OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Evaluation Report

Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks

Report No. 2006-P-00036

September 21, 2006

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Abbreviations

DoD	Department of Defense
EPA	U.S. Environmental Protection Agency
NELAC	National Environmental Laboratory Accreditation Conference
OCEFT	Office of Criminal Enforcement, Forensics, and Training
OEI	Office of Environmental Information
OGWDW	Office of Ground Water and Drinking Water
OIG	Office of Inspector General
PT	Proficiency Testing
QA/QC	Quality Assurance/Quality Control
SOP	Standard Operating Procedures

Cover photo: Microbiological analysis of a water sample (EPA New England Regional Laboratory photo).

U.S. Environmental Protection Agency
Office of Inspector General

2006-P-00036
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At a Glance

Catalyst for Improving the Environment

Why We Did This Review

Between Fiscal Years 2000 and 2003, our Office of Investigations laboratory fraud unit saw an increase in cases. Drinking water samples, if not appropriately analyzed, will increase the risk of public exposure to harmful contaminants. We conducted this review to identify vulnerabilities in the drinking water sample analysis process and promising techniques to improve laboratory integrity.

Background

The Safe Drinking Water Act of 1974 provides that a laboratory must obtain approval by the U.S. Environmental Protection Agency (EPA) or a State before analyzing public drinking water samples for compliance with health-based standards. EPA certification and National Environmental Laboratory Accreditation Conference accreditation programs provide oversight of drinking water laboratories.

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/2006/20060921-2006-P-00036.pdf

Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks

What We Found

Within the drinking water sample analysis process we identified hundreds of vulnerabilities that are not addressed by EPA's process. These vulnerabilities can compromise the integrity of the analysis process and the quality of data produced. Many of these vulnerabilities were identified by the Office of Inspector General in 1999 and the Agency's own review in 2002, with no action by the Agency. Moreover, States that have implemented new techniques to detect laboratory integrity problems have found additional deficiencies, inappropriate procedures, and even cases of fraud. Their findings and those of our own investigators show integrity can be, and has been, compromised. However, without any national studies of water quality data that include examining the integrity of laboratories, the full extent of the problem remains unassessed.

Through our work with States, laboratory organizations, and other Federal agencies, we identified promising techniques to help improve oversight and protect against inappropriate procedures and fraud in the drinking water analysis process. This report contains details on those promising techniques.

What We Recommend

Given the potential impact of poor quality data on human health, we recommend that EPA assess drinking water laboratory integrity and incorporate promising techniques to better identify inappropriate procedures and fraud into the laboratory oversight process. Our specific recommendations include reforms to laboratory oversight processes, policy, guidance, and training. In addition, the Office of Ground Water and Drinking Water should improve awareness of the vulnerabilities and realities of fraud and inappropriate procedures affecting drinking water data quality. The Office of Environmental Information should develop a mechanism to identify, and a policy to address, data in Agency databases from laboratories under investigation, indictment, and/or conviction. EPA suggested modifications to several of our recommendations, preferring to encourage rather than require the use of promising techniques. We made changes where appropriate.

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

OFFICE OF
INSPECTOR GENERAL

September 21, 2006

MEMORANDUM

SUBJECT: Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks
Report No. 2006-P-00036

TO: Benjamin Grumbles
Assistant Administrator for Water

Linda A. Travers
Acting Assistant Administrator for Environmental Information
and Chief Information Officer

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. 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 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 $764,803.

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 corrective action plans for agreed upon actions, including milestone dates. We have no objections to further release of this report to the public. The report will be available at http://www.epa.gov/oig.

If you or your staff have any questions regarding this report, please contact me at (202) 566-0847 or roderick.bill@epa.gov, or Dan Engelberg, Product Line Director for Water Issues, at (202) 566-0830 or engelberg.dan@epa.gov.

Sincerely,

Bill A. Roderick
Acting Inspector General

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Chapter 1
Introduction

Purpose

The safety of America's drinking water rests on a system of standards, monitoring, and compliance determinations. To ensure health-based standards are met, the U.S. Environmental Protection Agency (EPA), under the Safe Drinking Water Act, requires periodic sampling and analysis of drinking water provided by public water systems. Testing laboratories play a critical role, alerting water system managers when health-based standards are not met and providing information for making public health decisions. Accurate and reliable data from certified drinking water laboratories are also needed to report EPA performance information to Congress and the public.

We conducted this evaluation to identify:

- Vulnerabilities in the drinking water sample analysis process,
- Techniques to mitigate those vulnerabilities, and
- Opportunities to further safeguard human health.

Background

Laboratory integrity is crucial to EPA's strategy for providing the public with safe drinking water. Public water systems test for over 80 contaminants[1] on a periodic basis. EPA has determined that these regulated contaminants can pose serious health risks ranging from diarrheal episodes to nervous system, kidney, and liver problems; an increased risk of cancer; and, in some cases, death. Every year, through the use of Consumer Confidence Reports, water systems notify their customers of the level of contaminants in drinking water. Between these reports, if the level of contaminants exceeds health-based standards, a public notice is issued to customers.

Public Health Considerations

False or inaccurate reporting of drinking water sample results could result in an increased level of risk – in some extreme examples, where water is severely contaminated, disability or death. EPA has not yet conducted a national review of laboratory performance or analyzed State data on laboratory deficiencies to determine the extent to which public health may or may not be at risk from

[1] Primary drinking water regulations include tests for 7 Microorganisms, 4 Disinfection By-products, 3 Disinfectants, 16 Inorganic Chemicals, 53 Organic Chemicals, and 4 Radionuclides. A list of contaminants regulated, maximum contaminant levels, and potential health effects is at http://www.epa.gov/safewater/mcl.html#mcls.

inappropriate or fraudulent laboratory procedures. Investigations by Federal and State agents have turned up a number of cases of inappropriate procedures and fraud that have the potential to affect human health. Because of the complexities of evaluating the effects of data manipulations and falsifications that occurred in several of the laboratory fraud cases, the EPA Office of Inspector General (OIG) investigators have been unable to determine the actual health risks and magnitude of population affected.

An OIG fraud case involving even a single laboratory can have a significant impact, affecting more than a million people, as demonstrated by the example in Figure 1.1.

Figure 1.1 - Widespread Potential Impact of an OIG Laboratory Fraud Case

City and County Residents	**1.8 million people**
School Districts and Individual Schools Served	**129**
Hospitals Served	**12**
Bottled Water Companies Served	**104**

Source: EPA OIG Office of Investigations analysis

Of interest in this example is the number of school districts and hospitals with particularly vulnerable populations that could be affected. The completed OIG investigation found machine calibrations associated with volatile and semi-volatile organic analyses were altered. Several of the standards and samples had surrogates[2] manipulated. While the surrogates are not on the list of national primary drinking water standards, their manipulation calls into question the accuracy of the results of all the contaminants for which the surrogates are monitors. Additional information on OIG laboratory fraud cases is in Appendix A.

No waterborne disease outbreaks or documented cases of illness related to drinking water have been directly tied to cases of inappropriate laboratory procedures or fraud in the United States. However, according to the U.S. Centers for Disease Control and Prevention, the incidents of illness related to drinking water contaminants can go unreported. When outbreaks are reported, epidemiological investigations generally do not include an assessment of laboratory procedures or a review of the quality of laboratory data reported.

[2] Surrogates are compounds added to each sample that monitor method performance with each sample. Typically one surrogate is the indicator for 10-20 compounds in a given sample analysis. Some of the compounds are regulated, some are not.

EPA Roles in Drinking Water Laboratory Certification

The Safe Drinking Water Act requires all laboratories to obtain an EPA or State certification before analyzing public drinking water samples. EPA suggests certified laboratories: (1) analyze proficiency test samples, (2) use EPA-approved analytical methods, and (3) successfully pass periodic on-site audits. Public water systems as well as the general public served by these systems rely on these audits and EPA's certification process to ensure drinking water quality information provided by laboratories is reliable and accurate. The Safe Drinking Water Act does not specify the nature of the audit, although EPA has developed audit training and offers guidance through a laboratory certification manual. As discussed in greater detail in Chapter 2, EPA has taken the audit requirements to be a best case assessment of laboratories' capability to perform EPA methods, not an assessment of actual performance by laboratories under day-to-day conditions.

Public water system regulations for those laboratories testing drinking water supplies for lead contamination include an additional provision that the EPA Administrator shall assure that programs for the certification of those testing laboratories certify only laboratories that provide reliable, accurate testing.[3]

The certification program for all drinking water laboratories (those testing for lead as well as other contaminants) is managed and operated from the Office of Ground Water and Drinking Water (OGWDW) Technical Support Center in Cincinnati, Ohio. A division of EPA's Office of Water, OGWDW oversees certification activities in the EPA regions and is responsible for training certification officers, providing guidance on laboratory certification, and maintaining a database of laboratory IDs. Regional certification program managers and regional certification authorities oversee State Principal Laboratories and State certification programs. In addition:

- OGWDW has also accepted National Environmental Laboratory Accreditation Conference (NELAC) accreditation[4] as an alternative to laboratory certification. EPA region, State, and commercial labs that are NELAC accredited are under the oversight of that program, which was developed with the support of EPA's Office of Research and Development. NELAC-accredited laboratories must still meet OGWDW certification requirements.
- The Office of Environmental Information (OEI) provides guidance and training for use by the environmental laboratory community.
- The Office of Criminal Enforcement, Forensics, and Training (OCEFT), as part of the Office of Enforcement and Compliance Assurance, performs enforcement actions through its Criminal Investigations Division.

[3] Title 42, U.S. Code, Section 300j-26

[4] Additional information on NELAC as well as the NELAC Standards document which describes the guidelines for laboratory accreditation is available at www.epa.gov/nelac

- The OIG's Office of Investigations investigates fraud, waste, and abuse in laboratories; and provides training in fraud detection when requested. OIG laboratory fraud cases are initiated through referrals from laboratory employees, or State and local inspectors.

State Roles Related to Public and Private Laboratories

It is the States, for the most part, that actually issue public and private laboratory certification or accreditation status for the analysis of public drinking water samples and have direct oversight responsibility for those laboratories. State certification officers visit laboratories and provide information to the State certification program manager, which is used to determine the certification status of the laboratory. These individuals are encouraged to attend and pass the EPA certification officers training course, but it is not required. The content of this course and exam vary between microbiology and chemistry, but both are based on EPA testing methods.

Guidance on methods to audit certified laboratories is provided to States via OGWDW's Laboratory Certification Manual, but there are no legal requirements on techniques to use. EPA relies on quality control measures built into drinking water analytical methods, proficiency testing, certification and accreditation audits, and any other measures implemented by States to control drinking water laboratory integrity and data quality.

OGWDW has historically not offered a specific radiochemistry course or exam, although it recently partnered with a provider of such training for a September 2006 course. Laboratories analyzing drinking water samples for radiochemical contaminants exist in 20 States and are fewer in number than those analyzing samples for microbiological or chemical contaminants. State radiochemistry Certification Officers are currently encouraged to participate in the certification training course for chemistry and pass the exam for inorganic chemistry.

Occurrence of Fraud and Inappropriate Procedures

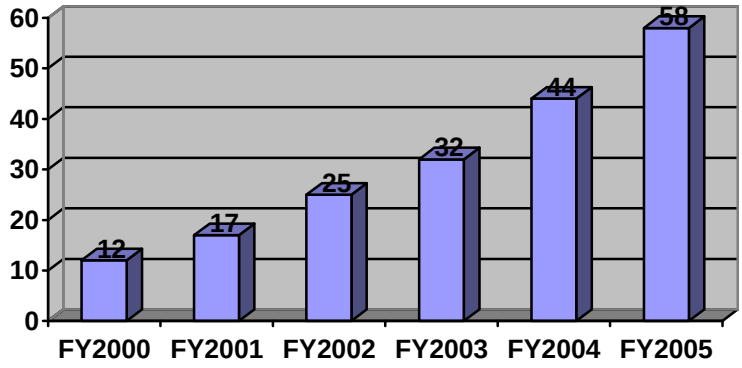
Four key areas of concern in this report are inappropriate procedures, laboratory fraud, data quality, and laboratory integrity, which we define as follows:

- **Inappropriate procedure:** A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required quality control parameters, making the results appear acceptable.
- **Laboratory fraud:** The deliberate falsification during reporting of analytical and quality assurance results that failed method and contractual requirements to make them appear to have passed requirements.

- **Data quality:** The degree of acceptability or utility of data for a particular purpose – in this case, reporting public drinking water sample information.
- **Laboratory integrity:** The laboratory's meeting general standards of objectivity, data quality, and ethical behavior, thus reporting accurate, complete, and valid information.

Over the past 6 years, the number of laboratory fraud cases reported to the EPA OIG Office of Investigations has increased steadily (Figure 1.2). Laboratories responsible for analyzing public drinking water samples represented over 35 percent of the 44 OIG laboratory fraud cases in 2004 and just fewer than 30 percent of the 58 cases in 2005 (see Appendix A for additional details). EPA Office of Water reports that there are approximately 6,000 laboratories certified for drinking water. The total percentage of certified laboratories under investigation or convicted of fraudulent procedures is currently unknown since no national database tracks certified drinking water laboratories by these parameters.

Figure 1.2: Number of EPA OIG Laboratory Fraud Investigations



Source: EPA OIG Office of Investigations

A 1999 OIG memo cited problems with laboratory data integrity and provided suggestions for improvement. In 2001, the OIG issued an open letter to the environmental analytical laboratory community to draw attention to inappropriate laboratory procedures and fraud. In 2002, OCEFT issued a laboratory fraud workgroup report with the Department of Justice acknowledging the severity of problems in environmental laboratories. Although these reports do not explicitly refer to laboratories analyzing drinking water samples, it is reasonable to conclude that the problems cited in these documents would be applicable to all types of laboratories, including those analyzing drinking water samples.

More Detailed Audits Look for and Find Problems

Arizona is using more advanced and aggressive techniques when compared to the minimal EPA requirements, and no other State has found the same magnitude of

problems as this State. Arizona identified 20 cases of what OIG considers to be severe inappropriate procedures, including fraud, following certification audits of over 140 laboratories seeking certification from the State (about 1 in 7 laboratories). Arizona representatives also reported that of the six largest laboratories operating in the State, five have gone out of business after incidents involving falsification or inappropriate procedures.

In our evaluation, we did not find any evidence to suggest that the quality of laboratories analyzing drinking water samples for residents of Arizona were any different than laboratories in operation throughout the United States. In fact, while Arizona auditors have found severe problems, including fraudulent procedures during drinking water laboratory certification audits, other States, performing EPA (OGWDW) certification audits as well as NELAC accreditation audits at the same laboratories, have issued reports finding minimal deficiencies.

Figure 1.3 provides examples of what Arizona Certification Officers found at laboratories both in-State and out-of-State, as well as both NELAC-accredited and not NELAC-accredited. Of the 106 laboratories currently certified by Arizona to test drinking water, 49 are located outside the State. Details on Arizona's audit methods are in Chapter 3.

Figure 1.3 - Inappropriate or Fraudulent Procedures Found in Laboratories Seeking Arizona Certification

- Falsified drinking water reports
- Contaminated samples not reported to water system operators
- Data falsified to make it appear testing done correctly
- Testing falsified and, when discovered by lab director, not redone
- Lab director tore up drinking water result showing coliform at request of system operator and allowed the operator to submit new sample
- Lab director substituted purified water for sample when sample lost and testing dates falsified
- Inconsistencies between lab records and results reported to Department of Environmental Quality
- No peer review of analytical/electronic data
- 30 percent of samples in one laboratory were not analyzed at all
- Analyst told to fill in past calibration dates while Arizona auditors were on-site
- Lab director altered time of analyses on data requested by Arizona auditors
- Laboratory reported several analytical methods that were not actually used

Source: Arizona Department of Health Services, Office of Laboratory, Licensure, Certification and Training

A survey of EPA regions and discussions with some State certification officers suggest that those individuals believe fraud and inappropriate procedures occur infrequently in drinking water laboratories and the impact is low (see OIG Supplemental Regional Survey Report for further details). However, no national studies have gauged the actual extent of laboratory fraud, although problems have been documented and reported to EPA regions for several years. We cannot, with any accuracy or reliability, quantify the extent to which this is a problem without

the use of accepted techniques to identify both inappropriate procedures and fraud. We do, however, note an association between identified cases of inappropriate procedures and laboratory fraud, and the use of on-site auditing methods additional to those required by EPA.

