equivalent information for fiscal years (FYs) 2005, 2010 and 2015.

According to data provided by the ASB, the budget for the CLP has decreased by over 16 percent from FY 2005 levels, and a near 24-percent decrease from FYs 2010 through 2015. Staff have decreased 36 percent from FY 2005 levels.

[2] The QATS "special investigative audits" are small, targeted and focused audits of particular data from multiple sample delivery groups. These investigative audits are different from the lab fraud investigations we describe in Chapter 3.

Table 1: Headquarters CLP resources

	FY 05	FY 10	FY 15
Cost of CLP Lab Contracts	9,723,855	10,343,788	6,237,383
Cost of Blanket Purchase Agreements	0	670,425	367,360
Subtotals	9,723,855	11,014,213	6,604,743
Cost of CLP support contracts:			
QATS	3,484,469	3,754,715	4,217,841
SMO	10,703,329	11,519,629	9,182,590
Subtotals	14,187,798	15,274,344	13,400,431
Grand Total	23,911,653	26,288,557	20,005,174
Total Full-Time Equivalents	--	7.3	6.4

Notes: Data for Blanket Purchase Agreements in FY 2005 were not readily available. FY 2005 full-time equivalent data were also unavailable.
Source: OIG analysis of CLP data.

Lab Fraud Allegations

The ASB defines inappropriate laboratory practices as "a technical unjustified omission, manipulation, or alteration of data that bypasses the required QC parameters, making the results appear acceptable." Lab fraud investigations focus on the manipulation of data or equipment, and the falsification of analytical and quality assurance results, where failed methods and contractual requirements are made to appear acceptable. Fraud can involve the backdating of test data, manipulating test samples, or not performing analysis in accordance with established methods among other things.

Primary investigative responsibilities

- **OIG/OI:** Fraud, waste and abuse in EPA programs or operations.
- **OCEFT/CID:** Criminal violations of federal environmental laws.

Lab fraud allegations are investigated either independently or jointly by the EPA OIG's Office of Investigations (OI); and/or the agency's Office of Enforcement and Compliance Assurance (OECA), Office of Criminal Enforcement, Forensics and Training (OCEFT), Criminal Investigation Division (CID), according to statutory authorities (see box at right) of each office[3] and the terms of an OIG/OECA 2006 Memorandum of Understanding. The EPA's contract labs are at potentially high-risk for fraud because profits are based on the volume of analytical work produced.

[3] The Inspector General Act of 1978, as amended, gives OIG Special Agents law enforcement authority to conduct investigations relating to the programs and operations of the EPA. Law enforcement authority is granted to OCEFT/CID Special Agents by 18 U.S.C. § 3063.

Internal Control Standards

The U.S. Government Accountability Office (GAO) defines internal control in the following manner:

> [A] process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. Internal control comprises the plans, methods, policies and procedures used to fulfill the mission, strategic plan, goals and objectives of the entity. Internal control is not one event, but a series of actions that occur throughout an entity's operations. Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls, and evaluates the internal control system.[4]

Internal control has five components:

1. **Control Environment.** The foundation for an internal control system. The control environment provides the discipline and structure to help an entity achieve objectives.

2. **Risk Assessment.** Assesses the risks facing the entity as it seeks to achieve its objectives. This assessment provides the basis for developing appropriate risk responses.

3. **Control Activities.** Actions that management establishes through policies and procedures to achieve objectives and respond to risks in the internal control system, which includes the entity's information system.

4. **Information and Communication.** Quality information that management and personnel communicate and use to support the internal control system.

5. **Monitoring.** Activities that management establishes and operates to assess the quality of performance over time, and to promptly resolve audit findings and other reviews.

GAO notes that 17 principles support the effective design, implementation and operation of the associated components, and represent the requirements necessary to establish an effective internal control system.

Office of Management and Budget (OMB) Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control* (July 2016), defines obligations for risk management and internal control in federal agencies. EPA Order 1000.24 CHG 2, "Management's Responsibility for Internal Control,"

[4] GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014.

requires all EPA organizations to establish and maintain internal controls to achieve the objectives of effective and efficient program operations, including evaluating internal controls on an on-going basis and taking prompt actions to correct any vulnerabilities identified.

Responsible Offices

The CLP is administered by the Analytical Services Branch within the Office of Land and Emergency Management, Office of Superfund Remediation and Technology Innovation. Allegations of fraudulent laboratory data and analysis are handled by the Criminal Investigation Division within the Office of Enforcement and Compliance Assurance, Office of Criminal Enforcement, Forensics and Training; as well as by the OIG's Office of Investigations.

Noteworthy Achievements

The ASB developed an electronic data validation package—the Electronic Data Exchange and Evaluation System (EXES)—which assesses data within 24 to 48 hours after receipt. The ASB is now making EXES available to other agency programs (e.g., the Great Lakes program) via pilot implementations. A new version of EXES is in the works and will incorporate added controls based on the ASB's experience with a current CLP lab fraud case. The new version of EXES demonstrates the ASB's view of EXES as a dynamic system periodically updated to reflect changes in the program.

Scope and Methodology

We conducted our performance audit from April to November 2016. With the exception described below, our work was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Two entities within the EPA are responsible for investigating lab fraud: OCEFT/CID and OIG/OI. To address our objectives, we were required to obtain information and interview employees in both OCEFT/CID and OIG/OI.

