



OFFICE OF INSPECTOR GENERAL

*Catalyst for Improving the Environment*

# **Supplemental Report**

## **Survey Results: EPA Regional Drinking Water Laboratory Certification Authorities**

**October 5, 2006**

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## Abbreviations

EPA	U.S. Environmental Protection Agency
NELAC	National Environmental Laboratory Accreditation Conference
NELAP	National Environmental Laboratory Accreditation Program
OIG	Office of Inspector General
OGWDW	Office of Ground Water and Drinking Water
PT	Proficiency Testing
PWS	Public Water System
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedures

# Introduction

## Purpose

This supplemental report provides the results from our preliminary research survey of U.S. Environmental Protection Agency (EPA) regional certification officers. Information in the report is limited to what was collected during the survey to the regions. We conducted this survey to obtain information on regional and State certification oversight methods and the viewpoints of the regional certification officers on the effectiveness of current certification/accreditation practices as well as the occurrence of inappropriate and fraudulent laboratory procedures.

We found, in collecting and analyzing information for the larger evaluation report, the survey responses do not acknowledge the potential for inappropriate and fraudulent procedures to occur. In the evaluation report *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks (Report No. 2006-P-00036)*, issued September 21, 2006, a more comprehensive overview of those issues is presented. The information in this supplemental report was used in that evaluation, and is presented here to document the range and scope of certification practices.

## Background

The EPA certification program for drinking water laboratories was implemented in 1978. It is divided into three categories: microbiology, chemistry, and radiochemistry. A laboratory can request certification in any of the three areas.

The National Environmental Laboratory Accreditation Conference (NELAC) was established by State and Federal officials in 1995, and in 2002, EPA recognized it as an acceptable alternative to the EPA certification program for laboratories that analyze drinking water compliance samples. Both the EPA certification and NELAC accreditation support the EPA-promulgated methods for the analysis of drinking water samples and the requirements in methods for the analysis of individual contaminants. In general, to obtain certification or accreditation, a laboratory should analyze a proficiency test sample, use EPA methods of analysis, and pass a periodic on-site audit. Appendix A provides a description of the oversight procedures and attributes of each program.

## Scope and Methodology

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 EPA's

Office of Ground Water and Drinking Water (OGWDW) and NELAC commented on content and terminology of the survey questions, but the Office of Inspector General made all decisions on the survey's final content.

The survey was divided into three parts. In Part I, the regional respondents reported for each primacy State in the region as well as any U.S. territories that have a principal State laboratory. We specifically focused on the EPA regional oversight of principal State laboratories. We requested information on the specific certification criteria used and the frequency of laboratory audits. In addition, respondents were asked to identify methods used to detect fraudulent or inappropriate laboratory procedures.

The terms used in the survey, including fraudulent and inappropriate, were defined for the respondents in a glossary (see Appendix B). Forty-nine States and four territories were reported as having primacy. Wyoming (Region 8) and the District of Columbia were the only ones reported not to have primacy, although the District of Columbia does have a principal drinking water laboratory and therefore was listed in this section. Territories with certification programs/primacy were American Samoa, Puerto Rico, Guam, and the Virgin Islands. Final numbers used in the analysis (54) resulted from the total number of States (49), territories (4), and District of Columbia (1).

In Part II, we requested the same information, focusing specifically on State oversight of public and private laboratories. The regions reported for each primacy State in their region as well as any U.S. territories that certify public and private laboratories. Forty-nine States and three territories (Puerto Rico, Guam, and the Virgin Islands) were reported as having primacy. The District of Columbia and American Samoa do not conduct audits of public and private laboratories and therefore were not listed in this section. Although Wyoming does not have primacy, it was still listed since Region 8 is responsible for certifying the public and private labs in the State. Final number used in the analysis (53) resulted from the number of States (50) and territories (3).

In Part III, we inquired about regional views of the effectiveness of current certification and accreditation criteria used by the regions and the States – specifically, the EPA criteria (as specified in the EPA Certification Manual) and the NELAC criteria (as specified in the NELAC standards). In addition, we requested regional viewpoints on the occurrence of fraudulent or inappropriate procedures within laboratories that analyze drinking water samples and potential impacts.

Viewpoints expressed in the survey were limited to the experiences of the regional certification authority or designees, which varied from region to region. One region explained that the regional drinking water certification officers generally audit only State and tribal principal laboratories and only co-audit commercial and municipal laboratories with State drinking water auditors. It is also important to note that while all respondents have used the EPA certification criteria for drinking water laboratories, no EPA region is a NELAC accrediting authority. As a result, some regions were unable to respond to questions about NELAC or responded using only a limited amount of experience with the accreditation process.

In addition, regional viewpoints may not necessarily be representative of the collective viewpoint of all EPA staff in a particular region. We did not contact any State or territory to verify the information provided by the EPA regional representatives and we acknowledge regional and State procedures may have changed since our interviews in 2005.

## **Details on Regional and State Laboratory Certification Programs**

According to survey results, the majority of the regions and States follow the guidelines in the EPA Certification Manual to audit laboratories that analyze drinking water samples. Most of the audits are pre-announced by the regions and States and conducted on an average of once every 3 years. Regional respondents rated EPA certification program elements more effective than NELAC in all areas.

### ***Criteria Used for Laboratory Audits***

EPA regions audit a majority of the principal State laboratories (47 of 54) solely with EPA certification criteria and guidance. Only five of the principal State and territory laboratories are audited with the NELAC standards and guidance; two are audited through a combination of both the EPA criteria and the NELAC standards. A region may use either the EPA certification program or NELAC accreditation program for oversight of principal State laboratories; however, no EPA region is currently a NELAC accrediting authority. Principal State laboratories opting to obtain NELAC accreditation in lieu of EPA drinking water laboratory certification are reviewed by another State that is a NELAC accrediting authority. For example in Region 2, the State of New York is reviewed for accreditation by the State of Florida.

A majority of States or U.S. territories (34 of 53) with primacy responsibilities also audit public and private drinking water laboratories using only EPA criteria and guidance. Only six of the States and territories use a combination of the EPA criteria and State-developed criteria; the remainder use NELAC standards (five), a combination of the EPA criteria/NELAC standards (four), a combination of the EPA criteria/NELAC standards and State-specific methods (one), or their own State-specific criteria and guidance (three). States with primacy for their drinking water programs may utilize the EPA certification program, the NELAC accreditation program, or a State-developed equivalent. The cost to be certified or accredited can vary from State to State.