Scope and Methodology

We conducted our evaluation from August 2004 through February 2006 in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. We evaluated drinking water laboratory procedures by identifying vulnerabilities in the sample analysis process and examining techniques used by EPA, States, and other Federal agencies to identify and address inappropriate and fraudulent laboratory procedures. Further, we identified potential promising techniques by organizing a five-member expert panel to provide input. The panel consisted of representatives from a certification program, an accreditation program, a Federal agency, an environmental and data quality consulting organization, and a large commercial laboratory.
We reviewed EPA headquarters, regional, and selected State guidance for the certification and accreditation of laboratories analyzing drinking water samples. We compared EPA OGWDW guidance and regulations to those used by other Federal agencies, interviewing managers and staff. We also interviewed staff and managers from all relevant EPA program offices regarding training, guidance, and enforcement activities. Every EPA regional certification authority or their designees were surveyed and interviewed. State certification or accreditation program managers and staff were interviewed in Arizona, Pennsylvania, Kentucky, and Utah. We also interviewed public health experts.

Appendix B provides further details on scope and methodology.

Chapter 2

Vulnerabilities Compromise Laboratory and Data Integrity, Increase Public Risk

We compiled lists numbering over one hundred vulnerabilities in the drinking water sample analysis process that could lead to fraud and inappropriate procedures. The Agency itself (OCEFT) identified many vulnerabilities in its own review in 2002, but these vulnerabilities have not been adequately addressed. Economic conditions in the laboratory testing industry, combined with limited oversight controls, increase the likelihood an analyst or manager will exploit an existing vulnerability. When inappropriate or fraudulent laboratory procedures occur, the true quality of drinking water is unknown and health risks for consumers are increased.

Sample Analysis Process

To evaluate the integrity of drinking water laboratories and the process used to analyze and report drinking water sample data, we first constructed and examined the drinking water sample analysis process and determined which steps would be most prone or vulnerable to inappropriate or fraudulent procedures.

The process is divided into 13 steps (Figure 2.1). An inappropriate or fraudulent procedure used in one step will affect subsequent steps and, ultimately, the final determination of drinking water sample quality. For example, an instrument that is not calibrated properly results in inaccurate and unreliable measurements from the time the calibration is put into use.

Figure 2.1 - Steps in Drinking Water Sample Analysis Process

a. Sample Collection*
b. Sample Tracking and Recording
c. Adherence to Standard Operating Procedures (SOPs) for Analytical Methods
d. Preparation of Samples and Standard Solutions
e. Instrument Performance
f. Instrument Maintenance
g. Instrument Calibration
h. Lab Technician Performance
i. Adherence to Quality Assurance/Quality Control (QA/QC) Plan
j. Data Validation and Verification
k. Data Handling and Maintenance
l. Data Reporting
m. Data Security and Backup

* Step occurs mainly outside the control of testing laboratories, although a laboratory may choose to reject a sample arriving in poor condition.

Source: EPA OIG analysis with input from OGWDW and consultation with OIG expert panel

Multiple Vulnerabilities Identified

EPA program offices, States, and members of the OIG expert panel provided multiple examples of vulnerabilities within the drinking water sample analysis process. Although there were unique vulnerabilities listed for each group, several were similar.

Vulnerability, for the purposes of this evaluation, is defined by the OIG as any weakness, deficiency or feature of the current system, which, if exploited (intentionally or unintentionally) by a laboratory analyst or manager would compromise: (1) the integrity of the drinking water sample analysis process or (2) the quality of data produced.

Source: EPA OIG evaluation team

OCEFT Noted Problems, Urged Improved Integrity of Laboratory Data

In 2002, the OCEFT Lab Fraud Workgroup noted in a report an increasing trend in laboratory fraud cases and the potential for laboratory fraud to "undermine the foundation of EPA's regulatory programs." The report provides several examples of common types of laboratory fraud, and notes 73 "laboratory problems" or vulnerabilities. The workgroup cites 29 of the 73 problems (40 percent) as items that might not require detailed technical knowledge for detection. Appendix C provides the full list; selected common examples of laboratory fraud follow:

- ***Pencil whipping*** – Changing data or records (now often through computer manipulations) without a legitimate reason.
- ***Juicing*** – Adding or diluting analyte[5] in the sample, calibration standard, or quality control samples to change results or make reported results appear acceptable.
- ***Peak dialing*** – Adjusting the instrument dials, resistors, attenuators, other controls or computer outputs to achieve the desired output for the sample or calibration.
- ***Time travel or time warping*** – Changing times and dates to make documentation requirements appear acceptable.[6]

EPA Team Acknowledged Sample Analysis Process Vulnerabilities

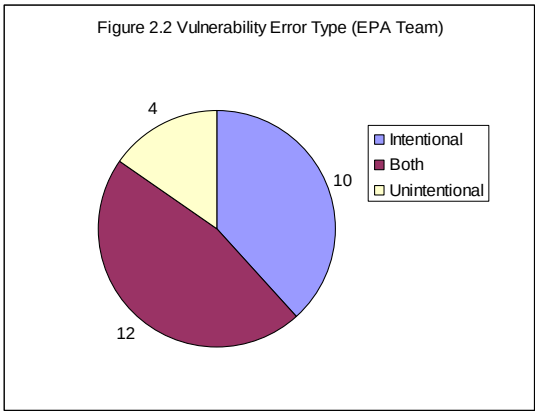
An EPA team composed of OGWDW Technical Support Center staff and two staff members from the Office of Research and Development[7] with experience in drinking water laboratory certification, responded to an OIG questionnaire on laboratory procedures. Vulnerabilities listed in the questionnaire completed by the EPA team indicate an awareness of shortcomings associated with the analysis process. Acknowledging that their expertise is with the analytical methods (and with the certification process established to evaluate laboratory capability to properly use the methods), that their field expertise with commercial laboratories was quite limited, and they are not trained in fraud detection, certification team

[5] The sample constituent that is sought or intended to be measured.
[6] For example, volatile organic samples may degrade rapidly with time or lack of refrigeration; therefore, there is an incentive to analyze samples within prescribed holding times or make it appear as though they had.
[7] The two individuals were the only Office of Research and Development representatives asked for input by OGWDW.

members offered their opinions regarding the potential for problems in the various sample analysis process areas. Using the list of process steps provided by OIG (Figure 2.1), the EPA team identified severe vulnerabilities in every step of the process, for a total of 26 (see Appendix D). Of these 26 vulnerabilities, 4 were categorized as unintentional only (Figure 2.2).

The most serious vulnerabilities listed were:

- falsification of data by a trained analyst (step h),
- falsification or failure to perform quality control data (step i), and
- failure to flag data outside acceptance criteria (step j).



Source: EPA Team

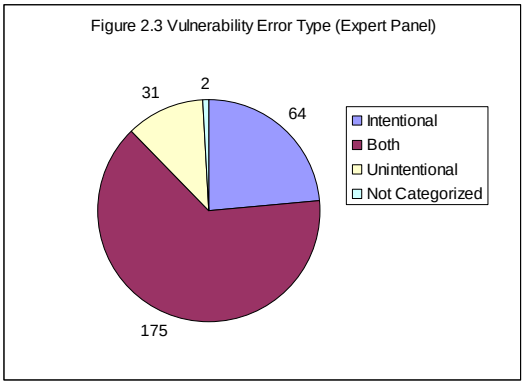
These three vulnerabilities, and seven others, were categorized by the EPA team as resulting from intentional errors. Several of these vulnerabilities listed in response to our 2005 request were similar to problems listed 3 years earlier in the OCEFT report (see Appendices C and D).

States Note Vulnerabilities, Inappropriate Procedures, and Fraud

Although State certification officers interviewed had mixed views as to what parts of the process would be more vulnerable than others, almost all steps – excluding instrument maintenance (step f) and data security and backup (step m) – were noted by at least one State as vulnerable or prone to fraud and inappropriate procedures. All States agreed that sample collection – the first step in the drinking water sample analysis process – is highly prone to inappropriate and fraudulent procedures. Specific concerns are that the sample may not actually end up in the laboratory, may be from the wrong location, may be collected by an individual with limited or improper training, or may be improperly processed or decanted at the collection site. We did not request State certification officers to identify vulnerabilities in each step of the process as we did for OGWDW and the expert panel.

Expert Panel Members Collectively Identify Hundreds of Vulnerabilities

To further evaluate the existence and severity of vulnerabilities in the drinking water sample analysis process, we convened a five-member panel of experts from the drinking water laboratory community (see Appendix B for additional information on selection methodology). In all, the panel members came up with 272 vulnerabilities in the drinking water sample analysis process prior to the meeting (Appendix E). Of the 272 vulnerabilities, 64 were categorized as intentional errors on the part of a laboratory analyst or manager, 175 as either intentional or unintentional errors (both), and 31 as unintentional errors or mistakes; 2 were not categorized (see Figure 2.3).



Source: EPA OIG expert panel

After deliberating on 30 vulnerabilities categorized by various members as having the most severe impact to the integrity of the drinking water sample analysis process, the panel agreed on a shortened list of 20 (see Figure 2.4).

Figure 2.4 - Most Severe Vulnerabilities Identified by Expert Panel

- Censoring of information based on reporting limits
- Data manipulation
- Failure to follow SOPs/reference methods
- Falsifying existing data
- Improper calibration
- Inappropriate manual integrations
- Overwriting files: peak shaving, juicing/peak enhancing, deleting
- Inadequate training
- Inappropriate collection process
- Incomplete record keeping
- Mislabeled sample
- No demonstration of competency
- No requirement for collector
- Reporting data for samples not analyzed ("dry labbing")
- Retention times not assured
- Sample integrity unknown
- Selective use of QC data
- Sequencing analysis
- Spiking samples after preparation
- Time travel (changing times and dates)

Source: EPA OIG expert panel

The panel rated the steps in the drinking water sample analysis process from most to least prone to inappropriate or fraudulent procedures (see Figure 2.5). The panel agreed that the initial step – Sample Collection (step a) – is the step most prone to the occurrence of inappropriate and fraudulent procedures.

Figure 2.5 - Areas of the Drinking Water Sample Analysis Process	
Most Prone Area	• Sample Collection (a)
Highly Prone Areas *(in order from most to least)*	• Data Validation and Verification (j) • Instrument Calibration (g) • Lab Technician Performance (h) • Preparation of Samples and Standard Solutions (d) • Data Security and Backup (m)

Source: EPA OIG expert panel

EPA Procedures to Address Data for Detected Instances of Inappropriate Procedures and Fraud Limited

When we reviewed actions taken by EPA (Agency organizations and regions) when inappropriate and fraudulent procedures are detected, we found that EPA lacked standardized methods and guidance on how affected data would be handled. OEI oversees implementation of the Agency's Quality System, which, in part, assures the quality of data is known and documented. Agency organizations are responsible for implementing the policy specific to their activities. While OEI has developed training to deter and detect improper laboratory practices, fraud detection and reporting are outside the scope of the existing Quality System policy.

There are no Agency processes to address data produced by public and private laboratories using inappropriate or fraudulent sampling procedures in drinking water or other laboratories. Although this evaluation was limited in scope to drinking water laboratory procedures and data produced by those laboratories, we found no mechanisms to identify data in Agency databases originating from laboratories using inappropriate or fraudulent procedures; no Agency policy exists on how to handle data from laboratories under investigation, indictment, or with convictions.

We did not find any plans to require certified laboratories to abide by ethics programs or certification officers to acquire training in additional auditing techniques, data integrity concepts, fraud detection, or reporting. No standard procedure or written guidance on the reporting of inappropriate laboratory procedures or fraud is issued to certification and accreditation officers. Since we began this evaluation, OGWDW has agreed to encourage certification officers to participate in fraud/data auditing courses offered by others and has included presentations on such in their own training course. A button on EPA's main

Website is used to promote reporting, but does not include a category applicable to laboratory fraud.

Various Factors Contribute to Vulnerabilities

In addition to those instances where people deliberately seek to cheat the system, OIG expert panel members, EPA program office staff, and State certification officers offered two theories as to why they believe laboratory fraud and inappropriate procedures may occur. Economic pressures create incentives for the laboratory industries to cut corners. Also, controls over the integrity of laboratories are often limited. Additional causes relate to time constraints, as well as expectations that no contaminants exceed maximum levels.

Economic Pressures Provide Incentive to Cut Corners

Economic pressures in the laboratory industry that contribute to sample analysis vulnerabilities include being profit driven and a loss of expertise, and these may work counter to the integrity of the industry. According to OCEFT, additional tests to show calibration accuracy, reproducibility, and methodology validity can add an extra 10 to 20 percent to the cost of analysis. Meanwhile, low profit margins and under bidding dictate that resources be spent on increasing the volume of samples analyzed rather than ensuring the quality of work. Thus, people may cut corners. In addition, because prices at labs have dropped, salaries may not support having qualified people at the analysis level of testing.

Lack of Laboratory Integrity Controls

OGWDW noted that the Laboratory Certification Program was not designed to prevent or detect fraud, but to establish the technical capability of a laboratory to conduct analytical measurements required by the Safe Drinking Water Act. OGWDW interprets fraudulent procedures to fall outside the scope of laboratory certification audits. Although OGWDW interprets the certification program to detect and deter inappropriate procedures, we found this to be true only for some inappropriate procedures.

In our survey to EPA regional certification officers, most regional respondents stated that the intent of the on-site audit is to determine laboratory compliance with EPA methods and not the occurrence of fraud. Respondents explained that auditors do not look for fraud because it is outside the scope of the laboratory certification audit. In addition, some respondents noted that the on-site audit was also not designed to focus on inappropriate procedures (see OIG Supplemental Regional Survey Report for further details).

EPA requires the use of very specific methods when drinking water is tested for contaminants. Although guidance is available in the form of certification officer training and the Laboratory Certification Manual, no Federal regulations exist to

prescribe or require the use of any specific techniques in the oversight and audit process used to certify drinking water laboratories. Once an individual becomes a certification officer, there are suggestions to take refresher courses every 5 years but no continuing education requirements. There is no Federal requirement for the submission of quality control data, no policy on manual integration or calibration, and no requirement that certification officers review laboratory data. While proficiency tests are encouraged, shortcomings have been noted, and there are no other competency requirements. Four of the five expert panel members and State certification officers noted current proficiency test methods could be more effective. Using a different analyst, process, conditions, or alternate QA/QC for proficiency test samples, as well as the sharing of proficiency test data between laboratories before submission, were cited as problems that could occur with the current proficiency test sample regimen.

New techniques to identify inappropriate and fraudulent procedures are emerging along with new technologies. The 1999 OIG memo report and the 2002 OCEFT Laboratory Fraud Workgroup report both suggest the implementation of accepted processes to detect and deter laboratory fraud and inappropriate procedures. OGWDW noted that it communicates with regions in monthly conference calls and during program reviews and certification training. OGWDW also works with the drinking water laboratory community to develop and update the guidance manual for laboratory certification periodically. However, there have been no changes to provide guidance on determining laboratory or process integrity, data quality, ethical laboratory practices, fraud detection, or fraud reporting. OGWDW acknowledges that it has not provided regional staff or State certification officers – the individuals who conduct on-site laboratory audits and determine whether a lab is qualified to analyze water samples – a plan to address inappropriate and fraudulent procedures when identified in laboratories.

Of the State certification programs where we interviewed staff, some programs are, on their own, actively looking for inappropriate procedures and fraud using many highly effective, promising techniques. These techniques, although determined effective, go beyond EPA requirements, and States do not receive additional funding or resources to conduct these types of audits.

Additional Causes Relate to Time and Expectations

Environmental samples, including drinking water samples, can change over time, which can result in laboratory time constraints. According to OCEFT, if a problem occurs and the process cannot be performed in the specified time, there is an incentive to falsify the time of analysis rather than obtain a new sample and re-run the necessary test. Also according to OCEFT, clients may motivate laboratories to commit fraud or inappropriate procedures. In addition, a laboratory may be concerned that test results the client will find unacceptable can result in losing that client's business, as well as the business of other clients.

Vulnerabilities Hinder Ability to Ensure Safe Drinking Water

Vulnerabilities in the drinking water sample analysis process impact EPA's overall strategy for providing the public with safe drinking water, thus increasing the health risks for consumers. To the extent that adequate processes are not in place to detect fraudulent or inappropriate procedures, decision makers will not have full assurance that drinking water data are accurate. Decision makers range from water treatment system managers and operators, EPA regulators (State and Federal), researchers, and even members of the public considering whether to install a filter or purchase bottled water.

Vulnerabilities in the sample analysis process increase the risk of public exposure to drinking water contaminants. According to EPA, there are a number of threats to drinking water: improperly disposed of chemicals, animal and human wastes, pesticides, wastes injected deep underground, and naturally-occurring substances. When contaminants are microbial (i.e., viruses, bacteria), the health effect is usually acute, while chemical contaminants most likely would impact consumer health over time. EPA and States use a multi-barrier approach to protect public health, but most efforts are linked in some way to the sample analysis process that occurs in laboratories and the data produced.