Because the staff that conducted this review and the OIG/OI fall structurally within the OIG, there could be the perception of a lack of independence. To address the issue of independence, we developed and adhered to the same procedures to obtain and review information and conduct interviews with both offices. We also adhered to the OIG's quality assurance procedures. We believe these actions mitigate and provide adequate safeguards that reflect our independence.

We analyzed numerous documents pertaining to the CLP,[5] QA, laboratory fraud and internal controls, including policies, procedures and guidance documents.

In addition to document reviews, and to address our first objective, we interviewed key staff and managers responsible for CLP program implementation, oversight and quality assurance in ASB, OEI, and OAM. We also interviewed all 10 EPA regional CLP CORs (users of the CLP). We developed an internal control checklist to assist us in assessing whether controls we identified within the CLP provide reasonable assurance that the potential for fraud is minimized. We used documentary and testimonial evidence to validate implementation of controls and whether controls were understood across CLP program managers, implementers and users. Our conclusions on the adequacy of CLP's controls do not include an evaluation of the effectiveness of the controls.

To address our second objective we interviewed EPA investigative staff and managers within OIG/OI and OCEFT/CID. We interviewed the OIG's Deputy Counsel on the terms of the 2006 Memorandum of Understanding between the two offices. We also interviewed the EPA's Scientific Integrity Official to understand her role in addressing laboratory fraud as it relates to instances of research misconduct.[6]

Prior Audit Reports

Three prior reports relate to our review on laboratory fraud or managing fraud risks (though none specifically on the CLP):

- **A 2006 EPA OIG report.**[7] The EPA OIG conducted the review to identify vulnerabilities in the drinking water sample analysis process and promising techniques to improve laboratory integrity. The EPA OIG found hundreds of vulnerabilities not addressed by the EPA's process—vulnerabilities that could compromise the integrity of the analysis process and the quality of data produced. The EPA OIG included appendices that listed vulnerabilities identified by error type and severity (see image on next page), and promising techniques based on a literature search. The EPA OIG made 10 recommendations, all of which the EPA completed.

[5] We did not review other Superfund contract programs, such as those that are a part of the Superfund Technical Assessment and Response Team, Emergency and Rapid Response Services, or Remedial Action Contracts; rather, we focused solely on the CLP.
[6] The EPA's Scientific Integrity Official does not investigate allegations of laboratory fraud. Instead, she focuses on research falsification, fabrication and plagiarism. She does not have a role in investigating laboratory fraud allegations. If she does receive any allegations of fraud, she said she refers them to the OIG.
[7] EPA OIG, *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks*, Report No. 2006-P-00036, September 21, 2006.

Vulnerabilities Identified by EPA Team

Sequenced based on the 13 steps in the drinking water sample analysis process (see Figure 2.1) and ordered within each step from most to least severe.

Error Type: U = Unintentional, I = Intentional, B = Both

Severity Rating: 5 = Most Severe, 1 = Least Severe

Description of Vulnerability	Error Type	Severity Rating
a) Sample Collection		
• Sample is mislabeled	B	4
• Sample not preserved/or no dechlorinating agent/adulteration of sample	B	4
b) Sample Tracking and Recording		
• Holding time/temp. exceeded	B	4
c) Adherence to Standard Operating Procedures (SOPs) for Analytical Methods		
• Adherence to SOP	B	4
• QA manager/lab mgmt. not knowledgeable about approved methodology	B	4
• Untrained/inexperienced analysts	B	4
d) Preparation of Samples and Standard Solutions		
• Incorrect preparations/inappropriate standards (i.e., no traceability; contaminated/expired)	B	4
e) Instrument Performance		
• Instrument response/sensitivity-needs documentation	B	4
f) Instrument Maintenance		
• Analyst/QA officer doesn't understand repair needs	U	4
• No repairs-maintenance log maintenance	U	4
• Repaired incorrectly	U	4
g) Instrument Calibration		
• Calibration curve incorrect-data biased high or low	B	4
• Calibration verification not performed	I	4
• Out of date reference materials	B	3
h) Lab Technician Performance		
• Trained analysts can falsify data	I	5
i) Adherence to Quality Assurance/Quality Control (QA/QC) Plan		
• Analysts can falsify/not performing QA/QC data	I	5
j) Data Validation and Verification		
• Not flagging data outside of acceptance criteria	I	5
• Selection of inappropriate QC acceptance criteria	I	4

Image from EPA OIG Report No. 2006-P-00036, September 21, 2006.

- **A 2014 EPA OIG report.**[8] The EPA OIG reviewed the due diligence process, which included the procedures used by the EPA, other federal agencies and states to manage the communication of, and appropriate action on, laboratory data determined to be fraudulent.

  The EPA OIG found that the EPA lacked a due diligence process for potential fraudulent environmental data. The agency had three policies and procedures that addressed how to respond to instances of fraudulent data, but they were out of date or unimplemented when the report was issued. The OIG made six recommendations, all of which were agreed to and will be completed by March 2017.