### ***Frequency of Laboratory Audits***

Although frequency can vary depending upon the certification criteria used, the majority of the principal State/territory laboratories (48 of 54) are audited by the regions once every 3 years. The remaining States/territories are audited either once every 2 years or were listed as other.<sup>1</sup> The three States/territories that were audited every 2 years were listed as NELAC States. No State/territory laboratories are being audited greater than every 2 years. For State certification

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<sup>1</sup> Other: There was no time frame indicated for the audit frequency of the principal State laboratory in Wisconsin. It is currently being audited by a NELAC authority. The Illinois principal laboratory is audited once every 2 or 3 years depending on the type of certification it holds. In Iowa, NELAC has been performing on-site audits every 2 years at this laboratory since 1997.

programs, the majority of the primacy States (32 of 53)<sup>2</sup> audit their public and private laboratories once every 3 years. Fifteen of the States/territories audit the laboratories once every 2 years, and the remaining States/territories were listed as once every year. Of the four States listed as other, two varied dependant on the type of certification and two had fallen behind schedule. Additional details are listed in the next section, *Details on Survey Results*.

### ***Announcement of On-Site Audits***

We found that all regional audits of principal State laboratories are announced anywhere from 1 to 4 months in advance; however, since most laboratories are on an audit schedule of once every 2 or 3 years, the laboratories may know up to 3 years in advance. For public and private laboratories, 40 of the primacy States/territories announce audits, while 13 use a combination of both announced and unannounced audits. Unannounced audits are used by the States/territories mostly as a followup when problems are detected during the initial announced audits. Some laboratory certification and accreditation authorities use unannounced laboratory audits to detect fraudulent or inappropriate procedures. Regional respondents said unannounced audits are not used for the following reasons:

- Unsure whether unannounced audits are allowed
- Lack of program resources to perform additional work
- Laboratory analyst of interest may not be on-site for an interview
- For analytical tests with short holding times, the laboratory could alter the test and results. However, many of the more costly analytical tests would still be on-site even after an audit is announced.

### ***Viewpoints on Criteria Effectiveness***

In our evaluation of drinking water laboratory procedures, we found numerous vulnerabilities not addressed by EPA's process. More specifically, we found the criteria used for certification and accreditation needs to be improved to address limitations in data quality reviews, ethical laboratory practices, laboratory oversight controls for inappropriate procedures and fraud, auditor training and guidance (see OIG report: *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks*).

The majority of the regions (7 of 10), however, view EPA certification program elements as effective (rating of 4 or 5) in all categories except laboratory program audits. Although the EPA Laboratory Program Audits received the (relatively) lowest mean rating, no region rated the audits as ineffective (1 or 2), and 6 of the 10 regions view them as effective. EPA's certification training programs were viewed as highly effective.

In contrast, few regions (three of nine) viewed the NELAC standards as completely effective in more than one program element. The most effective component was the Laboratory Program Audits, with a mean rating of 3.4. This is comparable to the regional view of the EPA Laboratory Program Audit except that less than half (four regions) view the NELAC Laboratory

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<sup>2</sup> This section does not apply to the District of Columbia (Washington, DC). DC does not certify laboratories. Drinking water certifications are secured by commercial labs through other States.

Program Audit as completely effective, and one region viewed it as ineffective. A majority of regions view the current NELAC training accreditation programs for microbiological and chemical accreditation as ineffective. A NELAC representative acknowledged that preparation for accreditors did not include method-specific training and many of the regional respondents were new to the accreditation process.

Additional details are listed in the next section, *Details on Survey Results*.

## **Methods Used and Issues Noted by Regional and State Programs**

The results of the survey show that the majority of regions and States use multiple techniques and methods to audit laboratories. Although problems were found in several State certification programs, no occurrences of fraudulent and inappropriate procedures were reported. In followup interviews, instances of fraudulent procedures were noted by some regions. For the purpose of this survey, we defined problems as those which may cause issues with a laboratory's certification status (e.g., obtaining, revoking, or downgrading certification) or those that may affect overall quality of the laboratory data.

### ***Methods Used to Determine Integrity of Analysis***

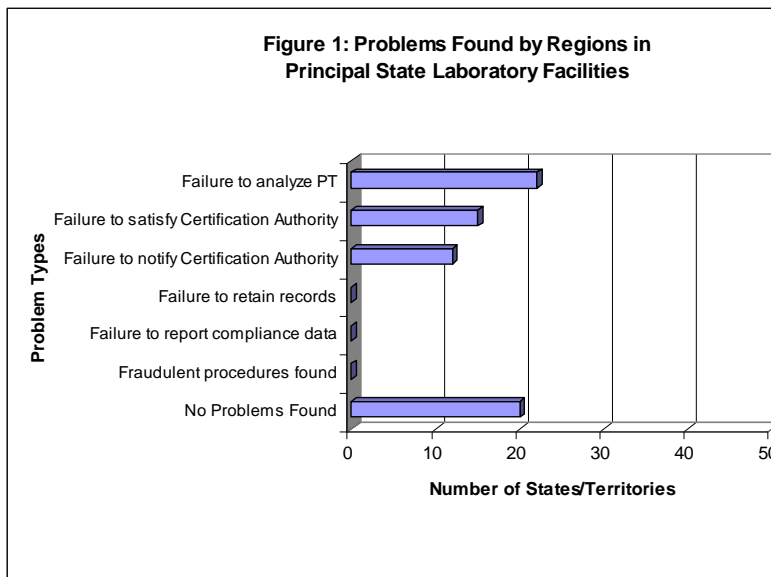
Working with investigators from the Office of Inspector General and OGWDW Technical Support Center staff, we created a list of seven currently available audit methods that may, to some extent, help identify inappropriate procedures or fraud if used by a trained auditor for that purpose. In followup interviews, we found these techniques are generally not used in this manner. Most regions 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 as 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.