If a sample is inappropriately or fraudulently analyzed, an operator may miss the opportunity to use a treatment technique to address the amount of contaminant present, or may use a treatment technique that is not sufficient. In addition, individuals may make decisions to purchase bottled water, install a water filter, or simply drink water from the tap based on this data. The integrity of drinking water laboratories can also affect the future of drinking water regulations and research efforts since EPA monitors reported drinking water data to determine if new rules or regulations need to be issued.

Finally, without adequately assuring data from laboratories are accurate and reliable, as well as verifying the integrity of the analysis process, EPA efforts to improve drinking water data in the EPA Safe Drinking Water Information System-Federal Version database may be limited. Certified laboratories are the starting point for data that enter this system. The information in the system is used in reports to Congress and the American people on the percent of population served by community water systems meeting health-based drinking water standards. In addition, it supports OGWDW's performance measurement and management processes.

* * *

Overall conclusions and recommendations are in Chapter 4.

Chapter 3

Opportunities Exist to Provide Additional Protection Against Inappropriate and Fraudulent Procedures

EPA can apply numerous promising techniques to better prevent, detect, or correct inappropriate and fraudulent laboratory procedures. An expert panel, as well as officials from EPA and States, agreed that many of the techniques we compiled could prove beneficial. These techniques relate to developing policy, training, and guidance, as well as oversight and enforcement practices. Further, some States and other Federal agencies already do more than EPA requires to assure the integrity of laboratory information, and EPA could consider encouraging some of those techniques. In addition, we noted some techniques used by EPA offices other than OGWDW that OGWDW should also consider using. The potentially promising techniques noted could be used to better protect against inappropriate and fraudulent procedures at laboratories that analyze drinking water samples, thus enabling EPA to better protect public health.

Promising Techniques Identified to Better Protect Against Inappropriate and Fraudulent Procedures

We conducted a literature search and interviews to identify promising techniques that EPA could use to better protect against inappropriate and fraudulent laboratory procedures. A full list of the promising techniques is provided in Appendix F. We provided EPA (OGWDW and OEI), selected States, and our expert panel with a questionnaire on these promising techniques. We asked the expert panel and EPA OGWDW to rate each technique for its effectiveness using a scale of 1 to 5, with 5 being most effective. We considered techniques to be highly effective if they received an average score of 3.5 to 5.0. We only asked States and EPA OEI to review the list of techniques and indicate whether they considered them as highly effective. Those techniques rated highly effective are shown in Figure 3.1. We divided the highly rated techniques into the three areas:

- Policy, Training, and Guidance
- Laboratory Oversight Practices
- Enforcement Practices

These techniques are intended to be used by EPA, States, and/or public and private laboratories, and we make appropriate recommendations in Chapter 4 applicable to the highly rated techniques.

Figure 3.1 - Techniques Predicted to be Highly Effective

Techniques	Expert Panel	EPA OGWDW	EPA OEI	States*
Policy, Training, and Guidance				
• Develop a training and education program on fraud		√	√	√
• Develop and/or use available guidance on fraud awareness	√	√		√
• Develop examples of prohibited practices as guidance			√	√
• Implement an ethics policy/program		√		√
• Implement a fraud detection policy/program	√			√
• Implement a fraud deterrence policy/program	√			√
Laboratory Oversight Practices				
• Perform on-site and followup audits	√	√		√
• Include double blind proficiency testing samples	√			√
• Include split sample analysis		√		√
• Conduct data accuracy reviews	√			√
• Use data validation and verification techniques	√			
• Review raw electronic data and use electronic data analysis/tape audits	√		√	√
• Use analyst notation and sign-off on manual integration changes to data	√	√		√
• Review inventory of laboratory supplies**				√
Enforcement Practices				
• Establish a fraud hotline		√		√

* States included Arizona, Kentucky, Pennsylvania, and Utah only.
** Technique was listed as an additional one by States and not listed on questionnaire provided.

Source: EPA OIG analysis

Techniques Not Required by OGWDW Implemented by Others

Through our research of EPA offices other than OGWDW, as well as our research of other Federal agencies and States, we found these groups to already be implementing several of the promising techniques identified in Figure 3.1 and some additional techniques. Although some of these groups deal with different types and aspects of laboratory testing (e.g., clinical, environmental), some of these techniques could be incorporated within the EPA certification program to better ensure laboratory integrity and further reduce public health risks.

Other EPA Offices

EPA's Office of Research and Development provided initial support for the NELAC accreditation process, which applies to environmental laboratories as well as all Agency and most EPA regional laboratories. The NELAC accreditation process follows OGWDW certification requirements for drinking water laboratories, but has incorporated some promising techniques into the assessment process. The program requires laboratories to provide data integrity training to employees that includes providing specific examples of breaches of ethical behavior, written ethics agreements, and examples of improper practices. While some NELAC program elements could strengthen oversight of drinking water laboratories, it is voluntary and OGWDW provides no incentives for laboratories or States who choose to take on this additional accreditation.

OEI has developed training courses to address the integrity of laboratory processes and the detection of improper laboratory practices. Specific OEI activities include:

- A course on detecting improper laboratory practices.
- A Website to provide best practices for laboratory quality systems.
- Guidance and training on environmental data verification and validation.
- A presentation on EPA quality staff ethics and data integrity activities.

The training courses and other tools are available on the EPA Quality System Website (http://www.epa.gov/quality/bestlabs.html) and are available for use by both EPA and non-EPA laboratories. OGWDW and OEI have not communicated about the use of these tools. Although not specific to drinking water laboratories, the OEI-developed tools could be adapted by OGWDW to improve laboratory integrity.

Other Federal Agencies

The Department of Defense (DoD) uses several promising techniques. DoD requires laboratories to have a program to detect and prevent improper, unethical, or illegal actions. DoD also requires laboratories to have an ethics policy in place with annual training requirements, and DoD may use double blind proficiency testing samples if problems are suspected. In addition, DoD provides guidance on inappropriate acts and is working on a procurement policy for laboratory services that specifies a list of prohibited laboratory practices.

While the U.S. Department of Health and Human Services Clinical Laboratory Improvement Amendments program has no specific processes or guidelines to protect against inappropriate or fraudulent procedures, the Department believes there are some Clinical Laboratory Improvement Amendments program activities that discourage analysts from performing inappropriate or fraudulent acts. Inspections every 2 years by experienced surveyors, review of documentation

dating as far back as 2 years, and steep fines for those who may use inappropriate or fraudulent procedures may be deterrents for clinical laboratories that consider the use of inappropriate procedures or fraud. The U.S. Department of Health and Human Services also noted as a strength regular communication between surveyors at the regional and national level. The promising technique of double blind test samples is used in some cases to verify the accuracy of laboratory results for unregulated analytes.

States

States take a variety of approaches to identify and address inappropriate and fraudulent procedures, dependent on available resources, technical expertise, and management preferences. For three of the four States visited, the programs operated solely on certification fees received from laboratories. In the fourth State, the majority of the program was funded by State dollars.

The regional survey showed two thirds of States were using data validation and verification techniques, and a small percentage (six States) were using electronic data review (see OIG Supplemental Regional Survey Report). These techniques are currently not required by OGWDW for the oversight of drinking water laboratories. The States we reviewed that were using promising techniques to identify inappropriate and fraudulent procedures have found a multitude of deficiencies, inappropriate procedures, and in some cases fraud.

We found Arizona and Pennsylvania to have been particularly aggressive in examining laboratory integrity, using on-site audits to look for inappropriate procedures, and spending additional time on data reviews. Using electronic data analysis software costing $15,000 and trained technical auditors, Arizona certification audits have identified various problems, such as manual integrations and overwriting calibration curves, which would have gone undetected in an audit using only EPA-required methods. Arizona's laboratory certification requirements include an additional requirement for "scientifically valid and defensible" testing. Pennsylvania issued new laboratory accreditation guidelines in August 2005 that include a paragraph on the potential impact of laboratory fraud and the undermining of public confidence in data from laboratories.

When microbiology certification officers in Kentucky decided to quiz laboratory analysts on testing methods during the on-site certification audit – a technique suggested by EPA, but not required – they found several laboratory analysts were unable to differentiate between the presence and absence of total coliforms. Total coliforms include fecal coliform and *E.Coli*, contaminants used to indicate whether other potentially harmful bacteria may be present.

To enhance communication and share potential promising techniques, 26 State certification and accreditation programs have formed a discussion group. The group, initiated in 2004, holds conference calls every other month. Any

environmental or drinking water auditor is welcome to participate in the call. Until recently, EPA had not participated in calls or communicated regularly with the group. The group provides an outlet for questions concerning EPA standard methods and specific applications in drinking water laboratories. The group may also take action and make suggestions to EPA. For example, the group is working on a guidance document to provide additional details on calibration protocol. With recent communication between EPA and the group, the group could potentially be used to assist OGWDW in developing drinking water laboratory certification process and oversight guidelines, including the use of promising practices already implemented by several State members.

* * *

Overall conclusions and recommendations are in Chapter 4.

Chapter 4
Conclusions and Recommendations

Significant vulnerabilities in the drinking water sample analysis process compromise laboratory integrity and data quality, and increase the risk of public exposure to contaminants. The Agency must take steps to better address the root causes leading to the existence of vulnerabilities, including limited laboratory controls and economic pressures. In particular, EPA needs to:

- Enhance guidance and further encourage EPA and State laboratory certification officers to use promising techniques, and reduce uncertainty by monitoring and assessing laboratory and certification program conditions.
- Review procurement policy and promote ethical practices.
- Create a policy and mechanism to identify affected data.

These actions will help EPA ensure data reliability and better protect public health by improving controls over laboratories and diminishing the reasons that can lead to laboratories engaging in inappropriate procedures and fraud. Further, decisions vital to public health can be made based on better laboratory data.

Promote Better Training and Use of Promising Techniques

Current requirements for laboratories that analyze drinking water samples, as well as those individuals who grant the certifications, should be enhanced to better ensure integrity and protect public health. Techniques used by certification officers may not assess severe vulnerabilities, impacting the Agency's ability to ensure safe drinking water. Techniques exist that, if incorporated into the drinking water laboratory certification program, could better detect and deter inappropriate and fraudulent procedures, improving the integrity of laboratory operations. By taking advantage of these techniques, EPA can make significant gains. Further, EPA can better monitor changes and identify emerging challenges in the laboratory testing environment.

We recommend that the Assistant Administrator for Water:

1. Prepare laboratory certification officers for the conditions and challenges they will face in testing laboratories associated with fraud by applying the following promising techniques (modified from those highlighted in Chapter 3):

   a) *Promote Training and Education Regarding Fraud*
   b) *Integrate Fraud Awareness into Laboratory Certification Training*

2. Ensure that all individuals within OGWDW, regions, and States who have oversight responsibility for laboratories analyzing drinking water samples are educated and proficient in the proper procedures to follow should a laboratory be suspected of inappropriate or fraudulent procedures. Specifically:

    a) Distribute written guidance and appropriate contacts at the suggested course for State certification officers; copies of the guidance should also be distributed to OGWDW regional and Technical Support Center staff.
    b) Establish the use of the EPA fraud hotline for environmental testing laboratories; certified and accredited laboratories should be provided with appropriate Office of Enforcement and Compliance Assurance or OIG contacts to report possible misconduct.
    c) Work with the Office of Enforcement and Compliance Assurance to determine if the form connected to the on-line violation reporting tool on EPA's Website could be used for laboratory fraud.

3. Create and use a training course, exam, and standard methods for the certification of laboratories analyzing drinking water samples for radiochemical contaminants.

4. Encourage certification officers to use the following promising techniques, as noted in Chapter 3, already developed by other groups in laboratory oversight. In addition, encourage certified or accredited laboratories to engage in techniques b and c:

    a) *Enhance On-Site and Followup Audits to Include Techniques to Identify and Deter Inappropriate Procedures and Fraud*
    b) *Use Data Validation and Verification Techniques*
    c) *Use Analyst Notation and Sign-off on Manual Integration Changes to Data*
    d) *Review Raw Electronic Data and Use Electronic Data Analysis/Tape Audits*
    e) *Review Inventory of Laboratory Supplies*
    f) *Include Double Blind Proficiency Testing Samples Reform* (or a combination of Double Blind and Split Sample Analysis)
    g) *Conduct Data Accuracy Reviews*

5. Reduce uncertainty associated with the integrity of drinking water laboratories as well as the occurrence of inappropriate procedures and fraud. At least every 3 years, perform a periodic assessment to:

    a) Review the drinking water sample analysis process for the existence of vulnerabilities.
    b) Assess the extent to which inappropriate and fraudulent procedures are occurring (using techniques described in Recommendation 4).

c) Assess the laboratory certification program as well as specific protection processes and techniques for effectiveness. Explore incentives to encourage States and laboratories to adopt innovative practices.

As part of this periodic assessment, consider adjusting laboratory and certification method requirements and resource allocations if needed.

6. Set up a workgroup – including representatives from regions, States, and laboratories – to review the sample collection requirements and seek opportunities to minimize vulnerabilities.

Actively Discourage Fraud and Inappropriate Procedures

Economic pressures can provide incentives for analysts and managers to utilize inappropriate and fraudulent procedures, while limited laboratory oversight provides an opportunity for exploitation. Additional techniques available to protect against vulnerabilities and the occurrence of fraudulent and inappropriate procedures will better address the underlying causes that contribute to their existence. By addressing economic pressures and a lack of oversight, the Agency can discourage inappropriate procedures and fraud.

We recommend that the Assistant Administrator for Water:

7. Meet with Agency contract officers and the Office of Policy, Economics, and Innovation to determine if appropriate procurement guidance for EPA, States, and public water systems (including language similar to what is under development by DoD) specifying a list of prohibited practices and possible incentives for laboratories or analysts that meet higher integrity standards can be developed to offset economic pressures to cut corners.

8. Provide the following training programs and guidance information for laboratories, as noted in Chapter 3, that analyze drinking water samples:

   a) *All Certified Laboratories Should Have an Ethics Policy/Program*
   b) *Encourage Certified Laboratories to Implement a Fraud Detection and Deterrence Policy/Program*

Reduce Risk to Agency Systems and Decision Making

There is no standard means by which EPA identifies, reports, or handles data from suspect laboratories in any media, including those that analyze public drinking water samples. The Agency faces additional costs and unnecessary delays when it has to identify and assess the impact of questionable data and undertake additional sampling. With a policy and method to identify altered data, the Agency can better ensure that environmental and public health decisions,

including the development of new environmental rules and regulations, are made using quality data.

We recommend that the Assistant Administrator for Environmental Information, as the national program manager for quality:

9. Create a mechanism to identify data in Agency databases originating from laboratories under investigation, indictment, and/or conviction.

10. Develop an Agency-wide policy on how data originating from laboratories under investigation, indictment, and/or conviction will be handled.

Agency Comments and OIG Evaluation

The Office of Water and OEI provided written comments on a draft of this report. In its response the Office of Water pointed out that we had not indicated the extent of fraud in the nation's drinking water laboratories, and suggested that without a more precise estimate of the extent of the problem it could not support expanding the resources of the Laboratory Certification program to address the vulnerabilities we had identified. The Office of Water also pointed out that many of the vulnerabilities we had identified are already addressed in some manner in its current programs. Moreover, other practices, such as those related to sample collection, are not germane to the issue. The Office of Water also indicated that while the OIG characterized drinking water laboratory fraud as a substantial/growing problem, we have not brought these cases to its attention.

In response, we acknowledge there is a great deal of uncertainty about the extent of inappropriate practices and fraud. We believe that we correctly portrayed both the uncertainty in the extent of these practices, and the extent of EPA's activities to detect, prevent, and correct them. The Office of Water's response focuses on the limited number of fraud cases rather than the existence of vulnerabilities for which it has limited controls in place to address. It also fails to consider that several EPA regions stated the laboratory audits do not look for fraud and that cases of waterborne disease outbreaks generally do not include a review of laboratory procedures and data produced. Further, many States are not using techniques that, according to the OIG expert panel and others, could offer more evidence as to whether there is a problem. In addition, the Office of Water has not systematically collected data on the extent to which inappropriate procedures are found in laboratories. While it suggests a resource burden on States to employ additional techniques, there has been no analysis on the part of the Office of Water to demonstrate that the manner in which the resources have been used to date was effective, or for us to say they were not.

We continue to believe that the intense and growing economic pressures on laboratories cannot be ignored. EPA needs to be assured that it and delegated States are taking all reasonable precautions to ensure the quality of the

information on which regulatory and compliance decisions are based in this program. Concerning OIG not communicating fraud occurrences, the Office of Investigations, in addition to States interviewed, has contacted regional offices as far back as 2000 to alert them to cases located in their geographical jurisdiction. In addition, specific cases are included in the OIG Semiannual Report to Congress. As the steward of drinking water data and the responsible party for the certification of laboratories that analyze public drinking water samples, the Office of Water should maintain an awareness of issues in all laboratories and consider the relevance to drinking water laboratories.

