

**Innovation and Integration Docket EPA-HQ-QA-2011-0161**  
**State Local and Tribal Governments Docket EPA-HQ-QA-2011-0163**  
**and**  
**General Docket EPA-HQ-OA-2011-0156**  
**Comments Filed in Response to Federal Register Noticed**  
**Dated February 23, 2011**  
**by U.S. Environmental Protection Agency**

**Improving U.S. Environmental Protection Agency Regulations**

**Comments provided by:**

The NELAC Institute

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The following comments are submitted in response to a notice published in the Federal Register by the U.S. Environmental Protection Agency (EPA) on February 23, 2011. In the notice, EPA requested public input to a retrospective review of its rules.

These comments address the quality of laboratory data used by EPA to make regulatory decisions. These comments address specifically the following areas:

- The intended environmental results can be achieved using less costly methods;
- Regulations could be improved by harmonizing requirements across regulatory programs to better achieve regulatory objectives,
- The regulations are overlapping and could be streamlined,
- There are low cost alternatives to strengthen the existing regulatory programs,
- There are opportunities to better partner with state, local, and / or tribal governments,
- The program can be made more flexible within the existing legal framework.

**Background**

Each year, hundreds of millions of measurements are performed by over 5,000 environmental testing laboratories in the United States to determine whether or not a regulated entity is in or

out of compliance, evaluate the extent and nature of environmental contaminants in air, soil and water, and to collectively provide information used to protect human health and environment. For example, a municipality may seek testing of their tap water to see if it is safe to drink; a wastewater treatment plan may test their discharge to demonstrate compliance with a permit limit, the Federal Government may test soil at its facility to determine if the site can be redeveloped, or a community may contract to test the air in its community to determine the impact of a new industrial activity that has moved into the area. These measurements are performed by environmental testing laboratories that may be operated by local, state or federal government, or commercial for profit entities.

Many of these measurements are performed without adequate assurance and documentation to ensure that the measurements are reliable. Without this surveillance, government agencies and the public often make decisions that may be based on incomplete or inaccurate information. The accuracy of test results is commonly assumed, but not so often is it actually known. Such decisions

- Increase the anxiety over environmental contaminants where no such anxiety is justified, or provide assurance of no risks when such assurances cannot be proven,
- Result in unnecessary expenditure of funds to remedy a non-existent environmental concern, or insufficient actions taken when such remedies are needed,
- Result in devaluation of property when such devaluation is based on inaccurate measurements, and
- Result in over regulation of some industries when such regulation is not required.

Although there are stringent compliance monitoring requirements placed on regulated facilities, there is little oversight of the laboratories used to generate the data for compliance monitoring, outside of the Drinking Water program. In order to strengthen EPA's environmental regulatory programs and provide a solid foundation for regulatory decisions, EPA and the public need consistent access to data of known and documented quality to make critical environmental management decisions.

## **Discussion**

Since 1978, EPA has implemented a certification program for laboratories performing drinking water analyses for compliance with regulations issued pursuant to the Safe Drinking Water Act. These laboratories include EPA Regional laboratories, certain Federal laboratories, Tribal Nation laboratories, principal State laboratories in primacy States, and drinking water laboratories in non-primacy States. EPA has concluded that laboratories that adopt the approaches discussed in this manual will generate reliable analytical data. Consequently, EPA recommends that States follow these procedures and criteria in their drinking water certification decisions.

In the wastewater program at EPA, dischargers are required to participate in Discharge Monitoring Report Quality Assurance (DMRQA) studies to demonstrate the quality of data

submitted to this regulatory program. In this program, responsibility for data quality clearly falls upon the permittee or laboratory client.

The solid waste program has taken yet another approach to managing data quality by requiring waste generators to develop a sampling and analysis plan. The Agency provides guidelines for laboratory testing, but not the mandated protocols of the drinking water program. While many prefer this “performance approach,” laboratory accreditation can address whichever methods or types of methods are utilized.

The Superfund program has relied on its Contract Laboratory Program, a *de facto* certification program, but without the rigor of a quality systems focus. The emissions monitoring program relies on mandated test methods, with no requirements for accreditation.

While all of these programs have some degree of effectiveness, the result for laboratories, regulated facilities and the public, is a fragmented system for assuring the quality of laboratory data that is used to make decisions that often have huge economic impacts. There is no comprehensive program in place at EPA to assure laboratory data quality by ensuring the competency of laboratories generating environmental data.