Over 90 percent of the time, regions and States use five out of the seven methods: Standard Operating Procedure (SOP) reviews, instrumentation, analyst interviews, Quality Assurance (QA) document reviews, and Proficiency Testing (PT) samples. The other two methods – Electronic Data Analysis and Data Validation – are used less frequently. Data validation is used less by regional and State certification programs than most other methods (33 States compared to over 50 for other methods). Electronic data analysis is used by six State certification programs to audit public and private laboratories. It is not used by any regional certification programs in audits of principal State laboratories. Regional respondents noted resource constraints as contributing to the less frequent use of data validation and limited usage of electronic data analysis techniques.

### ***Identified Problems in Regional and State Laboratories***

A majority of the primacy States/territories (34 of 54) have some problems and issues of concern in their principal laboratories (see Figure 1). Most regional respondents stated that the majority of the problems found by the States have to do with failed PT samples, although it is not clear

whether an initial failed PT analysis was followed by a successful analysis, in compliance with the PT requirements.<sup>3</sup>



Source: EPA Regional Survey Respondents

The problems identified, such as failure to analyze PT samples and failure to notify and satisfy the certification authority, may affect the laboratory’s certification status as well as the overall quality of the laboratory data, but are not necessarily indications of fraudulent or inappropriate procedures. To determine a procedure is fraudulent or inappropriate depends upon a number of factors, including the specifics of the situation and auditor assessment. The determination of fraud is the conclusion of a legal process that includes proving intent and unfair or unlawful gain. No fraudulent procedures were found by the regional reviews of any principal State laboratories.

Problems identified to a lesser degree of occurrence than those in Figure 1 include:

- Not following appropriate testing standard/method.
- Unqualified laboratory analysts.
- Failure to report to State major changes to instrumentation, laboratory facilities, or personnel.
- Failure to correct deviations found during an audit or to respond to the audit report.
- No certification or outside contract for laboratories analyzing drinking water samples for radiochemical contaminants.

### ***Records Not Shared with Regions***

Forty-eight of the primacy States/territories keep records regarding laboratory deficiencies and 19 keep records regarding fraud. Records of fraudulent and inappropriate procedures are kept by States but not shared with the regions. As a result, regions could not provide additional information as to what these records entail.

<sup>3</sup> A laboratory may repeat a failed PT. We did not re-survey the regions to clarify which of the failure to analyze PT responses were first time failures compared to repeat failures.



## Regional Viewpoints on Occurrence and Impact of Fraudulent and Inappropriate Procedures

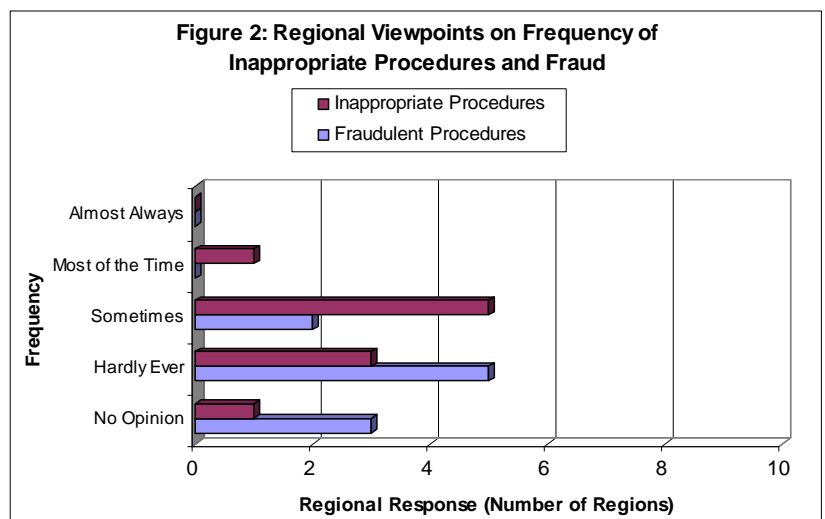
Survey results show that regional respondents do not view fraudulent and inappropriate procedures as an issue of concern within laboratories. According to regional respondents, fraudulent and inappropriate procedures occur infrequently and the impact is low. On the other hand, respondents stated that certification and accreditation processes are designed to determine the capability of a laboratory to analyze drinking water samples and are not effective for detecting inappropriate or fraudulent procedures.

By contrast, in our completed evaluation, we note an increase in laboratory fraud cases reported to the OIG Office of Investigations as well as several cases of what OIG considers to be severe inappropriate procedures, including fraud found by a State using techniques additional to EPA requirements. As a result of these findings, we recommended OGWDW improve awareness of the vulnerabilities and realities of fraud and inappropriate procedures as well as reduce uncertainty associated with the occurrence of procedures of this type (see OIG report: *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks*).

### Occurrence of Fraudulent and Inappropriate Procedures

Regional respondents stated that the purpose of their programs and audits was to ensure laboratories were in compliance with regulations. This includes the laboratory's capability of conducting analytical measurements of drinking water contaminants and establishing programs for the certification of laboratories. The on-site audit does not include, and is not currently designed to include, a review of the laboratory to determine if fraudulent or inappropriate procedures may be taking place.

Despite statements describing program and audit limitations, regional certification officers reported, for the most part, that they believe fraudulent and inappropriate procedures occur infrequently in laboratories (see Figure 2). Five regional respondents believed that fraudulent procedures hardly ever occur, while two indicated that they occur sometimes. Three regions declined to answer, saying that they had no experience in detecting and determining fraud. None of the regions reported fraud as occurring greater than sometimes.



Source: EPA Regional Survey Respondents

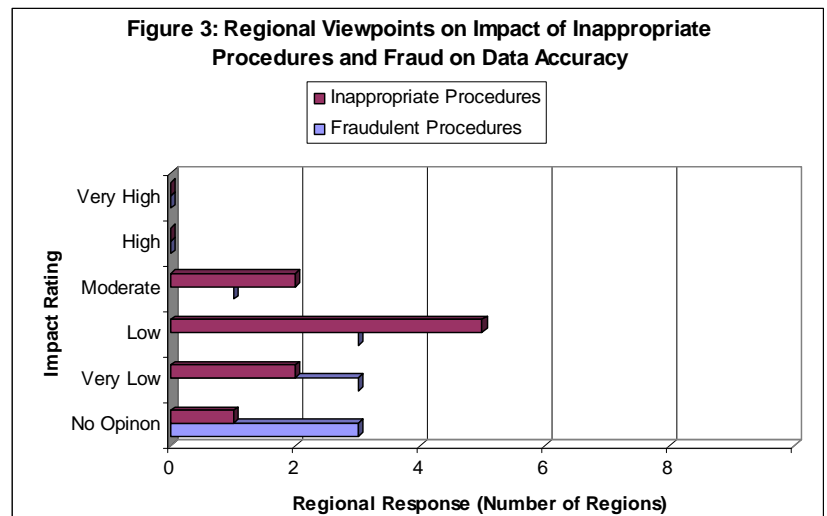
Only one region viewed inappropriate procedures as occurring greater than sometimes. Three of the regions indicated that they hardly ever occur, while five indicated that they occur sometimes. One of the regions declined to answer, stating that it had no experience in detecting and determining inappropriate procedures.