With respect to taking future steps, the Office of Water indicated that although we had not gauged the precise extent of the problem, it is prepared to "play a greater role" in preventing and detecting these practices. In response to several of our draft recommendations that had suggested that EPA require States to take particular actions to address the potential for inappropriate practices and fraud, the Office of Water replied that it would be more effective for it to encourage States to take these steps. It argued that it would be difficult to justify a Federal regulation given the uncertain extent of the problem and the resource burden on States. It stated that in carrying out its lab certification program, it has successfully trained and mentored hundreds of certification officers and is committed to working with States and other offices within EPA to identify best practices to ensure continuous improvement for the program. The Office of Water believed, however, that recommendations directed at the development of ethics and fraud detection/deterrence programs would be more appropriately directed at offices that manage those types of programs for the Agency.

The Office of Water noted that expanding the portfolio of the drinking water lab certification program to encompass fraud-related activities could represent a significant burden because such work requires specific expertise that the Office of Water currently does not maintain. As the Office of Water works to address OIG's recommendations, it would be interested in working with the OIG; OEI; Office of Policy, Economics, and Innovation; and Office of Enforcement and Compliance Assurance to more clearly define the roles and responsibilities the respective offices can and should play with respect to fraud prevention, detection, and response.

We have agreed to many of the suggested recommendation modifications since they are consistent with our desire to address the root causes of the cited vulnerabilities. We were not seeking to regulate change, but to establish reasonable and effective approaches and techniques to address potential fraudulent and inappropriate procedures. More importantly, we recognize that there is an absence of Agency data available to determine the extent of the problem. There is a need to create a system to track, assess, and measure the reasons and effects of flawed analytical data. We therefore added language to the revised recommendations to emphasize this.

We are encouraged by the Office of Water's interest in working with other EPA offices and the States to use available training courses and applications and to establish better coordination and defined roles and responsibilities in the areas of fraud prevention, detection, and response. We believe this will benefit all parties and strengthen the drinking water laboratory program. With regard to the Office of Water's comment on ethics programs, we believe the immediate need is an ethics policy/program for drinking water labs. Those labs hold an EPA certification and should be held to attest for the ethical nature of their operations. Though the scope of our evaluation did not include all environmental labs, we do agree that the development of ethics guidance would be a good idea.

OEI stated that it is committed to the quality of data in Agency databases. To that end, it has an active corrective action strategy to the data quality weakness identified under the Federal Managers' Financial Integrity Act. In addition, OEI will submit the OIG's recommendations to the Agency's Quality and Information Council Steering Committee for action. This committee provides a mechanism to address enterprise-wide issues and to develop Agency policies to guide EPA decision makers in the area of information technology/information management and related issues within the framework of OEI. We are pleased that OEI will be addressing our recommendations.

The full texts of the responses from the Office of Water and OEI are in Appendices G and H, respectively.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)[2]	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date[3]	Claimed Amount	Agreed To Amount
1	21	Prepare laboratory certification officers for the conditions and challenges they will face in testing laboratories associated with fraud by applying the following promising techniques (modified from those highlighted in Chapter 3): (a) *Promote Training and Education Regarding Fraud;* and (b) *Integrate Fraud Awareness into Laboratory Certification Training.*	O	Assistant Administrator for Water	TBD		
2	22	Ensure that all individuals within OGWDW, regions, and States who have oversight responsibility for laboratories analyzing drinking water samples are educated and proficient in the proper procedures to follow should a laboratory be suspected of inappropriate or fraudulent procedures. Specifically: (a) distribute written guidance and appropriate contacts at the suggested course for State certification officers; copies of the guidance should also be distributed to OGWDW regional and Technical Support Center staff; (b) establish the use of the EPA fraud hotline for environmental testing laboratories; certified and accredited laboratories should be provided with appropriate Office of Enforcement and Compliance Assurance or OIG contacts to report possible misconduct; and (c) work with the Office of Enforcement and Compliance Assurance to determine if the form connected to the on-line violation reporting tool on EPA's Website could be used for laboratory fraud.	O	Assistant Administrator for Water	TBD		
3	22	Create and use a training course, exam, and standard methods for the certification of laboratories analyzing drinking water samples for radiochemical contaminants.	O	Assistant Administrator for Water	TBD		
4	22	Encourage certification officers to use the following promising techniques, as noted in Chapter 3, already developed by other groups in laboratory oversight. In addition, encourage certified or accredited laboratories to engage in techniques b and c: (a) *Enhance On-Site and Followup Audits to Include Techniques to Identify and Deter Inappropriate Procedures and Fraud; (*b) *Use Data Validation and Verification Techniques; (*c) *Use Analyst Notation and Sign-off on Manual Integration Changes to Data; (*d) *Review Raw Electronic Data and Use Electronic Data Analysis/Tape Audits; (*e) *Review Inventory of Laboratory Supplies; (*f) *Include Double Blind Proficiency Testing Samples Reform* (or a combination of Double Blind and Split Sample Analysis); and (g) *Conduct Data Accuracy Reviews.*	O	Assistant Administrator for Water	TBD		
5	22	Reduce uncertainty associated with the integrity of drinking water laboratories as well as the occurrence of inappropriate procedures and fraud. At least every 3 years, perform a periodic assessment to: (a) review the drinking water sample analysis process for the existence of vulnerabilities; (b) assess the extent to which inappropriate and fraudulent procedures are occurring (using techniques described in Recommendation 4); and (c) assess the laboratory certification program as well as specific protection processes and techniques for effectiveness. Explore incentives to encourage States and laboratories to adopt innovative practices. As part of this periodic assessment, consider adjusting laboratory and certification method requirements and resource allocations if needed.	O	Assistant Administrator for Water	TBD		
6	23	Set up a workgroup – including representatives from regions, States, and laboratories – to review the sample collection requirements and seek opportunities to minimize vulnerabilities.	O	Assistant Administrator for Water	TBD		

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)[2]	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date[3]	Claimed Amount	Agreed To Amount
7	23	Meet with Agency contract officers and the Office of Policy, Economics, and Innovation to determine if appropriate procurement guidance for EPA, States, and public water systems (including language similar to what is under development by DoD) specifying a list of prohibited practices and possible incentives for laboratories or analysts that meet higher integrity standards can be developed to offset economic pressures to cut corners.	O	Assistant Administrator for Water	TBD		
8	23	Provide the following training programs and guidance information for laboratories, as noted in Chapter 3, that analyze drinking water samples: (a) *All Certified Laboratories Should Have an Ethics Policy/Program;* and (b) *Encourage Certified Laboratories to Implement a Fraud Detection and Deterrence Policy/Program.*	O	Assistant Administrator for Water	TBD		
9	24	Create a mechanism to identify data in Agency databases originating from laboratories under investigation, indictment, and/or conviction.	O	Assistant Administrator for Environmental Information	TBD		
10	24	Develop an Agency-wide policy on how data originating from laboratories under investigation, indictment, and/or conviction will be handled.	O	Assistant Administrator for Environmental Information	TBD		

[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

[2] Identification of potential monetary benefits was not an objective of this evaluation.

[3] In accordance with EPA Manual 2750, the Agency is required to provide a written response to this report within 90 calendar days that will include a corrective actions plan for agreed upon actions, including milestone dates.

Appendix A

OIG Laboratory Fraud Cases

The OIG Office of Investigations has identified a fundamental shift that has occurred with laboratory fraud investigations over the last 3 years. Historically, the Superfund program had the greatest number of laboratory fraud investigations. However, wastewater and drinking water-related testing now comprises over 52 percent of the current OIG laboratory fraud investigations. Several of these investigations involved fraudulent laboratory analyses or monitoring reports, used to determine the compliance of public water supplies with Federal drinking water standards. This is of particular concern because the water programs are delegated to the States and they, in conjunction with EPA, may not be exercising due diligence in correcting and reporting these problems. The shift was related to an increase in case referrals for these laboratories and not initiated by OIG actions.

OIG Office of Investigations drinking water laboratory fraud cases increased by more than 40 percent from Fiscal Years 2000 to 2003. Figure A.1 shows the total number of OIG laboratory fraud cases opened or under investigation. Numbers show the total cases as well as those involving water and those specific to drinking water only.

Figure A.1 - OIG Laboratory Fraud Cases 1998-2005 (as reported June 2006)

Cases Opened and Under Investigation Involving Allegations Related to Water								
	1998	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**
Total Number of Cases Opened	4	5	3	5	8	12	23	28
Number Involving Drinking Water	**3**	**2**	**2**	**1**	**1**	**3**	**6**	**8**
Number Involving Water	0	3	0	1	1	2	9	9
Total Cases Under Investigation	4	9	12	17	25	32	44	58
Number Involving Drinking Water	**3**	**5**	**7**	**8**	**9**	**12**	**13**	**17**
Number Involving Water	0	3	3	4	5	6	13	15

Source: EPA OIG Office of Investigations

The case numbers (amounts involving drinking water) corresponding to the fiscal years are end-of-year numbers. The total number of drinking water cases opened, minus any cases closed during the fiscal year, provides the balance of the total number of drinking water cases under investigation. In the table above, no drinking water cases were closed in Fiscal Years 1998-2003. Five drinking water cases were closed in Fiscal Year 2004 and 4 cases were closed in Fiscal Year 2005.

Background on Number of Cases Proven

There are few cases of laboratory fraud when compared to the total number of testing laboratories. Cases do not have to result in an indictment or conviction in order for fraud to have

been proven. Cases can be rejected for many reasons. One is that not enough money is involved, which is the situation with most laboratory fraud cases. Other cases get settled before trial and the agreements are structured such that the laboratory does not admit wrongdoing.

Appendix B

Details on Scope and Methodology

We conducted our evaluation from August 2004 through February 2006 in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. This evaluation focused on identifying vulnerabilities in the drinking water sample analysis process and we did not examine internal controls. We evaluated EPA's efforts to address identified vulnerabilities to ensure the integrity of drinking water laboratories and the sample analysis process. Although laboratory and analyst integrity can be a concern in all environmental laboratories, for the purpose of this evaluation, we limited our review to laboratories responsible for the analysis of drinking water samples. We used the following methods to gather information concerning five specific questions:

- What is the process used to protect against inappropriate or fraudulent procedures within laboratories?
- What parts of the drinking water sample analysis process are most prone to inappropriate or fraudulent procedures?
- How do EPA and/or States identify inappropriate or fraudulent procedures in the analysis of drinking water samples, and what actions are taken when they occur?
- What is the most effective way for EPA and States to detect and deter the occurrence of inappropriate or fraudulent procedures in laboratories that analyze drinking water samples?
- What are the implications to human health and environmental quality resulting from the occurrence of inappropriate or fraudulent drinking water laboratory procedures?

Literature and Document Reviews

We conducted a literature review and reviewed documents pertinent to drinking water laboratory certification and the occurrence of inappropriate and fraudulent procedures within laboratories. This included a review of EPA documents, other Federal agency documents, State documents, academic literature, and news articles including but not limited to environmental laboratories. A list of the documents we reviewed and used as sources is in Appendix F, Figure F.1.

EPA Regional Survey

Through a survey database sent on November 19, 2004, to respondents from EPA regions, we collected information on all regional and State programs and methods of laboratory oversight. All 10 EPA regions responded by December 3, 2004. The survey was sent to the regional certification authority, and that authority, as well as regional certification program managers and certification offices, responded to the surveys. To verify the contents and accuracy of information recorded, we interviewed all respondents in March 2005. Representatives of OGWDW and NELAC commented on the content and terminology of the survey questions, but the OIG made all decisions on the survey's final content. Additional details on survey methodology are in the OIG Supplemental Report on the Regional Survey.

State Selection and Visits

The evaluation team visited four State drinking water laboratory certification programs during field work. We sought to have a range of geographic locations. To develop a paired comparison, we selected two States that were proactive in their approach to inappropriate and fraudulent procedures (e.g., that use electronic data analysis or data validation and have reported cases of fraud) and two States that were less active in their approach (e.g., that do not use electronic data analysis and data verification, and have not reported cases of fraud). We selected Arizona and Pennsylvania as the proactive States and Kentucky and Utah as the less active ones. Selection was based on input from EPA, NELAC, and OIG analysis.

Structured interviews were conducted with each State and information collected included:

- Background and history of the certification/accreditation program.
- Processes used for laboratory certification/accreditation (e.g., EPA, NELAC).
- Details on inappropriate or fraudulent laboratory procedures identified, including review of audit files (if necessary).
- Techniques used by the State to protect against inappropriate and fraudulent procedures.
- Viewpoints as to vulnerabilities within the sample analysis process.
- Technical assistance and training programs offered.
- Recommendations for improvement to the EPA certification program.

Following the State interviews, we sent representatives a copy of the promising techniques list to verify which techniques the certification officers viewed as highly effective. We also requested the implementation status for each of these techniques.

Expert Panel

As part of our field work, we convened an expert panel for review of the current drinking water sample analysis process, laboratory procedures, oversight, effectiveness, and the occurrence of fraudulent or inappropriate procedures in drinking water laboratories. To assemble the panel, we first requested nominees be provided from individuals and organizations identified as major stakeholders in the area of drinking water laboratory procedures. Criteria used to select panelists included scientific and technical expertise in the drinking water analysis process, laboratory certification and accreditation, laboratory management, and laboratory quality assurance and quality control. It was our intent to select panel members outside of the Agency. Thirty individuals were nominated, and 5 were selected for the expert panel.

1) Wisconsin State Certification Officer – Alfredo Sotomayor
2) National Institute for Science and Technology Federal Research Chemist – Reenie Parris
3) General Manager of Severn Trent Laboratories – Robert Wyeth
4) Technical Director of Chemistry for Environmental Standards – Rock Vitale
5) North Carolina State Certification Officer – Mike King

A 2-day expert panel meeting was held November 2-3, 2005, to collect information from panelists. We gave panel members pre-meeting questionnaires to rate the techniques listed in

Appendix F for their effectiveness in protecting against inappropriate procedures and fraudulent procedures, as well as their effect on data quality. We also asked panel members to identify vulnerabilities within the sample analysis process that could impact the integrity of the sample analysis process as well as data integrity. In addition to rating the level of severity, we asked them to determine whether they thought errors in these vulnerability areas were intentional or unintentional. In addition, panelist discussed management challenges and laboratory data quality. The laboratory management challenges discussion included vulnerabilities in laboratory management, potential solutions, and recommendations for EPA's role in this area. The laboratory data quality discussion included a consideration of the assurance level needed for decision making and methods to generate quality data considering costs.

Comparison of Similar Laboratory Certification Programs

As part of field work, we reviewed other laboratory certification programs to determine if techniques used by these agencies/programs could have application and utility for EPA's oversight of drinking water laboratories. The laboratory programs reviewed were:

- National Environmental Laboratory Accreditation Conference
- Department of Defense
- Department of Health and Human Services, Clinical Laboratory Improvement Amendments program

The review included interviews with each of the agencies and review of program documentation.

EPA Program Staff Interviews

We conducted interviews with EPA program offices considered stakeholders in drinking water sample analysis and laboratory certification. These offices included:

- **OGWDW Technical Support Center:** We conducted several interviews with staff in Cincinnati, Ohio, to collect background information on the certification program, obtain expert opinions as to our evaluation questions, and provide progress updates.
- **Office of Research and Development/NELAC:** We conducted interviews with the NELAC Director to collect background information on the accreditation program, obtain expert opinions as to our evaluation questions, and provide progress updates.
- **Office of Enforcement and Compliance Assurance's OCEFT:** We obtained further information regarding the June 2002 Laboratory Fraud Workgroup Report.
- **OEI:** We interviewed Quality Staff members to determine steps underway or planned by OEI to identify and address inappropriate or fraudulent procedures. We also obtained OEI's viewpoints as to the most effective ways for States and EPA to detect and deter the occurrence of inappropriate and fraudulent procedures.

Interviews with Health Experts

We interviewed three experts involved with health-related effects from contaminated drinking water not meeting public health standards set by EPA. The following three individuals selected

provided a good cross-section of professionals with experience dealing with health-related concerns from contaminated water, analytical techniques, and data quality concerns:

- *Dr. Dennis Juranek*, Senior Scientist and Epidemiologist, Centers for Disease Control and Prevention, Atlanta, Georgia
- *Dr. Rolf Halden,* Assistant Professor, Johns Hopkins School of Public Health, Center for Water and Health, Baltimore, Maryland
- *Dr. Rebecca Parkin*, Associate Dean for Research and Public Health Practice, School of Public Health and Health Services, George Washington University, Washington, DC

Technical Assistance Provided by OIG Office of Investigations

The OIG Office of Investigations Laboratory Fraud Directorate staff provided technical assistance and information during the evaluation. This included data on relevant cases concerning laboratories found to commit fraudulent acts, and guidance on the technical aspects of analyzing drinking water samples.