- **A 2015 GAO report.**[9] GAO reported on the importance of evaluating outcomes using a risk-based approach and adapting activities to improve fraud risk management. GAO said to collect and analyze data from reporting mechanisms and instances of detected fraud for real-time monitoring of fraud trends; and to use the results of monitoring, evaluations and investigations to improve fraud prevention, detection and response.

[8] EPA OIG, *EPA Has Not Implemented Adequate Management Procedures to Address Potential Fraudulent Environmental Data*, Report No. 14-P-0270, May 29, 2014.
[9] GAO, *A Framework for Managing Fraud Risks in Federal Programs*, GAO-15-593SP, July 28, 2015.

Chapter 2
CLP's Internal Control System Addresses Four of Five Components and Should Formally Assess Program Risks

The CLP has a system of controls in place that provides reasonable assurance that the potential for fraud is minimized. Based on our analysis, the CLP has demonstrated four of five internal controls, whereas one element—risk assessment—has not been formally documented. Rather, one CLP manager said they address risk assessment informally but on a continual basis, which results in the development of new tools and updated guidance documents that address any potential risks identified.

Federal standards and EPA Order 1000.24 CHG 2 require that federal entities conduct risk assessments and emphasize the responsibility of government managers in managing risk. A formal risk assessment would provide the program with assurance that its controls address risks, help determine whether controls are implemented and operating effectively, and provide a picture (to regional CLP leads and others) of efforts the program undertakes to address performance deficiencies by CLP labs.

CLP's Internal Control System Meets Most of the Principles for Effective Internal Controls

We reviewed the CLP's system of internal controls and assessed whether the system met the intent of GAO internal control principles.

Table 2 summarizes our assessment and illustrates that the CLP has controls to detect or prevent fraudulent analytical services; and that, with one exception, those controls provide reasonable—though not absolute—assurance that the potential for fraud is minimized.

OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control* (July 2016), notes that no matter how well designed, implemented or operated, an internal control system cannot provide absolute assurance that all of an organization's objectives are met. Factors outside the control or influence of management can affect the entity's ability to achieve all of its objectives—factors that could be identified through formal risk assessment.

Table 2: Summary of CLP controls that meet GAO internal control principles

Internal control components and principles	Met	Partially met	Not met
Control Environment			
1. The oversight body and management should demonstrate a commitment to integrity and ethical values.	●		
2. The oversight body should oversee the entity's internal control system.	●		
3. Management should establish an organizational structure, assign responsibilities, and delegate authority to achieve the entity's objectives.	●		
4. Management should demonstrate a commitment to recruit, develop and retain competent individuals.	●		
5. Management should evaluate performance and hold individuals accountable for their internal control responsibilities.	●		
Risk Assessment			
6. Management should define objectives clearly to enable the identification of risks and define risk tolerances.		●	
7. Management should identify, analyze and respond to risks related to achieving the defined objectives.		●	
8. Management should consider the potential for fraud when identifying, analyzing and responding to risks.		●	
9. Management should identify, analyze and respond to significant changes that could impact the internal control system.		●	
Control Activities			
10. Management should design control activities to achieve objectives and respond to risks.	●		
11. Management should design the entity's information system and related control activities to achieve objectives and respond to risks.	●		
12. Management should implement control activities through policies.	●		
Information and Communication			
13. Management should use quality information to achieve the entity's objectives.	●		
14. Management should internally communicate the necessary quality information to achieve the entity's objectives.	●		
15. Management should externally communicate the necessary quality information to achieve the entity's objectives.	●		
Monitoring			
16. Management should establish and operate monitoring activities to monitor the internal control system and evaluate the results.	●		
17. Management should remediate identified internal control deficiencies on a timely basis.	●		
Totals	**13**	**4**	**0**

Source: OIG analysis based on interviews and document reviews.

Federal Guidance and EPA Policy Require Risk Assessment

> A precondition to risk assessment is the establishment of clear, consistent agency goals and objectives at both the entity and activity levels. Internal control should provide for an assessment of the risks the agency faces from both internal and external sources.

OMB Circular A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control*, requires that federal programs conduct and document a risk assessment[10] based on GAO's *Standards for Internal Control in the Federal Government*. The aim of the assessment is to identify the major risks facing the entity as it seeks to achieve its objectives. This assessment provides the basis for developing appropriate risk responses.

EPA Order 1000.24 CHG 2, *Management's Responsibility for Internal Control* (July 18, 2008), states that in accordance with GAO standards, a risk assessment is the identification and analysis of relevant risk associated with achieving the agency's mission. The EPA order further states that program managers should identify internal and external risks that may prevent the organization from efficiently and effectively meeting its objectives.

In discussing fraud risk, the GAO standards state that management consider the following factors:

- **Incentive/pressure.** Management or other personnel have an incentive or are under pressure, which provides a motive to commit fraud.

- **Opportunity.** Circumstances exist, such as the absence of controls, ineffective controls, or the ability of management to override controls, and this provides an opportunity to commit fraud.

- **Attitude/rationalization.** Individuals involved are able to rationalize committing fraud (i.e., possess an attitude, character or ethical values that allow them to knowingly and intentionally commit a dishonest act).