When asked to further break down the process used to analyze water samples, sample collection and data validation and verification were rated as relatively more vulnerable to fraud when compared to the other steps in the process. The assigned vulnerability ratings, however, were still below the scale’s midpoint of 3.0 (see full results on page 16).

### **Vulnerabilities and Potential Impacts**

Few regions view both the EPA criteria and NELAC standards as an effective means to detect fraudulent procedures. Effectiveness for detecting inappropriate procedures was rated slightly higher than fraud with five regions rating either EPA or NELAC as completely effective. The average rating for both inappropriate and fraudulent procedure detection was at or below the midpoint of 3.0. However, in followup interviews, the majority of regions stated that certification and accreditation criteria were not designed to detect fraudulent procedures, and some also did not believe they were designed to detect inappropriate procedures. Regions and OGWDW stated that laboratory auditors have not been trained in fraud detection methods and were not actively looking for fraud.

One region indicated that there is a moderate impact on the accuracy of data from fraudulent procedures and two regions indicated that there is a moderate impact from inappropriate procedures. However, the majority of the regions (seven regions for inappropriate procedures and six for fraudulent procedures) view the impact on the accuracy of the data as a result of fraudulent and inappropriate procedures as very low to low (Figure 3). No region viewed the impact as greater than moderate.



Source: EPA Regional Survey Respondents

Based on the work completed in our full evaluation, we believe there are vulnerabilities to data accuracy that, if unaddressed by EPA processes, may compromise the quality of data used to report drinking water compliance information and can increase the risk to public health (see OIG report: *Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks*).

## Details on Survey Results

### Survey Part 1:

**Question #1:** Select the response that best represents the region's *frequency* of routine, on-site drinking water laboratory audits for each primacy State/territory in FY04.

EPA Region	Audit Frequency		
	Once every 2 years	Once every 3 years	Other <sup>4</sup>
1	ME, NH	CT, MA, RI, VT	—
2	NY	NJ, PR, VI	—
3	—	DC, DE, MD, PA, WV, VA	—
4	—	AL, FL, GA, KY, MS, NC, SC, TN	—
5	—	IN, MI, MN, OH	IL, WI
6	—	AR, LA, NM, OK, TX	—
7	—	KS, MO, NE	IA
8	—	CO, MT, ND, SD, UT	—
9	—	AS, AZ, CA, GU, HI, NV	—
10	—	AK, ID, OR, WA	—

**Question #2:** Select the response that best represents regional policy for *how* on-site laboratory audits were announced for each State in FY04.

Regional audits of principal State laboratories are all announced.

**Question #3:** Select the response that best represents the regional *certification/accreditation criteria* used to audit each State's principal drinking water laboratory facility in FY04.

EPA Region	Certification/Accreditation Criteria		
	EPA	NELAC	Both EPA & NELAC
1	CT, MA, RI, VT	ME, NH	—
2	NJ, PR, VI	NY	—
3	DC, DE, MD, PA, VA, WV	—	—
4	AL, GA, KY, MS, NC, SC, TN	—	FL
5	IN, MI, MN, OH	WI	IL
6	AR, LA, NM, OK, TX	—	—
7	KS, MO, NE	IA	—
8	CO, MT, ND, SD, UT	—	—
9	AS, AZ, CA, GU, HI, NV	—	—
10	AK, ID, OR, WA	—	—

<sup>4</sup> WI and IA are audited in accordance with the NELAC Standards. IL is a combination of EPA and NELAC.

**Question #4: Select the response that best represents the *methods* used by the region to detect fraudulent or inappropriate procedures in each primacy State.**

Frequency	Methods used by Regional auditors in each primacy State/Territory				
	Data Validation	Electronic Data Analysis	PT Samples	QA Document Review	Analyst Interviews/ Instrumentation/ SOP Reviews
Not used	AL, CT, CO, FL, GA, IA, KY, MA, ME, MS, NC, NH, MT, ND, RI, SC, SD, TN, UT, VT, WI	All States and Territories	—	FL, IA, WI	FL, IA, WI
Greater than once every year	—	—	IA, ME, NH, NY	—	—
Once every year	DC, DE, MD, PA, VA, WV	—	AK, AL, AS, AZ, CA, CT, CO, DC, DE, FL, GA, GU, HI, ID, IL, IN, KS, KY, MA, MD, MI, MN, MO, MS, NC, ND, NE, NJ, NV, OH, OR, PA, PR, RI, SC, SD, TN, UT, VA, VI, VT, WA, WI, WV	NC	—
Once every 2 years	NY	—	—	ME, NH, NY	ME, NH, NY
Once every 3 years	AK, AR, AS, AZ, CA, GU, HI, ID, IL, IN, KS, LA, MI, MN, MO, NE, NM, NJ, NV, OH, OK, OR, PR, TX, VI, WA	—	AR, LA, MT, NM, OK, TX	AK, AL, AR, AS, AZ, CA, CT, CO, DC, DE, GA, GU, HI, ID, IL, IN, KY, KS, LA, MA, MD, MI, MN, MO, MS, MT, ND, NE, NJ, NM, NV, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VA, VI, VT, WA, WV	AK, AL, AR, AS, AZ, CA, CT, CO, DC, DE, GA, GU, HI, ID, IL, IN, KY, KS, LA, MA, MD, MI, MN, MO, MS, MT, NC, ND, NE, NJ, NM, NV, OH, OK, OR, PA, PR, RI, SC, SD, TN, TX, UT, VA, VI, VT, WA, WV

*Other techniques used by States:* Track Sample Receipt (AL); State Drinking Water Certification Questionnaire (AL, GA, KY, TN, NC, SC); NELAC Accreditation Renewal (FL, IA); Pictures of Poor Facility Conditions in Labs (MS); and Ethics Training (DE, MD, VA, PA, WV, DC).