Appendix C

Laboratory Problems Identified by OCEFT Workgroup

Examples of Findings Indicating Fraud
• Substitution of previous acceptable QC (quality control) or calibration computer files for bad to make run appear acceptable • Full sample containers after data reported* • Materially misrepresenting actual laboratory methods and practices to clients

Suspicious Condition or Practice
• Reported results without supporting records of analyses • Lack of required equipment to perform required analysis* • Lack of required chemicals, reagents, other raw ingredients to perform the analyses • Instruments or other equipment in poor or non-operational condition • No log books (paperless lab?)* • Entries in log books missing* • Missing data • More samples analyzed than reported (indicating that results are illegitimately altered by selection) • Discrepancies in times between various stages of sample handling and analyses* • Discrepancies between values reported in raw, intermediate, and final results • Illegitimately selecting calibration points or data to meet method criteria • Illegitimately adjusting, altering, or improperly selecting peak heights or counts and ratios during tuning or calibration • Illegitimately selectively picking scan data to achieve tune criteria in GC/MS methods • Different print styles in reports* • Other suspicious anomalies in appearance of report or data outputs* • No QC failures over a significant period of time • Tough or “ridiculous” QC requirements (e.g., inviting alteration to pass) • Deliberately omitting QC steps such as method blanks and control samples to avoid unfavorable QC results • Use of affiliate labs to analyze performance samples for tests normally done in-house* • Altering QC performance summaries • Removing statistical outliers to improve reported detection limits • Illegitimate use of manual integration in chromatographic techniques • Inappropriate “averaging” to achieve calibration or performance criteria or to stay in compliance • Suspicious computer calculation subroutines or macros • Unexplained editing of electronic files • Unexplained erasures, white-outs* • Altered or forged signatures on report* • Report signature not of the author (e.g., supervisor or manager signing analyst’s lab report)* • Extraordinary lab results (ultra low detection limits, impossible productivity, etc.) • Special phone logs on positive or other results* • Other suspect “special” files* • Failing to tell the “whole” truth • Abnormal directives to employees, oral or written; directives to change results* • Intimidated employees* • Abnormal pressure to produce results* • Employee(s) out of town when analyses performed (travel and charge card records)*

Questionable Condition or Practice
• No maintenance records on instruments • Log books missing from series* • No original or primary records kept* • Data on scraps of paper* • Missing reports from files* • Missing computer files • Incomplete data packages • Unexpected or abrupt change in lab practices*, procedures, conditions • Problem found in raw data • High, arbitrary or unjustified detection limits; detection limits that exceed regulatory limits • Results differing using two different methods • Deviations from required methodology • Numerous “stupid” errors indicative of sloppy work • Differing SOPs without explanation • Unexpected high or low analyte recoveries • Not following required or stated procedures • Lax QA/QC or no QA/QC* (May directly evidence fraud if a government contract requirement) • Not following laboratory QA requirements • Large number of QC failures • Adding surrogates after sample extraction rather than prior to sample extraction; reporting pre-digested spikes or duplicates as post-digested spikes or duplicates • Closer than expected agreement on PE samples between affiliate labs, sister labs, industry organization laboratories • Data too consistent • Owner or supervisor acting suspiciously (e.g., wants to do all the work himself)* • Discrepancies between sample identifications in log-in and chain-of-custody sheets versus samples tallied in final reports* • Faulty data parameter correlations (anion/cation balance, mass balance, COD vs. BOD, etc.) • No receipts for instruments, chemicals, equipment in their absence*; no billings for maintenance* • Other*

Sampling Related
• Samples not taken* • Samples purposely biased through selection, sampling the “good batch” or the “good portion”; avoiding the “hot spots” or avoiding sampling during certain batch dumps; sampling at certain times versus others, etc. • Fraudulent location* • Fraudulent time* • Samples purposely switched or corrupted (e.g., cyanide samples left in the sun; volatile samples left open or caused to aerate) • Samples purposefully subsampled incorrectly • Continuous monitor probe placed in static sample

* = Items that might not require detailed technical knowledge for discernment.

NOTE: Data presented are specifically what was provided by OCEFT Workgroup. Items are listed by significance, most significant first; sampling problems indicating fraud are listed thereafter.

Source: Laboratory Fraud Workgroup: EPA OCEFT, Department of Justice

Appendix D

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

Description of Vulnerability	Error Type	Severity Rating
k) Data Handling and Maintenance		
• Data transcription errors not detected	U	4
• Falsifying raw data/no verification	I	4
• Miscalculations	B	4
l) Data Reporting		
• Data adjusted to meet predetermined levels	I	4
• Not all data reported	I	4
m) Data Security and Backup		
• Data tampering by unauthorized user	I	4
• No back ups	I	4
• Store data back ups off site	B	4

NOTE: Data presented are specifically what was provided by EPA Team (OGWDW and Office of Research and Development staff).

Source: EPA Team

Appendix E

Vulnerabilities Identified by Expert Panel

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
0 = Uncertain
CS = Case Specific
NR = No Response

Description of Vulnerability	Error Type	Severity Rating
a) Sample Collection		
• Appropriate training (and periodic monitoring by lab or other assessor is critical for this component. It's hard to design appropriate "practical" exam. Vulnerabilities include sampling of wrong site, under inappropriate conditions, use of wrong sample container, contamination of container, cross contamination, inappropriate storage, etc.	B	5
• Collection at wrong location	B	5
• Mislabel sample identity	B	5
• No requirements for collector	B	5
• Not sure of sample collection site	B	5
• Not sure of sample integrity	B	5
• Vague or lack of sample collection instructions (collector not lab employee)	B	5
• Chain of custody errors	B	4
• Improper preservation	B	4
• Improper sampling procedures	B	4
• Lack of enforcement of requirement to reject improperly preserved samples arriving at the laboratory	B	4
• Omitting dechlorinating agent for volatile organic compound (VOC) collection	B	4
• Error in field data	B	3
• Improper sampling equipment	B	3
• Inappropriate sampling equipment	B	3
• Lack of attention from collector that correct sampling techniques have been used	B	3
• Lack of training in legal chain of custody procedures	U	3
• No temperature controls	B	3
• Uncalibrated field equipment	B	3
• Presumption that laboratory is always in control of sampling event	U	2
• Inadequate chain of custody	U	1
b) Sample Tracking and Recording		
• Mislabeling sample identification	B	5
• Misplacing sample	U	5

Description of Vulnerability	Error Type	Severity Rating
• Unless double-blind PT samples are sent along with other "real" samples, this step is difficult to assess for its routine practice by either PT or on-site assessment. Training and on-going monitoring are critical.	U	5
• Dates logging	I	4
• Lack of uniformity for recording condition of samples on receipt	U	4
• Need to ensure that samples received are stored under required conditions. Require assessors to check at all on-sites. Requirements for bar-coding and tracking from receipt through storage, preparation and analysis with time stamp would make this less of a vulnerability. Vulnerabilities: errors in transcription, loss of sample, "time-shifting" of samples progress in process, etc.	B	4
• Vague requirements for Laboratory Information Management Systems (LIMS) security	B	4
• Failure to check custody seals	B	3
• Failure to note air bubbles in volatile organic analysis (VOA) vials	B	3
• Improper handling during log-in	B	3
• Improper pH checks	B	3
• Inadequate preservation	B	3
• Inappropriate storage	B	3
• Receipt condition notation	B	3
• Uncertain requirements of sample treatment or storage after arriving at lab but before logged into system	U	3
• Violating sample integrity - e.g., opening volatile organic analysis (VOA) vials, etc.	U	3
• Manual obliteration of records or data	B	2
• Not all information recorded at collection	U	2
• Sample condition not properly checked (e.g., temperature)	B	2
• Sometimes more than one person deals with samples and none are considered sample custodians	B	2
• Segregated storage	B	1
c) Adherence to Standard Operating Procedures (SOPs) for Analytical Methods		
• Failure to follow SOP	B	5
• Assessors focus on reviewing SOP, not assessing its proper execution	B	4
• Focus on format and not content of SOP	B	4
• Lack of uniformity of records such as bench stats for documenting adherence to SOPs	B	4
• Presumption that having an SOP means laboratory is following it	B	4
• SOP inconsistent with required method	B	4
• SOP with gaps and ambiguities (no corrective action report (CAR) for failing QC)	B	4
• Failure to update SOPs consistent with required method	B	3
• Inadequate analyst training	B	3
• Irregular review of SOPs for accuracy and conformance with methods	B	3
• Lab not using SOP	B	3
• Lack of review of SOPs for correspondence with approved methods	B	3
• Poor mechanisms for demonstrating proficiency using SOPs (initial demonstration of competencies (IDCs) are weak indicators)	U	3

Description of Vulnerability	Error Type	Severity Rating
• Use of wrong method or version	B	3
• Lab not using most recent version of method or withdrawn method	B	1
• Following wrong method (Using 624 for 524.2)	B	0
• SOP not following method exactly (3pt calibration curve instead of 5pt)	B	0
• Vulnerability: Lack of adherence to SOP not being documented, reported by lab staff. Training, appropriate oversight of lab staff is critical - hard to detect after analyses completed.	B	CS
• Vulnerability: Use of inappropriate SOP for specific type of sample (analyte/matrix/program) should be noted during internal review	B	CS
d) Preparation of Samples and Standard Solutions		
• Spiking samples after preparation	I	5
• Adjustment of spikes to ensure compliance	I	4
• Backdating for holding time compliance	I	4
• Double spiking solution concentration (e.g., semi volatiles)	I	4
• Failure to keep accurate log of all standards and/or solutions	B	4
• Failure to use or calibrate equipment used to make standards	B	4
• Measurement errors (samples, solvents, etc.)	B	4
• Record keeping	B	4
• Segregation of QC sample glassware	I	4
• Spiking at inappropriate step of process	B	4
• Use of inappropriate/unverified source of QC/calib. solution components	U	4
• Use of wrong or outdated materials	B	4
• Volume errors of concentration or other process steps	B	4
• Absence of clear requirements to verify spiking solution before they are used	B	3
• Failure to maintain secure and/or temperature controlled storage	B	3
• Inconsistencies in the sources used for preparing integrity check values (ICVs) and continuing calibration verifications (CCVs)	B	3
• Lab not performing required verifications of pipette volume, balance mass, etc. critical in value-assigning QC and calibration solutions	B	3
• Lab preparing "multiple" sets of calibrants, method blanks, etc. and discarding the results of those not consistent with requirements but then having appropriate number of results to report	I	3
• Lack of emphasis on reviewing sample prep methods	B	3
• Lack of uniformity for verification of accuracy of prepared standards (e.g., integrity check values (ICVs); standard reference materials (SRMs))	B	3
• Not enough emphasis on tracking preparation of reagents	B	3
• Overheating to speed up process	B	3
• Reagent water quality - contamination	U	3
• Separate blank process	I	3
• Solutions made incorrectly	U	3
• Use of single-source references for everything (e.g., calibration=continuing calibration verification (CCV)=spike)	B	3
• Using "old" calibration solutions, QC checks without assessing current validity (often in conjunction - see prep of "new" solutions just prior to analysis of PT or reference material	B	3

Description of Vulnerability	Error Type	Severity Rating
• Improper traceability of reference preparation	B	0
• Solutions expired	B	0
e) Instrument Performance		
• Improper calibration (e.g., single-point, peak shaving, historical library)	I	5
• Retention time/retention window monitoring critical for appropriate results as to ID of sample constituent or reporting as "non-detected"	U	5
• Consistent Laboratory. Use of laboratory control samples (LCSs), other monitoring QC samples at "high" end of analyte concentration range - need to monitor performance over entire range - if not with each sample set - then ensure that range is covered adequately over a series of sets of analyses. And – use of LCSs in appropriate matrix, spike samples, etc.	I	4 (more severe for reported results near quantitation limits)
• Inadequate training/experience to recognize instrument problems (e.g., sensitivity loss)	U	4
• Indiscriminant use of software to compensate for poor instrument response	B	4
• Lack of clear guidance on keeping and maintaining chronological run logs	B	4
• Mislabeling sample (dry labbing)	I	4
• Vulnerability: unless a specific criteria, etc. are available and checked - or staff knowledgeable and experienced in the specific analyses to monitor output of instruments - need for unscheduled maintenance repair may be missed	U	4
• Emphasis on analytical instrument performance and not much on support equipment	B	3
• Excessive deferral to instrument manufacturer instructions which at times conflict with approved methods	B	3
• Failure to run performance checks	B	3
• Inappropriate adjustment or performance check maintenance	I	3
• Instrumental adjustment to match performance check response	I	3
• Insufficient QC (e.g., not running blanks)	B	3
• Not routine	B	3
• Record keeping	B	3
• Repeating QC and calibration without re-running samples (overwriting files)	B	3
f) Instrument Maintenance		
• Failure to repair as needed	I	3
• Poor upkeep of maintenance logs - reliance on analysts to complete them and of assessors to review them	B	3
• Record keeping	I	3
• Vagueness about when maintenance triggers performing another MDL (Method Detection Limit) or IDC (Initial Demonstration of Competence) study	B	3
• Failure to keep determined maintenance schedule	B	2
• Lack of prep guidance or maintenance of support equipment	B	2
• Source cleaning, column changing, etc.	B	1

Description of Vulnerability	Error Type	Severity Rating
g) Instrument Calibration		
• Failure to assure retention times and mass spectra	B	5
• Overwriting/deleting files/peak shaving/juicing	I	5
• Allowance in some procedures for checking the entire calibration analytes with selected few (this is not much of a concern with Safe Drinking Water Act)	B	4
• Allowance in some procedures for reporting analytes out of calibration	B	4
• Analysis with non compliant curve	I	4
• Calibrations performed correctly and verified	B	4
• Day to day file switching	I	4
• For some tests, especially excessively broad calibration acceptance criteria	B	4
• Frequency of calibration and review of results as appropriate for specific method not adhering to requirement	I	4
• Improperly made standards	B	4
• Inappropriate manual integration	I	4
• Initial calibration (e.g., cherry picking, dropping points, repeating points)	I	4
• Lack of a defensible calibration primer	B	4
• Manipulation of injection volumes to get appropriate response	I	4
• Prepared mixes not verified	I	4
• Record keeping	B	4
• Repeating continuous calibration and tweaking until passed	I	4
• Running many batches of QC samples right after ICAL (instrument calibration)	I	4
• Use of "manual" mode for many of calibration solution integration, peak detection and/or peak area/height/baselines versus few for "real" samples	B	4
• Use of intentionally mis-made standards and solutions	I	4
• Reference material not accurate	B	3.5
• Emphasis on empirical demonstration of a calibration's effectiveness - i.e., dispersal or detection expected or learned behavior?	B	3
• Failure to complete chain of custody as required	I	3
• Improperly stored standards	B	3
• Inappropriate instrument adjustments	I	3
• Lack of clarity of use and sources of integrity check value (ICV) and continuing calibration verification (CCV)	B	3
• Over counting of files	I	3
• Time clock adjustments	I	3
• Use of calibration solutions inappropriately. Value assigned with non-verified identification of analytes	NR	NR
h) Lab Technician Performance		
• "Dry lab"	I	5
• Always vulnerable to intentional fabrication of data - as in "dry lab" - not analyzing sample at all	I	5
• Inadequate training and demonstration of competency	B	5
• Lab tech with insufficient training/expertise to recognize problems with analyses and with little supervision/monitoring	U	4
• Lab technician's ethics, results falsified	I	4

Description of Vulnerability	Error Type	Severity Rating
• Manual integration of criteria materials	I	4
• No "testing" on read and understand SOP and reference method	B	4
• Volume or instrument adjustment to insure compliance	I	4
• Date and time accuracy	B	3
• Failure to follow method/SOP	B	3
• Few guidelines on conducting internal audits or master sample runs (MSRs)	B	3
• Inadequate education	I	3
• Inadequate oversight and review of data	U	3
• Misuse of dilutions	B	3
• Noncompliance /short cuts in method	I	3
• Supervisor not knowledgeable	U	3
• Supervisor only "bean-counting" and not periodically reviewing row instrument outputs, results, etc., for signs of problems with analyses	U	3
• Training records and method proficiency	B	3
• Transcription errors	B	3
• Use of wrong or manipulated samples	B	3
• Weak requirements for experience and education of analytical personnel	B	3
• Few requirements for ongoing training of analysts (e.g., refresher courses)	B	2
• Record keeping	B	2
• Stress in the laboratory and management philosophy	B	2
• Verify credentials	B	2
• Not analyzing sample within required time frame and modifying date of analysis	I	varies
i) Adherence to Quality Assurance/Quality Control (QA/QC) Plan		
• QA/QC data fabricated	I	5
• Complete and accurate reporting	I	4
• Limited diagnostics for addressing quality of a result at the individual sample level	B	4
• Manual integration for method compliance	I	4
• QA plan not reflective of actual practice	B	4
• Analysts not "tested" on QA plan contents	U	3
• Approval of inappropriate SOP	B	3
• Failure to follow QAPP when required	B	3
• Failure to ID proper constituents	B	3
• Failure to insure proper review	B	3
• Inappropriate choice of QC samples for "real" samples could provide "valid" data not defensible for a given sample (e.g., poor matrix match, higher concentrations, etc.)	B	3
• Inappropriately established control limits	B	3
• Incomplete review process	B	3
• Inconsistency of focus between what is assistance problem or a localized problem	B	3
• Lack of support for root cause analysis	B	3
• More focus on the QA/QC plan and not on its correct execution	B	3