Because the CLP operates in an environment characterized by high volume and quick turnaround analysis requests, the CLP should consider the above factors when determining the types of laboratory fraud risks the program faces. The CLP should formulate an approach for risk management based on its mission to provide data of known and documented quality, and decide on the internal controls required to mitigate identified risks. Additionally, CLP program managers should incorporate regional CLP leads into any risk assessment approach since EPA regions are data end users.

[10] The OMB circular refers to this as a "risk profile."

One CLP manager stated that although they try to identify program risks on a continual basis, they have not conducted or documented a formal risk assessment process. The manager cited their recent updates to the EXES electronic data validation program, where they incorporated information obtained from an ongoing laboratory fraud investigation (in addition to ongoing updates to the *CLP Roles and Responsibilities Guidance Document*), as examples of their continued vigilance. We directed CLP program managers to appropriate sources containing information on how to conduct a risk assessment, including OMB Circular A-123 (July 2016), the GAO Internal Control Management and Evaluation Tool (August 2001), and other materials developed internally within the agency.

Conclusion

Our analysis indicates that the CLP's system of internal controls provides reasonable assurance that the potential for fraud is minimized. Even though the CLP's system of controls has been informed by the program's substantial history and experience in the field of laboratory analytical services, as well as its demonstrated willingness to continually improve and update the program, the CLP would benefit from a structured risk assessment process that reaffirms the strength of the controls already in place and, possibly, uncovers any gaps in the system.

Recommendation

We recommend that the Assistant Administrator for Land and Emergency Management:

1. Conduct and document a formal risk assessment of the EPA's Contract Laboratory Program to determine the adequacy of internal controls currently in place, and determine whether any additional controls are needed to mitigate detected risks.

Agency Response and OIG Evaluation

OLEM agreed with our recommendation and provided a planned completion date. Recommendation 1 is considered resolved with corrective actions pending. OLEM plans to conduct and document a formal risk assessment of the CLP by the fourth quarter of FY 2017. Appendix A contains OLEM's full response to our official draft report.

OLEM also provided technical comments, which we considered and included in Appendix A.

Chapter 3
Investigative Units Should Formally Share Information From Lab Fraud Investigations With Affected Organizations

We found that while Special Agents handling lab fraud cases share information with affected offices on an informal, ad hoc basis, investigative units do not have a formal, regular process for sharing relevant information from lab fraud investigations with other program and regional offices whose responsibilities include laboratory analytical services/data. GAO's 2015 fraud risk framework[11] recommends that agencies collect and analyze data from reporting mechanisms and instances of detected fraud for real-time monitoring of fraud trends, and use the results of monitoring, evaluations and investigations to improve fraud prevention, detection and response.

The EPA has various mechanisms to report allegations of laboratory fraud from program and regional staff to OIG/OI and OCEFT/CID (as well as the agency's Scientific Integrity Official). However, investigative office policies do not address or require formal information-sharing with EPA program offices and regions that could benefit from information concerning how and why fraud occurred.

According to the two investigative units, there are additional reasons as to why they do not share information: the lab fraud caseload is too small for them to data-mine for trends or lessons learned; the inability to share sensitive case information outside of the affected program; and resource limitations in both offices. As a result, program and regional offices with laboratory-related responsibilities do not always receive the information they need to strengthen their internal controls based on lab fraud findings.

No Formal Requirement to Share Information

OIG/OI and OCEFT/CID policies include guidance on coordinating with one another. However, the policies do not address sharing the root cause analyses about how or why fraud occurred with program and regional offices whose responsibilities include laboratory analytical services/data. There is no formal, consistent process in place for debriefing program offices; rather, each investigative office does so informally.

- **OCEFT/CID** updated its policy, *Investigative Process* (2015), OCEFT-I-002R1, in response to a 2014 OIG report recommendation to "develop guidelines outlining response steps when fraudulent laboratory data is discovered in ongoing criminal investigations," but this does not address

[11] See our summary of this report in Chapter 1.

sharing information with other offices as a routine practice. However, the CID policy does provide guidance for sharing lab fraud allegations that potentially present a threat to human health or the environment. OCEFT/CID said it does not have an internal procedure for briefing offices and does not conduct briefings on a regular basis. During the course of an investigation, OCEFT/CID might gather information from the affected office (e.g., through meetings, emails, etc.) as it develops the case. OCEFT/CID said post-case analysis is not its focus. OCEFT/CID stated, "There is no post-mortem lessons learned aside from what might happen naturally during the investigation in terms of back and forth with the offices." OCEFT/CID also added there is no debrief or formal report drawn up after a prosecution.

- **OIG/OI** Policy and Procedure 206, *Case Administration* (2016), encompasses administrative aspects of handling complaints and reporting results, but does not address information-sharing with the agency. OIG/OI said its special agents discuss lab fraud matters with Contracting Officers and others (e.g., the EPA's Suspension and Debarment Division). However, unlike the OIG/OI's investigative reports that are provided to the EPA concerning employee cases, OIG/OI does not send formal reports on lab fraud investigations. Like OCEFT/CID, OIG/OI said its agents are responsible for communicating relevant information with the affected program office while the case is ongoing, and that Special Agents-In-Charge are responsible for ensuring that this occurs.