**Question #5: Select the response that best represents any of the identified problems found by the region in this State’s principal drinking water laboratory facilities.**

Results in earlier “*Methods Used and Issues Noted by Regional and State Programs*” section.

## Survey Part 2:

**Question #1:** Select the response that best represents the State's *frequency* of routine, on-site drinking water laboratory audits for commercial and municipal laboratories in FY04.

EPA Region	Audit Frequency			
	Once every year	Once every 2 years	Once every 3 years	Other
1	—	NH	CT, MA, ME, RI, VT	—
2	PR	NY, VI	—	NJ <sup>5</sup>
3	—	—	DE, MD, PA, VA, WV	—
4	—	FL	AL, GA, KY, TN, NC, SC	MS <sup>6</sup>
5	—	—	IN, MI, MN, OH, WI	IL <sup>7</sup>
6	—	NM, OK, TX	AR	LA <sup>5</sup>
7	—	IA, KS	MO, NE	—
8	—	UT	CO, MT, ND, SD, WY	—
9	HI	AZ, CA, NV	GU	—
10	—	OR	AK, WA	ID <sup>5</sup>

**Question #2:** Select the response that best represents the State's policy for *how* on-site laboratory audits were announced for commercial and municipal laboratories in FY04.

EPA Region	Announced Audits	Both Announced and Unannounced Audits
1	CT	MA, ME, NH, RI, VT
2	NY, PR, VI	NJ
3	DE, MD, PA, VA, WV	—
4	AL, FL, GA, KY, MS, NC, SC, TN	—
5	IL, IN, WI	MI, MN, OH
6	AR, LA, TX	NM, OK
7	IA, KS, MO, NE	—
8	CO, MT, ND, SD, UT, WY	—
9	CA, GU, HI, NV	AZ
10	ID, OR, WA	AK

<sup>5</sup> Frequency dependent upon type of audit and accrediting authority.

<sup>6</sup> Chemistry drinking water labs has not been accredited for over 6 years for commercial and municipal laboratories.

<sup>7</sup> Audit schedule fell behind every 2 years. State is correcting problem by hiring third-party auditors for assistance.

**Question #3: Select the response that best reflects the *criteria* used by the States/territories to audit commercial or municipal drinking water laboratories.**

EPA Region	Certification/Accreditation Criteria					
	EPA	NELAC	EPA/NELAC	EPA/NELAC/ State Specific	State Specific	EPA/State Specific
1	CT, MA, ME, RI, VT	NH	—	—	—	—
2	VI	NY	—	—	NJ, PR	—
3	DE, MD, VA, WV	—	PA	—	—	—
4	AL, GA, KY, MS, NC, SC, TN	FL	—	—	—	—
5	IN, MI, MN	IL	—	—	—	OH <sup>8</sup> , WI
6	AR, OK, TX	—	LA, NM	—	—	—
7	IA, MO	—	KS	—	—	NE
8	CO, MT, ND, SD, WY	UT	—	—	—	—
9	HI, GU, NV	—	—	CA	—	AZ
10	AK	—	—	—	OR	ID, WA

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<sup>8</sup> State certifies individual analysts rather than laboratories.

**Question #4: Select the response that best represents the *methods* used by States/territories to detect fraudulent or inappropriate laboratory procedures.**

Frequency	Methods used by State auditors for public and private laboratories				
	Data Validation	Electronic Data Analysis	PT Samples	QA Document Review	Analyst Interviews/ Instrumentation/ SOP Reviews
Not used	AL, CT, CO, FL, GA, KY, MA, ME, MS, MT, NC, ND, NH, RI, SD, SC, TN, UT, VT, WY	All remaining States/Territories do not use Electronic Data Analysis	—	AL, TN	—
Greater than once every year	—	—	CA, IL, KS, NH, NJ, NV, NY, OH, OK, OR, TX, UT, WA	—	—
Once every year	HI, PR	—	AL, AK, AZ, CT, CO, DE, FL, GA, GU, HI, IA, IN, KY, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, PA, PR, RI, SC, SD, VA, VI, VT, WI, WV, WY	PR, HI	PR, HI
Once every 2 years	AZ, CA, IA, ID <sup>9</sup> , IL, KS, LA, NJ <sup>10</sup> , NM, NV, NY, OK, OR, TX, VI,	AZ, KS	ID <sup>9</sup> , LA, NM	AZ, CA, FL <sup>11</sup> , IA, ID <sup>9</sup> , IL, KS, LA, NH, NJ <sup>10</sup> , NM, NV, NY, OK, OR, TX, UT, VI	AZ, CA, FL <sup>12</sup> , IA, ID <sup>9</sup> , IL, KS, LA, NH, NJ <sup>10</sup> , NM, NV, NY, OK, OR, TX, UT <sup>13</sup> , VI
Once every 3 years	AK, AR, DE, GU, IN, MD, MI, MN, MO, NE, OH <sup>14</sup> , PA, WA, WI, WV, VA	MI <sup>14</sup> , NE, NJ <sup>14</sup> , WA	AR, TN <sup>15</sup>	AK, AR, CT, CO, DE, MD, GA, GU, IN, KY, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, OH, PA, RI, SC, SD, VA, VT, WA, WI, WV, WY	AK, AL <sup>16</sup> , AR, CT, CO, DE, GA, GU, IN, KY, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, OH, PA, RI, SC, SD, TN <sup>17</sup> , VA, VT, WA, WI, WV, WY

<sup>9</sup> Idaho conducts data validation at least once every 2 years; the frequency is once a year for chemistry.

<sup>10</sup> Once every 2 years for NELAC accreditation; once every 3 years at other New Jersey-Certified labs.

<sup>11</sup> Region answered, "Yes and No. Some assessors use this method and some do not. Very inconsistent."

<sup>12</sup> For Analyst Interviews only-region answered, "Yes and No. Some assessors use this method and some do not. Very inconsistent."