Description of Vulnerability	Error Type	Severity Rating
• QA plan out of date or not followed	B	3
• QA plan with gaps and ambiguities	B	3
• Record keeping	B	3
• Variable corrective actions to failing QC samples	I	3
• Failure to follow up on client complaints	B	2
• Failure to follow up on PT failures	B	2
• Failure to complete required internal audits	B	2
j) Data Validation and Verification		
• Data manipulated to pass QC	I	5
• Failing QC data ignored/manipulated	I	5
• Inappropriate manual integration	I	5
• Selective use/discarding of various QC results to enhance compliance criteria	I	5
• Time travel	I	5
• Calibration data manipulation	I	4
• Comparing of results as "average or mean" across numerous analytes with criteria can lead to not recognizing/reporting lack of compliance by specific analytes - aggregate masks individual results	B	4
• File transfers	I	4
• Sequence adjustments	I	4
• Wide acceptance criteria allowed by some procedures	B	4
• Application of inappropriate criteria	B	3
• Failure to appropriately comment or qualify data	B	3
• File overwriting	I	3
• Improper use of data review checklists	B	3
• Inadequate senior review of data	B	3
• Not sufficient review in data	I	3
• Omission of non-compliant data	B	3
• Rate evaluation of selected diagnostics against set criteria	B	3
• Record keeping	B	3
• Reliance on hierarchical decision making	B	3
• Dependence on automated software review	I	2
• QC acceptance criteria not properly generated/updated	U	2
k) Data Handling and Maintenance		
• Cursory spot checking by second party when procedures do not require secondary review	B	4
• Failure to provide adequate data review and approval	B	4
• Manual entry of data	B	4
• Transcription errors	B	4
• File corruption	B	3
• Lack of clear expectations on what constitutes raw data	B	3
• Lack of standards on specific documents to maintain and their storage under (what goes with what)	B	3

Description of Vulnerability	Error Type	Severity Rating
• Losing ability to regenerate records stored electronically	B	3
• Overwriting or not recording appropriate information	B	3
• Verification of calculations, algorithms, and software	B	3
• General record keeping including disposal	B	2
• Inappropriate record or sample (extract, digestive) retention	B	2
• Process change without training/notification	U	2
• Secure/backup files	B	2
• Timely down loading and storage to prevent data loss	B	2
• Uncontrolled logbooks and loose paper used and discarded	I	2
• Validity of software assumed	U	2
• Could always be intentionally falsified or safeguards not followed	B	varies
l) Data Reporting		
• Falsification of data - intentional change or "generation" of results for sample not analyzed	I	5
• Reporting data for samples not analyzed (dry labbing)	I	5
• Not flagging data where results from analyses with documented (or not) nonconformities with SOPs, reporting criteria, appropriate QA/QC results, etc.	B	4
• Transcription errors in government-required report forms	B	4
• Ethics agreement failures	I	3
• Failure to initiate data recalls when necessary	I	3
• Lack of clear requirements for data deliverables	B	3
• Lack of communication between regulator and regulated entity	B	3
• Lack of uniform flagging or qualifying corrections	B	3
• Reporting data without appropriate qualifiers (e.g., sample received at room temperature)	B	3
• Reporting of "draft" data prior to compliance reporting	I	3
• Failure to note and report method issues and concerns	B	2
• Late or incomplete reports submitted	B	2
• Reporting data without proper authorizing signature	B	1
• Transcription errors	U	0
m) Data Security and Backup		
• Data cannot be found nor retrieved from computer	B	4
• Lack of clear insistence on audit trails for electronic transactions	B	4
• Little review of correspondence of electronic and hard copy records	B	4
• Overwriting tapes	I	4
• Perceived and real case of altering electronic records	B	4
• Security system compromised in electronic system with other parts of software updated - need to verify with each update	U	4
• Appropriate electronic data retention	B	3
• Backups in same location as original	U	3
• Backups not timely, tapes unsecure and not off-site	B	3
• Failure to provide security of database	B	3

Description of Vulnerability	Error Type	Severity Rating
• No audit trails and/or audit trails not reviewed	B	3
• No single user/passwords for systems	B	3
• Obsolete GALP (Good Automated Lab Practices)	B	3
• Appropriate intellectual safeguard and access control	B	2
• Insure adequate capacity for all backup	B	2
Other		
• "Different" conditions, process, QA/QC, analyst, etc., used for PT samples versus "real samples"	I	5
• "Sharing" of PT data prior to submission	I	5
• For wet chemistry methods - need for some monitoring - of checks of reagents, apparatus, etc., as focused on in the questionnaire with regards to instrumentation	B	5
• Using library of historical consumer confidence reports (CCRs) to overwrite failing files	I	4
• Dosing extracts with additional surrogate	I	3
• Equating technical expertise with ability to assess technique	U	3
• Lack of training for assessors on how to properly assess	U	3
• Poor training of laboratory assessor in data review practices	U	3
• Inexperienced/unqualified management training staff in inappropriate procedures	B	2
• Lack of meaningful ethics training and testing	U	2

NOTE: Data presented are specifically what was provided by expert panel.

Source: EPA OIG expert Panel members

Appendix F

Promising Techniques

Comprehensive List of Techniques Based on Literature Search

To address our question, "What is the process used to protect against inappropriate or fraudulent procedures within laboratories?" we conducted a literature search and interviews to identify available techniques. The sources used are in Figure F.1.

Figure F.1 - Sources for Promising Techniques

1. *Best Practices for the Detection and Deterrence of Laboratory Fraud*; California Military Environmental Coordination Committee and Chemical Data Quality/Cost Reduction Process Action Team; Version 1.0; March 1997.
2. *Memorandum - Laboratory Fraud: Deterrence and Detection;* U.S. EPA, Office of Inspector General; June 25, 1999.
3. *Report of the Laboratory Fraud Work Group;* U.S. EPA, Office of Criminal Enforcement, Forensics, and Training; June 2002.
4. *Best Practices for Data Quality Oversight of Environmental Sampling and Testing Activities*; Department of Defense, Environmental Data Quality Workgroup, Department of the Navy, Lead Service; May 1999.
5. *Quality Systems Manual for Environmental Laboratories;* Department of Defense, Environmental Data Quality Workgroup, Department of the Navy, Lead Service; Final Version 2, June 2002.
6. *Fraud Control in the Health Care Industry: Assessing the State of the Art;* U.S. Department of Justice, Office of Justice Programs; National Institute of Justice, Research in Brief; December 1998.
7. *Publication of OIG Compliance Program Guidance for Clinical Laboratories;* Department of Health and Human Services, Office of Inspector General; Federal Register/Vol. 63, No. 163/ Monday, August 24, 1998/Notices.
8. *Responding to Allegations of Scientific Misconduct:* The Procedure at the French National Medical and Health Research Institute; Science and Engineering Ethics, Volume 6, Issue 1, Pg. 41-48; 2000.
9. Prohibited Practices (involving Environmental Sampling and Testing Activities). Procurement Policy for DoD Departments, Attachment 4a.
10. Information obtained from an interview conducted with the Department of Health and Human Services-Centers for Medicare and Medicaid-Clinical Laboratory Improvement Amendments (CLIA) Regional Program Staff, August 2, 2005.
11. Information obtained from an interview conducted with the Department of Defense-Laboratory Quality Accreditation Office Program Staff, August 18, 2005.

Source: EPA OIG analysis of literature reviewed

We divided these techniques recommended and/or used by Federal agencies and laboratory organizations into the three areas: *(1) Policy, Training, and Guidance; (2) Laboratory Oversight Practices;* and *(3) Enforcement Practices.* The complete listing is provided in Figure F.2.

Figure F.2 - Comprehensive List of Techniques Based on Literature Search	
Technique	**Source (see Figure F.1)**
Policy, Training, and Guidance	
• *Develop a Training and Education Program on Fraud:* Develop training for Agency or State on-site auditors/inspectors specifically focused on fraud and best practices for detection and deterrence.	[2]
• *Develop and/or Use Available Guidance Documents on Fraud Awareness:* Update and enforce guidance for oversight officials to incorporate fraud awareness techniques.	[2]
• *Develop Guidance and/or Training for QA/QC:* Implement written policies, procedures, and standards of conduct. Develop or improve guidance and training specific to the planning process to assist data users in determining laboratory QA/QC necessary and appropriate for the intended use of the data.	[2]
• *Develop Guidance on Prohibited Practices:* Create an example list of prohibited practices that could potentially occur within drinking water sampling and testing activities.	[9, 11]
• *Implement an Ethics Policy/Program*: Promote ethics in laboratories through outreach and training. Promote an ethics policy for laboratories that is read and signed by all personnel.	[1]
• *Implement a Fraud Detection and Deterrence Policy/Program:* Develop SOPs for detecting, deterring, and reporting; present fraud awareness workshops; develop no-fault policy that encourages lab personnel to come forward and report fraudulent activities, etc.	[5]
Laboratory Oversight Practices	
• *Perform On-site and Followup Audits*: Conduct internal and monitoring audits on a routine basis. Conduct followup audits if initial on-site audits reveal significant lab deficiencies. Ensure that corrective measures are taking place to sufficiently address the deficiencies. Ensure data quality requirements are being met.	[1]
• *Include Double Blind Proficiency Testing Samples*: Use proficiency testing samples where concentration and identity are not known by laboratory (i.e., known only to parties submitting the proficiency testing to the laboratory). Double blind proficiency testing labeling, packaging, and chemical composition samples should mimic those of routine samples.	[1]
• *Include Split Sample Analysis*: Send duplicate field samples to multiple laboratories. Send one of the duplicate samples to a second laboratory while the corresponding sample is submitted to the primary laboratory. Different labs that provide similar results confirm reliable data and minimize loss if a fraud problem should surface.	[1]
• *Use a Systematic Planning Process for Data Collection Activities:* Ensure that the requisite type, quality, and quantity of data are obtained.	[4]
• *Conduct Data Accuracy Reviews*: Ensure information systems used to track laboratory data are current and complete. Review the feasibility of implementing such systems in programs that do not currently use them.	[2]
• *Use Data Validation and Verification Techniques:* Review a body of data against a pre-established set of QC acceptance criteria to determine whether it is within the criteria windows to determine the quality of data.	[1]

• *Review Raw Electronic Data and Use Electronic Data Analysis/Tape Audits*: Review raw electronic data at the bench level when conducting audits. Use automated data screening tools that look for patterns in a data set that may not be predictable or observable by conventional data review techniques. Use statistical algorithms to discover patterns in data (i.e., mining tools).	[2]
• *Use Analyst Notation and Sign-off on Manual Integration Changes to Data*	[5]
• *Use a Laboratory/Research Notebook*: Rigorous maintenance of a bound laboratory notebook by analysts.	[8]
• *Conduct Impact Assessments*: Respond promptly to detected offenses and developing corrective action.	[7]
• *Conduct Laboratory Staff Reviews:* Review qualifications (e.g., education, training) of analysts to ensure that laboratories are adequately staffed.	[10]
• *Institute an Accreditation Program:* Maintain a secondary recognized laboratory accreditation to support primary certification and/or accreditation (e.g., EPA, NELAC).	[2]
Enforcement Practices	
• *Share Laboratory Performance Data and Histories (Interagency):* Agencies that use environmental laboratories should share performance data.	[1]
• *Involve Regulators*: Involve the regulators at such junctures as developing data quality objectives and incorporating the use of innovative monitoring and analytical capabilities.	[4]
• *Appoint a QA Officer:* This officer provides independent review and oversight of data collection. Same as appointing a compliance officer or a scientific integrity officer.	[4]
• *Create a Special Investigations Unit:* Create this unit to deal with the occurrence of inappropriate or fraudulent procedures.	[6]
• *Appoint a Fraud Control Officer:* Designate responsibility for fraud control (as separate from investigations) so that various contributory functions can be integrated into a strategy designed to reduce the level of fraud.	[6]
• *Establish a Fraud Hotline*: Pursue and publicize all means of providing individuals performing environmental testing with appropriate contacts to report possible misconduct.	[2]
• *Use a Fraud Profile Checklist:* Use this checklist to prompt on-site auditors to look for indicators of potential fraud (e.g., high personnel turnover rates or stretching acceptance limits).	[2]
• *Include Anti-Fraud Language in Subcontracts*	[5]
• *Establish Self-Policing within Laboratories:* (e.g., American Council of Independent Laboratories' Environmental Laboratory Data Integrity Initiative, which calls for a systems approach to ensuring that data is of known and documented quality).	[11]

Source: EPA OIG analysis of literature reviewed

Techniques Implemented and Recommended by OEI

EPA OEI quality staff have worked with Agency and non-Agency organizations to develop guidance and best practices for deterring improper laboratory data quality practices. Figure F.3 notes specific activities OEI is already implementing as well as activities it recommends. Recommendations are not intended as potential actions by OEI as several are outside its (and in some cases, EPA's) mission and expertise.

Figure F.3 - Techniques Implemented and Recommended by OEI

Techniques Already Being Implemented by OEI

- *Detecting Improper Laboratory Practices Course*: The detection of improper laboratory practices describes "red flags" and provides instruction on how an assessor or auditor should proceed if fraud or inappropriate procedures are suspected.
- *Website to Provide Best Practices for Laboratory Quality Systems:* Website developed to provide *Best Practices for Laboratory Quality Systems.* Website offers References, Training, as well as Examples and Other On-line Resources http://www.epa.gov/quality/bestlabs.html.
- *Guidance on Environmental Data Verification and Data Validation EPA QA/G-8:* Includes information on Data Verification, Data Validation, Data Integrity, Tools and Techniques for Data Verification and Validation, and Data Suitability. The chapter on Data Integrity will help the verifiers, validators, and data users detect improper practices.
- *EPA Quality Staff Ethics and Data Integrity Activities:* This presentation given at the National Environmental Monitoring Conference, July 2003.

Techniques Recommended

- Develop a training program on fraud for both Agency and State on-site auditors/inspectors that discusses best practices for detection and deterrence of fraud. This should be done using examples of prohibited practices as guidance.
- Require the review of raw electronic data and the use of electronic data analysis/tape when conducting bench level audits. Where possible, use automated data screening tools that look for patterns in a data set that may not be predictable or observable by conventional data review techniques and use statistical algorithms to discover patterns in data.
- Require the inclusion of anti-fraud language in contracts and sub-contracts.
- Require laboratory auditors to be fully capable of performing parameters for which they are responsible to inspect. Also, be fully capable of performing auditing procedures and aware that fraudulent procedures may occur.
- Require subject matter experts to be trained in conducting audits and aware of fraud.
- Develop a program for laboratory personnel to obtain credentials for their mastery of specific analytical procedures.
- Require certification or credentials for laboratory analysts, to assure they are qualified to analyze drinking water samples.

Source: EPA OEI quality staff

Techniques Considered as Highly Effective by States Reviewed

Figure F.4 highlights techniques we presented to State certification program officials that they considered highly effective in protecting against inappropriate or fraudulent procedures. States included Arizona, Kentucky, Pennsylvania, and Utah only.

Figure F.4 - Techniques Considered as Highly Effective by States

	State
Policy, Training, and Guidance	
• Develop a Training and Education Program on Fraud	AZ*, KY[1] (Micro)*, KY[1] (Chem), PA, UT
• Develop and/or Use Available Guidance on Fraud Awareness	AZ*, KY[1] (Micro)*, UT
• Develop Guidance and/or Training for QA/QC	AZ[2], UT
• Develop Examples of Prohibited Practices as Guidance	PA, UT*
• Implement an Ethics Policy/Program	KY[1] (Chem), KY[1] (Micro)*, PA*, UT*
• Implement a Fraud Detection Policy/Program	KY[1] (Chem), KY[1] (Micro)*, PA, UT
• Implement a Fraud Deterrence Policy/Program	KY[1] (Micro)*, UT
Laboratory Oversight Practices	
• Perform On-Site and Followup Audits	AZ*, KY[1] (Micro)*, PA*, UT*
• Include Double Blind Proficiency Testing Samples	KY[1] (Micro)*, UT
• Include Split Sample Analysis	UT
• Use Systematic Planning Process for Data Collection	AZ*, KY[1] (Micro)*, UT
• Conduct Data Accuracy Reviews	PA*, UT*
• Review Raw Electronic Data and Use Electronic Data Analysis/Tape Audits	AZ*, KY[1] (Chem), PA, UT
• Use Analyst Notation and Sign-off on Manual Integration Changes to Data	UT
• Conduct Impact Assessments	UT
• Conduct Laboratory Staff Reviews	KY[1] (Micro)*, PA*, UT
• Institute an Accreditation Program	UT
Enforcement Practices	
• Share Laboratory Performance Data and Histories	PA
• Involve Regulators	UT
• Appoint a QA Officer	UT*
• Create a Special Investigations Unit	AZ*, UT
• Establish a Fraud Hotline	KY[1] (Chem), KY[1] (Micro)*, UT
• Use a Fraud Profile Checklist/Data Checklists	AZ*, KY[1] (Micro)*, PA*, UT
• Include Anti-Fraud Language in Subcontracts	UT
• Establish Self-Policing within Laboratories	PA[3], UT

***** State is currently implementing technique as part of its certification program.

1 Kentucky does not have a specific office or division for laboratory certification. Chemistry certification ("Chem") is completed by State chemists; microbiology certification ("Micro") is contracted out.