The purpose of the 2006 Memorandum of Understanding between OIG/OI and OCEFT/CID is to clarify each office's respective areas of investigative responsibility. The memo included general obligations of cooperation and information sharing with one another and stated, "Both OIG and CID must immediately notify the other as to any criminal violations that fall within the other organization's area of independent investigative authority." Beyond these requirements, investigative office policies do not address sharing fraud techniques with program and regional offices with laboratory responsibilities. However, offices could use this information to strengthen internal control systems for preventing and detecting lab fraud.

Few Lab Fraud Cases, Resource Limitations and Sensitive Information Limit Information-Sharing

Lab fraud investigations comprise a small percentage of the total caseload for OIG/OI and OCEFT/CID—just over 1 percent in each office from 2010 to 2016,[12] as shown in Table 3.

Table 3: OIG/OI and OCEFT/CID data on lab fraud from 2010 to 2016[13]

	Total caseload	Lab fraud investigations opened	Percent lab fraud
OIG/OI	1905	21	1.1%
OCEFT/CID	1883	25[14]	1.3%

Source: OIG summary of OIG/OI and OCEFT/CID information.

Each office described resource limitations that would limit detailed analysis of lab fraud investigations and the formal sharing of information outside of the affected program office. For example, OCEFT/CID said it does not have a large analytical group, and its staff numbers are down 20 percent or so over the past 6 to 8 years. OIG/OI said it conducted trend analyses when it had a lab fraud directorate; however, that group has since disbanded and now OIG/OI does not monitor or analyze proactively. Both offices noted that declining resources means they have to prioritize and shuffle workloads accordingly.

Additionally, staff in each office noted that there could be some instances where information-sharing would be delayed; for example, when a case is in prosecution or in grand jury proceedings. Thus, the formal sharing of information depends on the nuances involved in each case or situation.

Stakeholders Agree on the Need for Information Concerning Lab Fraud Methods/Techniques

As noted above, neither OCEFT/CID nor OIG/OI do trend analyses on lab fraud investigations. Staff in both offices questioned the value of formal information-sharing. One OIG/OI Special Agent said there is no benefit because convictions, suspensions and debarments stand on their own. An OCEFT/CID staff person said they are not hearing program offices ask for lessons learned. An OIG/OI Special Agent noted the benefit and said, "We are not required to brief the program [staff] but it's a good practice."

[12] Of these, per our first objective summarized in Chapter 2, only one CLP lab fraud investigation has been conducted.

[13] Table 3 captures lab fraud cases opened and investigated from 2010–2016, specifically January 2010 through May 2016 for OIG/OI, and January 2010 through September 2016 for OCEFT/CID. This does not include cases opened prior to 2010 still under investigation during the 2010–2016 timeframe.

[14] According to the CID, seven of its 25 lab fraud investigations are still ongoing. Four of those seven investigations are being worked jointly with the OIG.

Stakeholders we interviewed on the CLP's lab fraud controls agreed that learning lab fraud case results would be useful:

- **Headquarters CLP Staff in OLEM.** ASB staff stated that they do not receive information from OIG/OI or OCEFT/CID on cases they are working or have worked on and were resolved, other than those cases that pertain to CLP where information is shared during the course of the investigation. They said such information would be very useful to them for strengthening their controls.

- **Headquarters Quality Staff in OEI.** The Director of OEI's Enterprise Quality Management Division said that when they learn about a situation of non-conformance, they share that information with the QA community through established communication channels (e.g., monthly QA meetings, annual conference and on the OEI website). The Director stated that they do not get information on fraud cases, but she indicated they would share the information if received.

- **Regional CLP CORs.** All EPA regions confirmed that it would be useful to receive more information on the techniques detected by lab fraud investigations. Eight regions said it would be useful to receive specific information on improper laboratory practices. Some of these regions said information could, for example, be utilized in their own monitoring and review of laboratory data. Three regions were not aware of the results of OIG/OI or OCEFT/CID investigations but would like to learn about the fraud techniques discovered. Four regions noted that past lab fraud briefings provided by OIG/OI were useful.

Because lab fraud cuts across so many of the EPA's functions, broad coordination is essential in addressing it.[15] Moreover, impacts of lab fraud are significant,[16] potentially risking human health and undermining the foundations of the EPA's regulatory programs. For example, drinking water regulations require testing for a list of potential contaminants to protect the public from harmful exposures. Testing under hazardous waste regulations may determine harm. Entities can incur harm through receipt and reliance on fraudulent test data. The resultant harm may be to the environment (i.e., through the release of what was thought to be safe material), a specific community or the government.[17] (See examples of impacts of lab fraud in the following box.)

[15] EPA, OCEFT, *Report of the Laboratory Fraud Work Group.* September 2001, with June 2002 update, at page 39.
[16] Though not specific to lab fraud, OMB Circular A-123 notes that fraud jeopardizes agency missions by diverting scarce resources from their intended purposes. A single case of fraud can undermine programmatic mission, disrupt services, and force management to expend valuable time and resources to resolve and recover property lost due to fraud. Reputational risks of fraud can damage the perception of an agency, impact employee morale, and create public distrust.
[17] EPA, OCEFT, *Report of the Laboratory Fraud Work Group.* September 2001, with June 2002 update, at pages 4, 24 and 25.