<sup>13</sup> Utah conducts analyst interviews once every year. Instrumentation and SOP reviews are conducted once every 2 years.

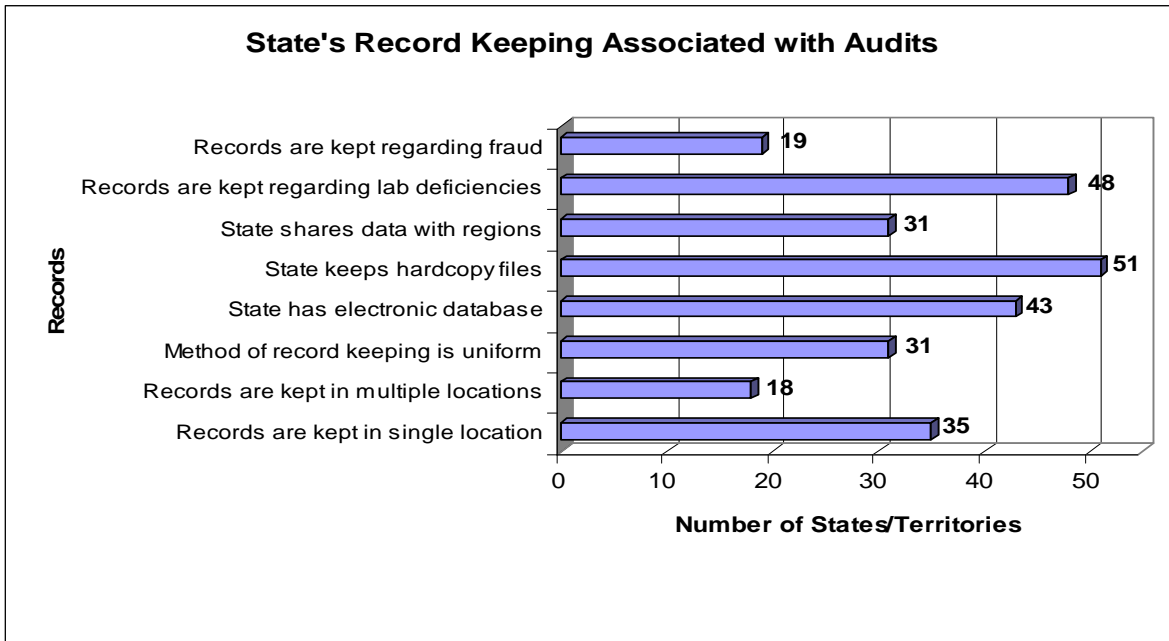
<sup>14</sup> Method is used only if there is suspicion of inappropriate procedures.

<sup>15</sup> Once every 3 years but method not according to EPA Drinking Water Certification Manual.

<sup>16</sup> Alabama does not conduct instrumentation reviews.

<sup>17</sup> For Instrumentation only-region answered, "On occasion. Yes and No." Once every 3 years is consistent with their audits.

**Question #5: Mark all that apply below regarding the State’s record keeping associated with drinking water laboratory certification/accreditation audits.**



**Question #6: Has the State reported cases of certification downgrading or disciplinary actions taken against commercial or municipal laboratories?**

Twenty-five of the primacy State certification programs reported cases of certification downgrading of public and private laboratories (AK, AR, AZ, CA, CT, DE, GA, GU, HI, ID, LA, MA, MD, ME, NH, NM, NV, NY, OR, PA, PR, RI, VA, VI, VT). A laboratory can be downgraded to “provisionally certified” status for a contaminant or group of contaminants if specified problems are found to occur.

**Question #7: How many Full-Time Equivalents were assigned by each State to certify or accredit drinking water laboratories in FY04?**

EPA Regions	Number of Full-Time Equivalents		
	0-4	5-10	>10
1	CT, MA, ME, NH, RI, VT	—	—
2	PR, VI	NJ, NY	—
3	DE, MD, VA, WV	PA	—
4	AL, FL, GA, KY, MS, NC, SC, TN	—	—
5	IL, IN, MI, MN, OH	WI	—
6	AR, LA, NM, OK, TX	—	—
7	IA <sup>18</sup> , KS, MO, NE	—	—
8	CO, MT, ND, SD, WY	UT	—
9	AZ, GU, HI, NV	—	CA
10	AK, ID	OR, WA	—

<sup>18</sup> Two full-time equivalents and 12 part-time.



**Questions #8: How many third party full-time equivalents were assigned by the State to assist in auditing drinking water laboratories in FY 04? and #10: What criteria are used by the State to select third party auditors?**

State	# of 3 <sup>rd</sup> Party Auditors	Overall Experience	Record Keeping	QA Programs	Freedom from Conflicts of Interest	Completion of EPA's Training Course	Ability to Provide Technical Assistance and Training	Other
GA	6	Yes	Yes	No	Yes	No	No	Georgia has an accreditation process & a memorandum of agreement to provide 3rd party service. Upon Region 4's 3-year evaluation, we found the process to be inconsistent & not adhering to the EPA Certification Manual.
KY	1.5	Not sure	Not sure	Not sure	Not sure	Not sure	Not sure	—
OR	Not sure. Part-time person only.	No	Yes	Yes	Yes	Yes	No	Follows NELAC requirements for 3rd party assessors, which includes the items detailed above.
RI	1	Yes	No	No	Yes	Yes	No	—
WA	1	No	No	No	No	Yes	No	—

**Question #9: How many drinking water laboratories were accredited or certified by each State from FY00-FY04?**

The survey results did not clearly differentiate between the numbers of laboratories or certifications and accreditations. This being the case, a laboratory that holds multiple certifications (e.g., microbiological, chemical, and radiological) may have been counted multiple times. Further information would be required directly from the States in order to obtain a reliable estimate.