2 Arizona indicated that developing guidance and/or training for QA/QC potentially could have some effect if set up right, but is not sure it would be "Highly Effective."

3 Encouraged in laboratories accredited by Pennsylvania, mandated for those seeking NELAC accreditation.

Source: EPA OIG analysis of State interviews

Additional Techniques Implemented and/or Recommended by States

Figure F.5 highlights additional identified techniques used or recommended by the State certification programs in addition to the techniques we provided.

Figure F.5 - Additional Techniques Recommended by States with the Intent of Protecting Against Inappropriate and Fraudulent Procedures

Technique	State
• *Standardize process/run a certification program similar to Clinical Laboratory Improvement Amendments or Federal Drug Administration*: Clinical Laboratory Improvement Amendments or the Federal Drug Administration. Across-the-board regulations for all laboratories (State, public, private) that analyze drinking water samples.	AZ
• *Review inventory of laboratory supplies*: Review the supply inventory of the labs to ensure that they are running the required tests. Check the quantity of supplies used versus number of tests run to determine whether test reported to the State are actually run.	AZ, KY[1] (Micro)*****
• *Identify "Red Flags" when reviewing data*: Look for specific red flags when reviewing data (e.g., lack of QC, repeat manual integrations, not reporting positive results).	PA
• *Expand the EPA Assessors Training Course to include guidance on fraud/ethics.*	KY[1] (Micro), PA, UT,
• *Conduct historical review of Public Water System labs:* Consider a historical review of Public Water System labs and determine whether a Public Water System has switched to labs that report non-detects	PA
• *Focus on repeat laboratory deficiencies*: Focus on repeat deficiencies to make sure that labs have a process in place to address and correct them.	UT
• *Promote good quality systems in labs*: Ensure that labs have good quality systems in place.	UT
• *Audit labs for each step in the sample analysis process*: Review the entire sample analysis process during the audits.	KY[1] (Chem)

* State is currently implementing technique as part of its certification program.

1 Kentucky does not have a specific office or division for laboratory certification. Chemistry certification ("Chem") is completed by State chemists; microbiology certification ("Micro") is contracted out.

Source: EPA OIG analysis of State interviews

Techniques Recommended by Expert Panel

The expert panel members recommended five techniques to protect against inappropriate and fraudulent procedures in addition to what was in the list we provided them. These five techniques are in Figure F.6; the first two were rated as highly effective:

Figure F.6 - Additional Techniques Recommended by Expert Panel

- Have regulators solicit sample data at sporadic but frequent intervals from lab. Review data packages for compliance with requirements.
- Procurement Reform Based on Qualification Based Selection. Awareness of realistic costs of analysis properly/appropriately conducted. Awarding of contracts to "bidder" with costs much lower than those of other bidders - may be a sign of a lab run very efficiently, or may indicate lab will "cut corners."
- Post articles of discovered fraud and protection as deterrent.
- As part of training, require an ethics exam to ascertain analysts' knowledge of what is acceptable and what is not.
- Rotate duties of analytical personnel temporarily to gauge ruggedness of quality system and detect inappropriate practices.

Source: EPA OIG expert panel members

Office of Water Response

MEMORANDUM

SUBJECT: Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks, Assignment No. 2004-1400, Draft Report

FROM: Benjamin H. Grumbles
Assistant Administrator

TO: Dan Engelberg
Director of Program Evaluation
Office of the Inspector General

Thank you for the opportunity to comment on your Office's draft report, *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks*. I will respond to the overall findings with more detailed responses to your recommendations and technical comments attached. My staff has provided additional technical comments on the text of the report under separate cover. Our comments also reflect feedback from staff in Regional offices to whom, with your Office's concurrence, we provided the draft report.

The Office of Water (OW) appreciates the attention that the Office of Inspector General (OIG) has brought to the potential ramifications of fraudulent laboratory activity on ensuring the safety of the nation's drinking water. The report includes some suggested activities that we believe can help to improve the quality of data, and OW is prepared to play a greater role in preventing and detecting fraudulent activity. However, we have significant concerns with some of the findings on the part of the OIG related to the role that OW has played to date in dealing with such activity.

Extent of the Problem

While the OIG report provides extensive information on potential vulnerabilities that may exist in laboratory procedures, the report acknowledges that the OIG "cannot, with any accuracy or reliability, quantify the extent to which this [fraud] is a problem." Further, as noted in the report "No waterborne disease outbreaks or documented cases of illness related to drinking water have been directly tied to cases of inappropriate lab procedures or fraud." OW does not deny the serious implications that could result from fraudulent activity. However, we are concerned that the report does not adequately distinguish between possibilities and likelihoods and, in not doing so, may be presenting an unnecessarily alarming picture to the American public. Given that the report includes recommendations that would require significant investments on the part of EPA and states, it is also critical to demonstrate more specific evidence of the problem. While OIG

characterizes drinking water laboratory fraud as a substantial/growing problem, we note that the OIG has not brought drinking water laboratory fraud cases to the attention of OW.

Inappropriate Procedures vs. Fraudulent Activity

The Drinking Water Laboratory Certification (Lab Cert) program is focused on ensuring that laboratories have the technical capability to conduct analytical measurements required by drinking water regulations issued under the Safe Drinking Water Act. The program is the first and still the only Agency program to offer laboratory certification criteria, guidance, and training. The Laboratory Certification Manual recently underwent an extensive update and continues to represent the most significant laboratory guidance provided by any EPA program.

Laboratories may produce flawed analytical data as the result of inappropriate procedures or fraudulent activity. The report discusses outcomes of each of these potential causes, but does not adequately distinguish between them. We believe it is critical to do this because our Lab Cert program does, in fact, address many inappropriate procedures. The report notes that an expert panel identified 272 vulnerabilities[8] in the drinking water sample analysis process and narrowed the list down to 20 that they deemed most severe. Many of these vulnerabilities are currently addressed by the Lab Cert program and others could be addressed through program modifications. Additionally, some of the identified vulnerabilities were in the area Sample Collection area – which is generally not within the purview of the laboratories because most samples are collected by public water systems.

Drinking water systems and their associated laboratories analyze hundreds of thousands of samples a year. In considering drinking water analysis, we concur with Regions and States who have suggested that the greater vulnerability is not due to fraud but the ability to perform the analysis and get an accurate result. The focus of the Lab Cert program has been to make sure accepted methods are used, analysts have proper training and develop appropriate skills, and laboratory procedures are correct and yield accurate results. As others have stated, we believe this has been an appropriate emphasis for the program over the years.

OW acknowledges that it plays a role in preventing inappropriate procedures through our existing Lab Cert program and we are committed to making improvements in that area. While OW has never had the understanding that fraud detection should be included as a primary focus of the drinking water Lab Cert program, we are committed to working with OECA, OIG, OEI and others to better address fraud.

The report notes a 1999 OIG memo to the Deputy Administrator and a 2002 report from OCEFT and faults OW with not following up with recommendations made in both documents. The 1999 OIG memo, while citing other programs, made no mention of drinking water. While OARM, OECA, OPPTS, ORD, OSWER, and 4 Regions were contacted as part of that OIG review, there was apparently no contact with, nor any distribution to, OW. As with the 1999 memo, the 2002 OCEFT report is written at a very general level, with no specific mention of

[8] Although the report describes 272 vulnerabilities, a review of Appendix D indicates that there is considerable overlap which, if addressed, would decrease the total number. For example, under Sample Collection, the table lists "improper sample equipment" and "inappropriate sample equipment" as discrete vulnerabilities.

drinking water. Moreover, the only transmittal memo that OIG was able to locate for the report was from the Director of Office of Criminal Enforcement, Forensics and Training to the AA for OECA. To the extent that it was distributed beyond OECA (which remains unclear), the Office of Ground Water and Drinking Water has no recollection of receiving it.

It is important to note, however, that expanding the portfolio of the drinking water Lab Cert program to encompass fraud-related activities could represent a significant burden because such work requires specific expertise that the office currently does not maintain. As we work to address the OIG's recommendations, we would be interested in working with the OIG, OEI, OPEI, and OECA to more clearly define the roles and responsibilities the respective offices can and should play with respect to fraud prevention, detection, and response.

With respect to the specific recommendations proposed in the draft report, we have suggested modifications to several of them in an effort to improve their feasibility. We believe some of the recommendations directed at development of ethics and fraud detection/deterrence programs would be more appropriately directed to offices that manage those types of programs for the Agency. Additionally, many of the recommendations asked that EPA "require" states and/or laboratories to undertake specific activities. While OW can encourage the activities, we note that EPA would only be able to require activities if they were included in a formal regulation, which would require a high burden of proof. Because the OIG does not document the extent of fraud related to drinking water samples, we believe a better approach would be to encourage the use of best practices to minimize the potential for fraud.

In carrying out our Lab Cert program, we have successfully trained and mentored hundreds of certification officers and we are committed to working with states and other offices within EPA to identify best practices to ensure continuous improvement of the program for the future. Thank you again for the opportunity to comment on the draft report. If you have questions regarding our comments, please contact Cynthia C. Dougherty, Director, Office of Ground Water and Drinking Water, at (202) 564-3750.

Attachments

Attachment 1
OGWDW Response to Recommendations in IG Report on Laboratory Practices – August 28, 2006

Recommendation	EPA Response	Revised Recommendation
Recommendation 1: Prepare laboratory certification officers for the conditions and challenges they will face in testing laboratories associated with fraud by applying the following promising techniques: a) Develop a Mandatory Training and Education Program on Fraud; b) Develop and/or use Available Guidance on Fraud Awareness.	OW is prepared to strongly recommend attendance at such training; however, making this mandatory would require regulation. We intend to continue to integrate fraud discussion into the Certification Officer training course, expanding on the approach we have recently employed. OW could also incorporate more detailed training by OIG into our on-site regional/state Certification Officer meetings and could encourage participation in fraud training offered by others (e.g., Arizona). OW would coordinate with OEI, OIG and OECA (i.e., those with the expertise) regarding the development and presentation of any new training. We would also work with the Regions that have done presentations on fraud to make their materials available to others.	OW suggests that the recommendation should be changed as follows: *Prepare laboratory certification officers for the conditions and challenges they will face in testing laboratories associated with fraud by applying the following promising techniques: Promote Training and Education regarding Fraud and Integrate Fraud Awareness into Laboratory Certification Training.*
Recommendation 2: Ensure that all individuals within OGWDW, regions, and States who have oversight responsibility for laboratories analyzing drinking water samples are educated and proficient in the proper procedures to follow should a laboratory be suspected of inappropriate or fraudulent procedures. Specifically: a)	OW agrees that more can be done to raise awareness of proper procedures for reporting suspected fraud and concurs with the recommendation.	No change

Recommendation	EPA Response	Revised Recommendation
Distribute written guidance and appropriate contacts at the required course for State certification officers; copies of the guidance should also be distributed to OGWDW regional and Technical Support Center staff. b) Establish the use of the EPA fraud hotline for environmental testing laboratories; certified and accredited laboratories should be provided with appropriate Office of Enforcement and Compliance Assurance or OIG contacts to report possible misconduct. c) Work with the Office of Enforcement and Compliance Assurance to determine if the form connected to the on-line violation reporting tool on EPA's Web site could be used for laboratory fraud.		
Recommendation 3: Create and require a training course, exam, and standard methods for the certification of laboratories analyzing drinking water samples for radiochemical contaminants.	OW is currently working with Minnesota to assist in the presentation of radiochemistry training in September 2006. Key aspects of the Laboratory Certification Manual are being integrated into the training. This training would supplement the inorganic chemistry training already presented to Certification Officers. OW is also prepared to encourage radiochemistry COs to participate in training offered by the Radiochemistry Society and similar organizations.	OW suggests that the recommendation should be changed as follows: *Create and use a training course, exam, and standard methods for the certification of laboratories analyzing drinking water samples for radiochemical contaminants.*

Recommendation	EPA Response	Revised Recommendation
Recommendation 4: Require all certification officers use the following promising techniques, already developed by other groups in laboratory oversight. In addition, require certified or accredited laboratories to engage in techniques b and c: a) Enhance On-Site and Follow-up Audits to Include Techniques to Identify and Deter Inappropriate Procedures and Fraud b) Use Data Validation and Verification Techniques c) Use Analyst Notation and Sign-off on Manual Integration Changes to Data.	OW is prepared to encourage these techniques (highlighting them as part of the Certification Officer training) and to encourage participation in the Arizona training course, which promotes the use of these techniques. Given the State and Regional concerns that have been expressed regarding the resource burden associated with the techniques vis-à-vis the uncertain effectiveness of the techniques, we would use our annual survey of the Regions to assess effectiveness and adjust our recommendations accordingly. Please note that the substantive aspects of Recommendation 5 have been integrated into the revised recommendation.	OW suggests that the recommendation should be changed as follows: *Encourage certification officers to use the following promising techniques, already developed by other groups in laboratory oversight, to the extent that they are not already employed. In addition, encourage certified or accredited laboratories to engage in techniques b and c: a) Enhance On-Site and Follow-up Audits to Include Techniques to Identify and Deter Inappropriate Procedures and Fraud; b) Use Data Validation and Verification Techniques; c) Use Analyst Notation and Sign-off on Manual Integration Changes to Data; d) Review Raw Electronic Data and use Electronic Data Analysis/Tape Audits; e) Review Inventory of Laboratory Supplies; f) Include Double Blind Proficiency Testing Samples Reform (or a combination of Double Blind and Split Sample Analysis); and g) Conduct Data Accuracy Reviews."*
Recommendation 5: Require the following techniques on a trial basis in a subset of laboratories, using certification officers or third party auditors trained and fully proficient in their use: use each technique in at least 25 percent of drinking water laboratories, and provide incentives for States. a) Review Raw Electronic Data	OW suggests that Recommendation 5 be deleted, since the substantive aspects have been integrated into our suggested revisions for Recommendation 4.	Delete

Recommendation	EPA Response	Revised Recommendation
and use Electronic Data Analysis/Tape Audits b) Review Inventory of Laboratory Supplies c) Include Double Blind Proficiency Testing Samples Reform (or a combination of Double Blind and Split Sample Analysis) d) Conduct Data Accuracy Reviews.		
Recommendation 6: At least every 3 years, perform a periodic assessment to: a) Review the drinking water sample analysis process for the existence of vulnerabilities. b) Assess the extent to which inappropriate and fraudulent procedures are occurring (using techniques described in Recommendation 5). c) Assess protection processes and techniques for effectiveness. As part of this periodic assessment, review State certification and accreditation programs, provide incentives for States and laboratories that identify new protection techniques, and adjust laboratory and certification method requirements as needed.	OW is prepared to incorporate the identification of new vulnerabilities into our regional questionnaire. OW is also prepared to work with OIG to review and assess available information regarding the number/nature of fraud allegations, investigations, and findings (to the extent that such information can be made available to OW). Regarding the assessment of techniques for effectiveness, OW will encourage Regions to assess State certification and accreditation programs for the effectiveness of techniques; see also OW's comments regarding Recommendation 4. OW will continue to incorporate appropriate QC into methods, adjusting as need be, and to update the guidance provided via the Laboratory Certification Manual. OW welcomes OIG suggestions regarding potential State and laboratory incentives.	OW suggests that the recommendation should be changed as follows: *At least every 3 years, perform a periodic assessment to: a) Review the drinking water sample analysis process for the existence of vulnerabilities. b) Assess the extent to which inappropriate and fraudulent procedures are occurring. c) Assess protection processes and techniques for effectiveness. Explore incentives to encourage states and laboratories to adopt innovative practices (including, but not limited to, those included under Recommendation #4).*
Recommendation 7: Set up a workgroup – including representatives from regions,	OW provides substantial training and guidance associated with sample collection	OW suggests that the recommendation should be changed as follows:

Recommendation	EPA Response	Revised Recommendation
States and laboratories – to review the sample collection requirements and determine if vulnerabilities can be minimized through sample collector requirements, accreditation or licensing.	and will continue to look for opportunities to improve such. OW has monthly calls with regional certification officers to discuss drinking water laboratory issues and has also begun to participate in the state workgroup described in the report that meets periodically to discuss environmental laboratory issues.	*Continue to work with regions, states, sample collectors and laboratories to review requirements and guidance associated with sample collection and seek opportunities to minimize vulnerabilities.*
Recommendation 8: Work with Agency contract officers and the Office of Policy, Economics and Innovation to determine if a procurement policy for States and public water systems, including language similar to what is under development by DoD specifying a list of prohibited practices and possible incentives for laboratories or analysts that meet higher integrity standards, can be developed to offset economic pressures to cut corners in the environmental testing laboratories that analyze drinking water.	OW suggests that this recommendation be deleted. If this recommendation is maintained in the final report, OW suggests that it be changed to apply to users of all environmental laboratories and that the recommendation be directed to OPEI. Perhaps guidance, based on DoD language and any lessons-learned from OSWER, ORD and/or others, could be developed and distributed Agency-wide and externally.	OW suggests that the recommendation should be changed as follows: *OPEI should work with Agency contract officers and program offices to provide appropriate procurement guidance for EPA, States and environmental labs, (including language similar to what is under development by DoD) specifying a list of prohibited practices and possible incentives for laboratories or analysts that meet higher integrity standards.*
Recommendation 9: Provide the following training programs and guidance information for laboratories that analyze drinking water samples: a) Require an Ethics Policy/Program for All Certified Laboratories b) Implement a Fraud Detection and Deterrence Policy/Program.	OW recommends that the recommendation be revised to apply to all environmental laboratories and that the recommendation be directed to OEI who could develop guidance and distribute it Agency-wide. OW would then add an appendix to the Laboratory Certification Manual encouraging the development of ethics policy/programs and fraud	OW suggests that the recommendation should be changed as follows: *OEI should provide guidance regarding the use of Ethics Policy/Programs and Fraud Detection and Deterrence Policy/Programs in laboratories. OW should include relevant guidance as an appendix to the Laboratory Certification Manual to encourage laboratories to adopt*

Recommendation	EPA Response	Revised Recommendation
	detection/deterrence programs by laboratories.	*ethics policy/programs and fraud detection/deterrence programs.*
Recommendations 10 and 11: Create a mechanism to identify data in Agency databases originating from laboratories under investigation, indictment and/or conviction and develop an Agency-wide policy on how data originating from laboratories under investigation, indictment, and/or conviction will be handled.	OW understands that these recommendations have been directed to OEI and will defer to OEI to address. We note, however, that we would anticipate issues associated with adverse actions against a laboratory that is not yet convicted of a crime.	

Attachment 2
Technical Comments on Draft Report

Chapter 1

- Page 1, first paragraph under *Public Health Considerations*. Based on information provided in the supplemental report, we believe the second sentence should be edited to read "EPA has not yet conducted a national review of laboratory performance or analyzed State data on laboratory deficiencies to determine the extent to which public health may or may not be at risk from inappropriate or fraudulent laboratory procedures, although a survey of EPA Regions and discussions with a number of States suggest that fraud and inappropriate procedures occur infrequently in drinking water laboratories and the impact is low."
- Page 2, paragraph below Figure 1.1. The report indicates that "The completed OIG investigation found machine calibrations associated with volatile and semi-volatile organic analyses were altered; tests for contaminants including methyl tertiary butyl ether (MTBE), nitrobenzene, tert-butyl alcohol, and dichlorodifluromethane were affected." We believe the report should also note that the contaminants cited are not regulated as national primary drinking water standards.
- Page 2, third paragraph below Figure 1.1. The paragraph implies that the case of increased lead in the drinking water for the District of Columbia was due to fraud. We are not aware of any such findings, and as such, do not believe it is appropriate to include this as an example. We recommend that the paragraph be deleted.
- Page 3, first paragraph under *EPA Roles in Laboratory Certification*. We believe the fourth sentence should be edited to reflect EPA efforts as follows: "SDWA does not specify the nature of the audit, although EPA has developed audit training and offers substantial guidance through a laboratory certification manual."
- Page 4, first paragraph under *State Roles Related to Public and Private Laboratories*. The report should clearly identify the role of states by changing the first sentence as follows: "It is the States, for the most part, that actually issue public and private laboratory certification or accreditation status for the analysis of public drinking water samples and have direct oversight responsibility for those laboratories."
- Page 4, second paragraph under *State Roles Related to Public and Private Laboratories*. We believe the first sentence should be edited to reflect EPA efforts as follows: "OGWDW ~~currently offers no~~ has historically not offered a specific radiochemistry course or exam, although it recently ~~looked into options to~~ partnered with a provider of such a training for a September 2006 course."
- Page 5, second paragraph under section on *Occurrence of Fraud and Inappropriate Procedures*. We recommend that the report clearly identify the number of cases and address the comments provided below with the excerpted text.

  > "Over the past 6 years, the number of laboratory fraud cases reported to the EPA OIG Office of Investigations has increased steadily (Figure 1.2). Drinking water cases (i.e., allegations of fraud) increased by more than 40 percent from Fiscal Years 2000 to 2003, from (#) to (#) ***(Comment: What are the figures for "convictions" vs. "cases"?).*** Laboratories responsible for analyzing public drinking water samples represented over 35 percent of the 44 OIG laboratory fraud cases in 2004 and just fewer than 30 percent of the 58 cases in 2005. ***(Comment: Many of those laboratories likely do other non-drinking water work. Were the investigations to***

which OIG refers specifically related to drinking water analyses by those labs?) The total percentage of certified laboratories under investigation or convicted of fraudulent procedures is currently unknown, since no national database tracks certified drinking water laboratories by name. ***(Comment: There are approximately 6,000 laboratories certified for drinking water, so this likely represents a very small percentage)***".

- Page 5, third paragraph under section on *Occurrence of Fraud and Inappropriate Procedures.* Given the scope of this investigation, the figures presented in the third sentence should be specific to drinking water; they should not be coupled with wastewater. The fourth sentence indicates that "Several of these investigations involved fraudulent laboratory analyses or monitoring reports, used to determine the compliance of public water supplies with Federal drinking water standards." Does the term "monitoring report" refer to the laboratory report or reports provided to the state from the public water system? Given the scope of this investigation, we believe it should only apply to laboratory analysis reports. Please clarify if appropriate.
- Page 5, last paragraph. The report should clarify that the focus of the 1999 report was not on drinking water. We believe the first sentence should be edited as follows: "A 1999 OIG memo, based on a review of programs with OECA, OPPTS, ORD, and OSWER, cited problems with environmental laboratory data integrity and provided suggestions for improvement."
- Page 6, paragraph which begins "In our evaluation…" We believe it is relevant to indicate the source of the respective audits in the second sentence. "In fact, while Arizona auditors found severe problems, including fraudulent procedures during a drinking water laboratory certification audit, another State, performing a NELAC accreditation audit for ~~auditing~~ the same laboratory around the same time period, issued a report of no findings."
- Page 6, first paragraph under Figure 1.3. The example provided for Kentucky is an example of an "inappropriate" practice that the laboratory certification program is designed to detect, and did, in fact, detect using techniques taught in our training course. We recommend that this paragraph be deleted, or presented in a different context (i.e. in the context of the certification program being effective at addressing inappropriate procedures).

Chapter 2

- Page 9, in section titled *OGWDW Acknowledged Sample Analysis Process Vulnerabilities*. Rather than addressing in footnote #6, we believe that this title and other relevant text be changed to clearly indicate that "OGWDW and ORD laboratory certification team members ~~staff~~" responded to the questionnaire and offered opinions on potential vulnerabilities.
- Page 12, last paragraph beginning "We did not find any plans…". We believe the first sentence should be edited to reflect EPA efforts as follows: "We did not find any plans to require certified laboratories to abide by ethics programs or certification officers to acquire training in additional auditing techniques, data integrity concepts, fraud detection or reporting, although OGWDW has recently encouraged certification officers to participate in fraud/data auditing courses offered by others and has recently included presentations on such in their own training courses."
- Page 13, first paragraph under *Lack of Laboratory Integrity Controls*. We believe this paragraph should be edited to reflect OGWDW's view that its program **does** address

inappropriate procedures. We recommend the following edits to the second and third sentences: "OGWDW interprets ~~inappropriate and~~ fraudulent laboratory procedures to fall outside the scope of laboratory certification audits. When asked about ~~inappropriate procedures and~~ fraud, a majority of EPA regions surveyed stated that the on-site certification audit does not include, and is not currently designed to include, a review of the laboratory to determine whether fraudulent ~~or inappropriate~~ procedures may be taking place (see OIG Supplemental Regional Survey Report for further details).

- Page 13, second paragraph under *Lack of Laboratory Integrity Controls*. If the OIG intends to include the numbers cited in the paragraph, they should provide additional details, including analysis/explanation regarding the reasons for the delayed Regional reviews.
- Page 14, paragraph beginning "EPA requires the use…". We believe the second sentence should be edited to reflect EPA efforts as follows" "Although guidance is provided in the form of certification officer training and the Laboratory Certification Manual, no Federal regulations exist to prescribe or require the use of any specific techniques in the oversight and audit process used to certify drinking water laboratories."
- Page 14, paragraph beginning "New techniques to identify…" We recommend the last sentence be deleted because it suggests that OW has been remiss in communicating with the laboratory certification community. Historically, the Lab Cert Bulletin has been developed on as as-needed basis. Since it was last issued, we have communicated with Regions in our monthly conference calls and with Regions and States during program reviews and certification training. We also worked extensively with the community to develop and publish an updated Laboratory Certification Manual that consolidates guidance that would otherwise be covered in bulletins and other forms of communication.
- Page 14, paragraph beginning "OGWDW does not provide…". As noted earlier, we believe the certification program does address inappropriate procedures. We also believe the last sentence should be deleted because our Lab Cert manual does recommend continuing education *["Periodic training for both laboratory auditors and analysts should be provided by the Regions. Certification officers should attend refresher training programs every five years to keep their knowledge current"]*. We believe the paragraph should be edited as follows:

  > OGWDW acknowledges that it has not ~~does not~~ provided regional staff or State certification officers – the individuals who conduct on-site laboratory audits and determine whether a lab is qualified to analyze water samples – a plan to address inappropriate and fraudulent procedures when identified in laboratories. The certification officer requirements also do not prepare the individuals who will be entering drinking water laboratories to identify ~~inappropriate or~~ fraudulent procedures. Identifying and addressing ~~inappropriate or~~ fraudulent procedures are not within the scope of the certification officers' training or exam. ~~Also, once an individual becomes a certification officer, that person is qualified for life; there are no continuing education requirements despite constant technological advancements.~~"

Chapter 3

- Page 19, first paragraph under *Other EPA Offices*. We recommend that the OIG delete the last sentence. OW notes that the certification program was rated by the Regions as more effective than the NELAP program in every measure included in the Regional survey

described in the Supplemental Report. To the extent that OIG is suggesting that OW consider adding some NELAP elements to the certification program, OW concurs and is examining this.

- Page 19, third paragraph under *Other EPA Offices*. We believe the second sentence should be edited as follows: "OGWDW and OEI have not communicated about the use of these tools ~~and OGWDW continues to operate the drinking water laboratory certification program without the requirement or inclusion of methods to identify or address inappropriate procedures and fraud~~." We have provided comments explaining how our program prepares individuals to identify and/or address inappropriate procedures. Even so, the issue does not seem relevant to this paragraph.
- Page 20, fourth paragraph under *States*. The example provided for the State of Kentucky does not really represent an innovative approach. OW's laboratory certification manual states that positive/negative controls should be run for all methods performed. The manual also outlines training criteria for analysts. We recommend that this fact be noted or the paragraph be deleted.
- Page 20, fifth paragraph under *States*. To accurately reflect current conditions and to recognize that calibration procedures are addressed in Section 10 of the promulgated methods that are used for compliance monitoring, we suggest the following edits to the second through fourth sentences. "Any environmental or drinking water auditor is welcome to participate in the call, although EPA has only recently begun to ~~does not~~ participate in calls and ~~or~~ communicate ~~regularly~~ with the group. The group provides an outlet for questions concerning EPA standard methods and specific applications in environmental ~~drinking water~~ laboratories. For example, ~~there are no guidelines for specific calibration procedures, so~~ the group is currently in the process of building a calibration/manual integration policy for submission."

Office of Environmental Information Response

MEMORANDUM

SUBJECT: OEI Response to OIG's Draft Report: "Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks"

FROM: Linda A. Travers
Acting Assistant Administrator and Chief Information Officer

TO: Dan Engelberg
Director of Program Evaluation, Water Issues
Office of Inspector General

Thank you for the opportunity to review and comment on the draft report "Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks." We appreciate your efforts to ensure the clarity of your findings.

This memorandum responds to the specific findings and recommendations for the Office of Environmental Information. Please contact Reggie Cheatham, Director, Quality Staff, at 202-564-7713 if you have any questions or need additional information.

cc: Benjamin Grumbles, Assistant Administrator for Water
Reggie Cheatham, Director, OEI Quality Staff
Charles Cavanaugh, Special Assistant, OEI

OEI Response to Draft Report
"Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks"

August 19, 2006

Summary of Quality Staff's review of May 2006 discussion draft report:

OEI submitted comments on a review draft of "Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks" on May 19, 2006. Throughout the document, our specific corrections to statements about OEI responsibilities, resources provided to the laboratory community, and activities were accepted verbatim. In addition, with the following exception, our requested changes and comments, intended to improve clarity and understanding, were addressed.

We commented that three of the "most severe vulnerabilities" identified in Chapter 2, Figure 2.4 (on page 11 of this version) are related to sample collection, and thus are beyond the control of the laboratory, which typically receives drinking water samples by courier or delivery service (and has no role in their collection). OIG declined to mention this point in Chapter 2 of its revised version and in Appendices B, C, and D, which display expanded lists of sample collection activities that are vulnerable to fraud. We consider that this shortcoming detracts from the utility and objectivity of the report, but does not impact the recommended actions for OEI.

Recommendation:

In its draft report, OIG recommends that EPA assess drinking water laboratory integrity and incorporate promising techniques to identify inappropriate procedures and fraud into the required elements of the laboratory oversight process, specifically, OIG recommends that OEI, as the national program manager for quality:

- Create a mechanism to identify data in Agency databases originating from laboratories under investigation, indictment, and/or conviction, and
- Develop an Agency-wide policy on how data originating from laboratories under investigation, indictment, and/or conviction will be handled.

OEI Response:

OEI is committed to the quality of data in Agency databases. To this end, we have an active corrective action strategy to the Data Quality weakness identified under the Federal Managers' Financial Integrity Act (FMFIA). In response to FMFIA, EPA has developed an effective Data Standards Program which now requires continuous monitoring as discussed in Attachment 2. Organizations, such as States and Tribes, are working together with OEI to develop data standards for the exchange of environmental data. OEI has developed a number of tools, processes, and guidance documents to facilitate the implementation of data standards by, e.g.:

- Providing technical assistance to National Program Managers, Regions, and States; and

- Establishing the technical and business guidelines for the use of standard data elements. This process is used to assist in data integration, improve reliability, and enable the rapid aggregation of data for emergency response. For more information, see the Environmental Data Standards Council Web site at http://www.envdatastandards.net/.

In 1999, EPA established the Quality and Information Council (QIC) with the intention that the QIC provide a mechanism to address enterprise-wide issues and to develop Agency policies to guide EPA decision makers in the area of information technology/information management and related issues within the framework of OEI. In order to address OIG's recommendations, OEI will submit these to the Agency's QIC Steering Committee (SC) for action at the first QIC SC quarterly meeting following the issuance of the final report. The primary role of the QIC SC is to assist the QIC in the development of the IT/IM and related policy agenda. Additionally, the QIC SC is charged with resolving issues that are not appropriate for QIC action or that are specifically delegated to the QIC SC (such as establishment of procedural or guidance documents in support of a given policy). The QIC SC members will determine how to address the OIG recommendations on an Agency-wide basis.

More information about the QIC is available at
http://intranet.epa.gov/oeiintra/imitpolicy/qic/index.htm

Current activities related to Recommendation:

It should be noted that the Agency and OEI have several activities in progress that are intended to capture "metadata," e.g., identifying the laboratories generating data, as well as the quality control and other parameters associated with those data. Please review the metadata information lists recommended by the National Water Quality Monitoring Council and the Methods and Data Comparability Board located at: http://acwi.gov/methods/data_products/index.html

In addition, the final Environmental Sampling, Analysis and Results data standard information is available on: http://www.envdatastandards.net/section/standards and
http://www.envdatastandards.net/content/article/detail/649

Appendix I

Distribution

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