Examples of Lab Fraud Impacts

- A recent CLP lab fraud case led OLEM to determine that the quality of the data could not be assessed and should not be used for any site cleanup decisions. OLEM issued a recall of all the data produced by the lab. The recall covered all 10 EPA regions and impacted a total of 237 sites. Funds expended on the analysis of the recalled data were approximately $2.3 million.
- Three former employees of a drinking water laboratory were found to have falsified QA/QC lab data over a 3-year period. Customers affected included schools, day care facilities, government entities, restaurants and mobile home communities.
- The operator of a mass spectrometer, located in a U.S. Geological Survey laboratory responsible for conducting coal and water quality assessments in projects both in the U.S. and abroad, was accused of scientific misconduct and manipulating data. The agency's review revealed far-ranging impacts: retracted or delayed publications due to inaccurate information, diminished employee morale, and reduced public trust in agency-generated information. Moreover, the agency found that 24 research and assessment projects of national and global interest were potentially affected, and that the projects represented about $108 million in funding.
- A lab president was sentenced to serve 48 months incarceration and pay a $50,000 fine stemming from concealing and falsifying pesticide residue tests used by the EPA to determine whether levels of pesticide residues in foods are safe and protective of public health. The lab was sentenced to pay a $15.4 million fine. The president and the company also each paid $3.7 million in restitution to defrauded pesticide manufacturers and the EPA. The defendants falsified the results of their tests in order to save time and money that would have been necessary to repeat tests that did not meet calibration or QC requirements.

GAO's 2015 fraud risk framework[18] describes the importance of using the results of investigations and prosecutions to adapt fraud risk management activities, such as incorporating new information like changing risks or the effect of actions taken to mitigate risks and address vulnerabilities. This point is particularly important considering that a current CLP lab fraud investigation revealed new techniques that offices need to inform their systems of controls. Sharing this information would inform the development and modification of risk assessments and other control activities described in Chapter 2.

OECA's Office of Site Remediation Enforcement (which manages Superfund enforcement) indicated it needs to know about fraud when a program office is contemplating a decision to recall data. The OECA office can then determine any impact of lab fraud on the EPA's enforcement actions.

For example, the current CLP lab fraud investigation impacted agency enforcement and cost recovery actions, and enforcement staff said prompt notification would help mitigate impacts.

Conclusion

Broad agency coordination is important to address fraudulent laboratory data and analysis. Although the EPA's investigative groups report few laboratory fraud

[18] GAO, *A Framework for Managing Fraud Risks in Federal Programs*, GAO-15-593SP, July 28, 2015.

cases, impacts from any lab fraud remain significant. As OMB has identified, fraud jeopardizes agency missions; and reputational risks of fraud can damage agency perceptions, employee morale and public trust. Information identified in investigations about the methods used to conduct fraudulent laboratory data analysis would be useful for program managers' assessments of existing internal controls.

Agency stakeholders have expressed interest in receiving information on methods/techniques used to perpetrate fraud in order to tighten their internal control systems. Collective agency efforts, such as increased information-sharing on fraud methods, would help the agency to further prevent and detect lab fraud.

Recommendations

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

2. Require the Criminal Investigation Division to share pertinent information from laboratory fraud findings with relevant EPA program and regional offices. Pertinent information includes the fraudulent method or technique used to commit fraud.

We recommend that the Inspector General:

3. Require the Office of Investigations to share pertinent information from laboratory fraud findings with relevant EPA program and regional offices. Pertinent information includes the fraudulent method or technique used to commit fraud.

Agency Response and OIG Evaluation

OECA agreed with Recommendation 2 and provided a planned completion date. Recommendation 2 is considered resolved with corrective actions pending. OECA suggested changes to the report, which we made where appropriate. Appendix B contains OECA's full response to our official draft report.

While OIG/OI did not explicitly agree or disagree with Recommendation 3, the OIG completed its corrective action prior to our final report issuance. Appendix C contains OIG/OI's full response to our official draft report.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	13	Conduct and document a formal risk assessment of the EPA's Contract Laboratory Program to determine the adequacy of internal controls currently in place, and determine whether any additional controls are needed to mitigate detected risks.	R	Assistant Administrator for Land and Emergency Management	09/30/17	
2	19	Require the Criminal Investigation Division to share pertinent information from laboratory fraud findings with relevant EPA program and regional offices. Pertinent information includes the fraudulent method or technique used to commit fraud.	R	Assistant Administrator for Enforcement and Compliance Assurance	12/31/17	
3	19	Require the Office of Investigations to share pertinent information from laboratory fraud findings with relevant EPA program and regional offices. Pertinent information includes the fraudulent method or technique used to commit fraud.	C	Inspector General	01/30/17	

[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Office of Land and Emergency Management Response to Draft Report

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

JAN 13 2017

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

NOW THE
OFFICE OF LAND AND
EMERGENCY MANAGEMENT

MEMORANDUM

SUBJECT: Response to Office of Inspector General Report, *EPA's Contract Laboratory Program Includes Adequate Fraud Controls That Can Be Strengthened with Formal Risk Assessment and Investigative Information Sharing* (Report # OPE-FY16-0022; December 13, 2016)

FROM: Mathy Stanislaus
Assistant Administrator

TO: Arthur A. Elkins, Jr.
Inspector General

Thank you for the opportunity to respond to the recommendation in the subject audit report. The following is a summary of the Office of Land and Emergency Management's (OLEM's) overall position, along with its position on the report recommendation. We have also provided a high-level corrective action and estimated completion date. For your consideration, we have included a Technical Comments Attachment to supplement this response.