### **Survey Part 3:**

**Question #1: Based on your overall experience evaluating and auditing drinking water laboratories, please rate how vulnerable you believe each laboratory analysis process is to fraudulent or inappropriate procedures.**

Scale: 1=Not At All Vulnerable 5=Completely Vulnerable		Not Vulnerable	Midpoint	Vulnerable	Mean Rating <sup>19</sup>	Total # of regions Responding <sup>20</sup>
		1 to 2 (# of regions)	3 (# of regions)	4 to 5 (# of regions)		
<b>Components of Sample Analysis Process</b>	Sample Collection <sup>19</sup>	3 (2)	3 (4)	2 (2)	2.9 (3.1)	8
	Sample Tracking & Recording	7	1	1	1.9 (1.8)	9
	Adherence to SOP	6	2	1	2.1 (2.2)	9
	Prep. of Standards & Samples	7	1	1	2.0	9
	Instrument Performance	6	2	1	1.9	9
	Instrument Maintenance	6	2	1	1.9	9
	Instrument Calibration	6	2	1	2.0 (2.1)	9
	Lab Technician Performance	6	2	1	2.1	9
	Adherence to QA/QC Plan	6	2	1	2.1 (2.2)	9
	Data Validation & Verification	5	3	1	2.3 (2.4)	9
	Data Handling & Maintenance	6	2	1	2.0	9
	Data Reporting	7	1	1	2.0 (2.1)	9
	Data Security & Backup <sup>19</sup>	6 (5)	2 (2)	1 (1)	2.1 (2.0)	9 (8)

#### ***Additional Details:***

In followup interviews, respondents were asked whether they would change their answers if fraudulent and inappropriate procedures were considered separately. Two regions changed their answers slightly for inappropriate procedures.

<sup>19</sup>Numbers in parenthesis indicate regional response for inappropriate procedures. These were the only variations to occur in regional responses based on rating the vulnerability to inappropriate procedures separate from fraudulent procedures.

<sup>20</sup>Not all 10 regions responded to all questions because they stated that they had no factual basis to answer the questions since they had no experience with fraudulent and inappropriate procedures. Averages are based upon the total number of regions responding.

**Question #2: In the region you represent, to the best of your knowledge, how often would you say fraudulent and inappropriate procedures occur in laboratories analyzing drinking water samples on an annual basis?**

Results can be found in the section “*Regional Viewpoints on Occurrence and Impact of Fraudulent and Inappropriate Procedures.*”

**Question #3: In the region you represent, to the best of your knowledge, please fill in the blank for the following sentence: “The frequency with which fraudulent and inappropriate procedures occur in laboratories analyzing drinking water samples on an annual basis presents a \_\_\_\_\_ risk to human health.”**

At this time, the results from this survey question do not accurately depict whether there is an impact on human health from fraudulent and inappropriate procedures that occur within laboratories that analyze drinking water samples. It was determined that the respondents for the survey do not have the proper public health or epidemiological experience necessary to determine whether there would be an impact to human health. Further information would be required directly from more experienced personnel before an accurate assessment could be made.

**Question #4: In the region you represent, to the best of your knowledge, please fill in the blank for the following sentence: “The frequency with which fraudulent and inappropriate procedures occur in laboratories analyzing drinking water samples on an annual basis has a \_\_\_\_\_ impact on the accuracy of data used to determine drinking water quality.”**

Results can be found in the section “*Regional Viewpoints on Occurrence and Impact of Fraudulent and Inappropriate Procedures.*”

**Questions #5a:** Rate the overall effectiveness of the certification/accreditation criteria used by the region in the detection of *inappropriate* laboratory procedures for FY00-FY04 & **5b:** Rate the overall effectiveness of the certification/accreditation criteria used by the region in the detection of *fraudulent* laboratory procedures for FY00-04.

Scale: 1=Not At All Effective 5=Completely Effective		Not Effective	Midpoint	Effective	Total # of regions Responding <sup>21</sup>
		1 to 2 (# of regions)	3 (# of regions)	4 to 5 (# of regions)	
Inappropriate Procedures	EPA	2	4	4	10
	NELAC	2	4	2	8
Fraudulent Procedures	EPA	7	3	0	10
	NELAC	6	2	0	8

<sup>21</sup> Two regions did not respond to the NELAC question, stating that they did not have any specific experience or history using the NELAC criteria. Averages in report are based upon the total number of regions responding.

**Questions #6: Based on your experience with the National Environmental Laboratory Accreditation Conference (NELAC), please rate the effectiveness of the NELAC-Laboratory Accreditation Program (NELAP) for FY00-04 based on the following components & 7: Based on your experience with the Office of Ground Water and Drinking Water (OGWDW), please rate the effectiveness of the OGWDW’s Drinking Water Laboratory Certification Program for FY00-04 based on the following components.**

Survey Scale: 1=Not At All Effective 5=Completely Effective		Not Effective	Midpoint	Effective	Total # of regions Responding <sup>22</sup>
		1 to 2 (# of regions)	3 (# of regions)	4 to 5 (# of regions)	
<b>NELAC</b>	Outreach	3	2	3	8
	Distribution of Guidance Documents	2	2	5	9
	Technical Assistance	4	2	1	7
	Training for Micro Accreditation	8	0	1	9
	Training for Chemical Accreditation	7	1	1	9
	Laboratory Program Audits	1	4	4	9
<b>EPA</b>	Outreach	1	2	7	10
	Distribution of Guidance Documents	0	3	7	10
	Technical Assistance	1	2	7	10
	Training for Micro Accreditation	0	1	9	10
	Training for Chemical Accreditation	1	1	8	10
	Laboratory Program Audits	0	4	6	10

***Additional Details:***

When asked to provide further information why EPA criteria were rated higher than NELAC standards, regional respondents commented that:

- EPA has a better training program for auditors.
- EPA technical staff (Cincinnati Technical Support Center) are great with answering questions and helping update the State certification officers in the regions each year.
- NELAC does not focus specifically on individual drinking water sample analysis processes (i.e., processes for chemical and microbiological certification). Instead, it uses a quality system approach.
- EPA certification stresses specific methods and parameters that are more closely related to the drinking water sample analysis process.
- Regions have been consistently conducting EPA certification audits for several years.
- The relative newness of the NELAC program can lead to variation between audits and auditors, uncertainty over regional audit responsibility.

<sup>22</sup> Not all of 10 EPA regions responded to all questions because they did not have any specific experience or history using the specified criteria to answer the question. Averages in report are based upon the total number of regions responding.

## **Drinking Water Laboratory Oversight Programs and Selected Attributes**

	<b>EPA Drinking Water Laboratory Certification Program</b>	<b>NELAC National Environmental Laboratory Accreditation Program</b>
<b>Year Established</b>	1978	1995, recognized by EPA as an alternative to drinking water laboratory certification in 2002
<b>Primary Guidance Document(s)</b>	EPA Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition (2005) <a href="http://www.epa.gov/safewater/labcert/pdfs/manual_labcert_2005.pdf">http://www.epa.gov/safewater/labcert/pdfs/manual_labcert_2005.pdf</a>	NELAC Constitution and Bylaws (2002) <a href="http://www.epa.gov/nelac/bylaw0.html">http://www.epa.gov/nelac/bylaw0.html</a>  NELAC Standards 2003 (effective July 2005) <a href="http://www.epa.gov/nelac/2003standards.html">http://www.epa.gov/nelac/2003standards.html</a>
<b>What Laboratories Should Do</b>	<ul style="list-style-type: none"> <li>• Proficiency testing sample: 1 per year</li> <li>• Pass on-site audits: once every 3 years</li> <li>• Demonstrate EPA drinking water method capability</li> </ul>	<ul style="list-style-type: none"> <li>• Proficiency testing sample: 2 per year</li> <li>• Pass on-site audits: once every 2 years</li> <li>• Demonstrate EPA drinking water method capability</li> <li>• Demonstrate quality system</li> </ul>
<b>What Certification Officers or Accreditors Should Do</b>	Take EPA certification training course and pass separate exams for chemistry and microbiology. Periodic training by the regions and refresher training programs at least every 5 years are encouraged. No renewal or continuing education requirements.	Take NELAP accreditation training and accompany experienced assessor on four site visits, method-specific courses recommended. No renewal or continuing education requirements.
<b>Training</b>	Separate courses for chemistry, microbiology; periodic refresher courses (non-mandatory). Radiochemistry course under consideration.	Overall course for accreditation, method specific course recommended, Web-based courses under development.
<b>EPA Regional Laboratories<sup>23</sup></b>	Certification status is determined by the OGWDW Technical Support Center.	NELAP, or other recognized accreditation authorities, accredit.
<b>Principal State Laboratories<sup>24</sup></b>	Certification status is determined by the EPA region in which the State is geographically located.	Accreditation may be obtained from any State nationally recognized as a NELAP accrediting authority.
<b>Public and Private Laboratories</b>	States with drinking water primacy <sup>25</sup> are responsible for certifying <sup>26</sup> . If a State lacks primacy or does not possess a certification officer, a State with primacy or the EPA region will determine certification status.	Public or private laboratories may acquire accreditation from the State it is geographically located in if the State is a NELAP accrediting authority. If not, accreditation status is determined by a NELAP accreditation authority.

<sup>23</sup> Certification is not required. The nine regions with laboratories are NELAP accredited or in the process of accreditation.

<sup>24</sup> **Principal State Laboratory System:** All facilities, whether part of the State laboratory or contracted by the State, producing data for the State and certified by the EPA, fulfilling the requirements for primacy as listed in the 40 CFR 142.10(b) (4).

<sup>25</sup> **Primacy:** Primary responsibility for administration and enforcement of primary drinking water regulations and related requirements applicable to public water systems within a State.

<sup>26</sup> States may certify or accredit laboratories both within and outside the geographic borders of the State.

## Glossary

**Analyst Interviews:** Analyst interviews are important to get a sense of how the laboratory functions from different perspectives (managers, technical staff, QA staff) and to establish whether there is consistency in the laboratory culture and work ethic. For example:

- Does management think QA is a staff responsibility and staff think it is management's responsibility? Is there QA independence?
- Is there a bonus system? How does it work?
- Is training provided to employees?
- Does management think overtime is needed or used? How does overtime work?

*(Detecting Improper Laboratory Practices: A Toolbox for Assessors)*

**Electronic Data Analysis:** Automated data review through the use of computer programs. An example of an automated data validation program is EPA's Computer-Aided Data Review and Evaluation (CADRE).

*(Best Practices for the Detection and Deterrence of Laboratory Fraud)*

**Electronic/Magnetic Data/Tape Audit:** An auditor regeneration and processing of raw, unprocessed analytical data produced by an analytical laboratory during the analysis of volatile and semivolatile samples by gas chromatograph, gas chromatograph/mass spectrometer, or other methods which have archival systems, and a review of laboratory processed files for the purpose of identifying deviations from methods and contracts. A comparison of results obtained by the auditor for calibrations and other criteria compounds against the results reported by the laboratory in the hard copy deliverables is made to identify possible discrepancies between what was reported by the laboratory and actual quality control results.

*(Best Practices for the Detection and Deterrence of Laboratory Fraud)*

**Data Audit/Validation:** A qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data meets specified criteria.

*(NELAC Website and Standards)*

**Inappropriate Practices:** A scientifically unsound or technically unjustified omission, manipulation, or alteration of procedures or data that bypasses the required QC parameters, making the results appear acceptable.

*(Detecting Improper Laboratory Practices: A Toolbox for Assessors)*

**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.

*(Best Practices for the Detection and Deterrence of Laboratory Fraud)*

**NELAC:** The National Environmental Laboratory Accreditation Conference (NELAC) is a voluntary association of State and Federal agencies with full opportunity for input from the private sector. NELAC's purpose is to establish and promote mutually acceptable performance standards for the operation of environmental laboratories. EPA's National Environmental Laboratory Accreditation Program (NELAP) office provides support to NELAC and evaluation of the accrediting authority programs.

*(NELAC Website and Standards)*

**On-Site Laboratory Audits:** On-site laboratory evaluation to determine the managerial and technical capability of the laboratory to perform analysis in conformance with specification in contracts and approved analytical methods. Audits normally evaluate a laboratory's technical expertise, operating procedures, facility and equipment sufficiency, and possible sources of sample contamination.

*(Best Practices for the Detection and Deterrence of Laboratory Fraud)*

**Proficiency Testing (PT) Sample:** A sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria.

*(NELAC Website and Standards)*

## Sources

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. *Detecting Improper Laboratory Practices: A Toolbox for Assessors*; U.S. EPA, Office of Environmental Information, Quality Staff; Power Point Presentation: <http://www.epa.gov/quality/trcourse.html#detectlab>

3. *NELAC Website and Standards*: <http://www.epa.gov/nelac>