OFFICE OF LAND AND EMERGENCY MANAGEMENT'S OVERALL POSITION

OLEM agrees with the recommendation that the OLEM Assistant Administrator conduct and document a formal risk assessment of the EPA's Contract Laboratory Program (CLP) to determine whether additional internal controls are needed to mitigate detected risks.

The Analytical Services Branch (ASB) within OLEM's Office of Superfund Remediation and Technology Innovation (OSRTI) administers the Contract Laboratory Program (CLP). To that end, ASB has initiated a formal CLP risk assessment and will provide the results to OLEM and the Office of the Inspector General by Fiscal Year 2017's fourth quarter.

As noted in the OIG report's Chapter 2 ("CLP's Internal Control System Addresses Four of Five Components and Should Formally Assess Program Risks"), the CLP has documented risk assessment on an informal but continual basis. This ongoing effort resulted in the development of new tools and updated guidance documents to address any potential risks identified. Going forward ASB will formally document risk assessment as part of its quality assurance process.

RESPONSE TO REPORT RECOMMENDATIONS

Agreements

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion by Quarter and FY
1	Conduct and document a formal risk assessment of the EPA's CLP to determine the adequacy of internal controls currently in place, and determine whether any additional controls are needed to mitigate detected risks.	The EPA will conduct and document a formal risk assessment of the CLP	4th Quarter FY 2017

CONTACT INFORMATION

If you have any questions regarding this response, please contact Kecia Thornton, OLEM OIG Audit Follow up Coordinator, at (202) 566-1913.

Attachment: Technical Comments

cc: Carolyn Copper, OIG
Patrick Gilbride, OIG
Erin Barnes-Weaver, OIG
Barry Breen
Nitin Natarajan
Jim Woolford
Dan Powell
Keith Upah
Daniel Ginsburg

Technical Comments Attachment

Audit Objectives

The Analytical Services Branch welcomes the opportunity to be the subject of this review because we continuously strive to maintain a thorough and effective capability to detect improper practices, and to provide relevant information to our stakeholders in a timely manner concerning the impacts of improper practices and fraud. ASB is always re-evaluating our processes to maintain a high level of effectiveness and efficiency, and we are grateful for the opportunity to learn from the experience of others.

Comment 1: Chapter 1, Quality Assurance / Quality Control Processes (paragraph 2)

ASB has included guidelines for evaluating and documenting data quality since the early days of the CLP through the National Functional Guidelines (NFG). These guidance documents (posted on the CLP website, along with the Statements of Work (SOW). The NFG are intended to provide a logical, stepwise approach to evaluating data quality, and a set of recommendations for documenting those findings for the data users. We recognize that data quality requirements are usually project-specific, depending on the project purpose and scope, and that project data reviewers should use our guidelines in conjunction with the project Quality Assurance Project Plan (QAPP).

The ASB and our EPA Regional counterparts conduct laboratory performance monitoring, beginning prior to contract award with pre-award on-site audits and pre-award performance evaluation samples (PES). On-site audits are also conducted post-contract award on an annual basis, and PES testing is routinely done, both on a quarterly basis, and as an optional part of Regional sample shipments.

Chapter 1, CLP Key Entities (paragraph 3, bullet 2)

The Quality Assurance and Technical Support (QATS) contractor is directed and tasked by the ASB. The QATS team provides a wide range of QA support to the CLP, and more broadly to the EPA in general, including conducting on-site laboratory audits, reviewing laboratory quality system documents; performing the development, preparation, management, distribution, evaluation, and reporting of performance evaluation samples for ASB and the EPA Regions to support Superfund activities, designing and conducting method validation studies, evaluating new sample preparation and analysis techniques, and conducting in-depth hard-copy and electronic data package audits. This latter task has proven most useful to ASB, in several Special Audit Investigations, to identify improper practices.

Chapter 1, Lab Fraud Allegations

The ASB strives to pursue all instances of improper practices identified either by our QATS team during their on-site or electronic data package auditing activities, or by our EPA Regional data review teams. To our knowledge, there is no regulatory authority involved with these activities, only the responsibility for contract administration. These monitoring activities focus on the

question of whether or not the requirements of the contract and the SOW have been followed, and occasionally instances of improper practice are found and are documented. ASB will then seek to discover whether the instance noted was a simple error, or is more common among a laboratory's product. Data, submitted by the labs, which resides in the SMO database, and the investigative tools and skills of the QATS team are our primary tools in this effort, and the information gained is communicated to our management, to OAM, our customers, and to the OIG at the appropriate time.

Chapter 2, Internal Control Systems

The ASB agrees that formal documentation of our assessment of risk, subjected to the type of periodic review and re-evaluation that is a normal part of our current operation, could make our system of internal controls more robust.

Chapter 3, Stakeholders Agree on the Need for Information Concerning Lab Fraud Methods/Techniques (paragraph 2, bullet 3)

ASB has presented information on its own experience with monitoring for and detecting improper laboratory practices to the CLP Regional stakeholders (most recently, at the CLP conference, November 2016); the Headquarters Quality Staff in OEI and the community of Regional QA Managers (on their monthly call, November 2016); and to the NELAC/TNI analytical chemistry community (National Environmental Monitoring Conference, August 2016)). These included evaluating the scope and temporal extent of improper practices, as well as the impacts of any subsequent data recall on the community of data users, including cost and delays in completion of EPA projects. In addition, OIG investigator Susan Chandler presented several examples of the types of improper practices her office had been investigating at the CLP Conference in 2014.

Office of Enforcement and Compliance Assurance Response to Draft Report

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

JAN 18 2017

OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

MEMORANDUM

SUBJECT: Response to Office of Inspector General Draft Report No. OPE-FY16-0022, "EPA's Contract Laboratory Program Includes Adequate Fraud Controls That Can Be Strengthened with Formal Risk Assessment and Investigative Information Sharing" dated December 13, 2016

FROM: Cynthia Giles
Assistant Administrator
Office of Enforcement and Compliance Assurance

TO: Arthur A. Elkins, Jr.
Inspector General

Thank you for the opportunity to respond to the issues and recommendations in the subject audit report. OECA generally agrees with the report's findings and recommendations, with one suggested edit to the report and one suggested edit to Recommendation No. 2.

Specifically, OECA suggests striking the statement on pages 5-6, which states, "According to OCEFT, the EPA's regulatory authority to inspect environmental labs is limited to labs that participate in the CLP" as that does not accurately reflect EPA's regulatory authority.

Additionally, OECA suggests revising Recommendation No. 2 to state, "Require the Office of Criminal Enforcement, Forensics and Training (OCEFT) to share pertinent information from laboratory fraud investigations with relevant EPA program, regional and enforcement offices and for the Analytical Services Branch within the Office of Land and Emergency Management, Office of Superfund Remediation and Technology Innovation to share pertinent information concerning laboratory fraud with EPA's regional and headquarters enforcement offices. Pertinent information, at a minimum, includes the fraudulent method or technique used to commit fraud."

Agreements

No.	Recommendation	High-Level Intended Corrective Action(s)	Estimated Completion by Quarter and FY
2	Require the Criminal Investigation Division to share pertinent information from laboratory fraud findings with relevant EPA program and regional offices. Pertinent information includes the fraudulent method or technique used to commit fraud.	Review current information dissemination policies and practices and meet with relevant EPA program, regional and enforcement offices to determine how to best communicate that information.	December 31, 2017 (1st Quarter FY 2018)

CONTACT INFORMATION

If you have any questions regarding this response, please contact Gwendolyn Spriggs, OECA's Audit Follow Up Coordinator on 202-564-2439, or via email spriggs.gwendolyn@epa.gov.

Office of Inspector General Response to Draft Report

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

THE INSPECTOR GENERAL

JAN 13 2017

MEMORANDUM

SUBJECT: Office of Inspector General Comments on OIG's Draft Report, *EPA's Contract Laboratory Program Includes Adequate Fraud Controls That Can Be Strengthened With Formal Risk Assessment and Investigative Information Sharing,* Project No. OPE-FY16-0022

FROM: Arthur A. Elkins Jr.

TO: Dr. Carolyn Copper, Assistant Inspector General
Office of Program Evaluation

This memorandum is in response to the subject Office of Inspector General (OIG) draft report. The OIG appreciates the evaluation of the Contract Laboratory Program. The OIG Office of Investigations has read the draft report's Recommendation 3, addressed to the Inspector General, that involves action to be taken by the Office of Investigations. The recommendation and OIG response are as follows:

Recommendation 3: Require the Office of Investigations to share pertinent information from laboratory fraud findings with relevant EPA program and regional offices. Pertinent information includes the fraudulent method or technique used to commit fraud.

> **OIG Response:** OIG Office of Investigations management believes pertinent information from laboratory fraud cases is already being shared with the relevant EPA program and regional offices at the appropriate times. However, to ensure that there is no misunderstanding, the Assistant Inspector General for Investigations will send an email message reminding the staff of this requirement. Moreover, the Office of Investigations will continue conducting fraud awareness briefings for its EPA stakeholders, as well as other federal, state, local and tribal partners.
>
> **Timeframe:** OIG will have the Assistant Inspector General for Investigations' email completed by January 30, 2017. The fraud awareness briefings will continue as needed.

If you have any questions regarding the OIG response, please contact Craig Ulmer, Deputy Assistant Inspector General for Investigations, at (202) 566-0943.

cc: Charles Sheehan, Deputy Inspector General
Patrick Sullivan, Assistant Inspector General for Investigations

Attachment

Appendix D

Distribution

The Administrator
Assistant Administrator for Land and Emergency Management
Assistant Administrator for Enforcement and Compliance Assurance
Inspector General
Agency Follow-Up Official (the CFO)
Agency Follow-Up Coordinator
General Counsel
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Deputy Assistant Administrator, Office of Land and Emergency Management
Deputy Assistant Administrator, Office of Enforcement and Compliance Assurance
Audit Follow-Up Coordinator, Office of the Administrator
Audit Follow-Up Coordinator, Office of Land and Emergency Management
Audit Follow-Up Coordinator, Office of Enforcement and Compliance Assurance