The Agency has recognized the limitations of the current regulations for laboratory analyses (see *Agency Policy Directive Number FEM-2011-01*) and requires organizations (e.g., laboratories, field sampling and measurement) generating environmental data under Agency-funded acquisitions submit documentation of their competency.

## **Recommendation**

EPA should require that all laboratories generating environmental data in the United States be accredited to a national consensus standard. Accreditation attests to the competency of a laboratory for conducting environmental measurements and provides assurance that data users can make decisions based on data of known and documented quality.

Using an accredited laboratory also increases confidence that decisions regarding multiple facilities are based on comparable data. Costs associated with laboratory problems, including re-testing, re-sampling, and lost time are minimized and false positives and negatives, which can directly affect compliance with regulations, are minimized. An effective accreditation program will thus reduce the overall costs to laboratories due to improved processes and procedures that are implemented. Accreditation provides an objective way of showing clients, the community and the government that a laboratory has demonstrated capability to provide testing services.

The NELAC Institute (TNI), a non-profit organization whose mission is to “foster the generation of environmental data of known and documented quality,” administers the National Environmental Laboratory Accreditation Program (NELAP) that ensures the competency of all

laboratories that measure environmental contaminants in all environmental media (e.g., air, soil, water).

TNI developed and will maintain a set of standards (the TNI NELAP Standard) based on international standards (ISO/IEC 17025, 17011, and 17043) that interpret the generic international laboratory standards for application to laboratories performing environmental testing. The NELAP program has adopted this standard and will begin to implement it in July of this year, as an upgrade to the standard formerly developed when EPA was more involved with the program.

TNI's program contains a number of unique attributes:

- Laboratories are periodically inspected by an authoritative, independent organization called an Accreditation Body, to ensure they have the staff, facilities, equipment, and professional practice to generate reliable data,
- Laboratories are held accountable to internationally-recognized requirements that have been supplemented by rigorous interpretive requirements specific to environmental testing as those essential for ensuring reliable data,
- Laboratories are periodically evaluated using proficiency test (PT) samples to evaluate the accuracy of their results. TNI regularly assesses the organizations that provide these test samples and evaluates the results to assure they are qualified to do so,
- Those organizations (Accreditation Bodies) that assess laboratories are monitored by TNI to ensure they have both the competency and the resources for the operation of an accreditation program.

No other organization has developed requirements specific for environmental testing that have the level of detail to ensure consistent application of the requirements of multiple state agencies. No other organization has established a system whereby state government agencies have confidence that laboratory assessors and accreditation bodies participating in the program have implemented the program to the same level of reliability. No other organization has established a comprehensive PT program that addresses all analytes and all media.

Standards used by TNI are developed through an ANSI-accredited consensus standards development process and as such meet the requirements of Office of Management and Budget (OMB) circular A -119 for use of consensus standards in federal regulations where available. Further, NELAP is the sole voluntary accreditation program using interpretive criteria specific to environmental testing. Similar interpretive criteria are available and used internationally for another important public health area, food and pharmaceutical testing (AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals.)

To date, 15 state agencies have been recognized as NELAP Accreditation Bodies and over 10 other states have incorporated some or all of TNI's standards into their laboratory accreditation regulatory programs. Using this existing accreditation framework, costs to EPA to implement a

requirement for national laboratory accreditation would be minimal, since the actual program is essentially self-sustaining at this point in time.

EPA's Office of Water has already recognized NELAP accreditation in lieu of drinking water certification and several other programs within EPA have sought TNI's assistance with aspects of their programs.

NELAP benefits the public by:

- Establishing a uniform set of standards by which environmental data is produced across the various states, agencies and programs that participate, thereby promoting comparability and defensibility.
- Being more cost effective, through the recognition and use of the accreditation status of a laboratory by multiple stakeholders and consequently reducing the number of assessments performed by accreditation bodies.
- Presenting greater opportunities for quality improvements. The NELAP standards development process encourages the pooling of expertise from multiple agencies, states and various stakeholder groups in the private sector. This larger range of expertise has strengthened the quality concepts and practices upon which this environmental interpretation of international standards is based.
- Improving the quality of laboratory assessments by establishing uniform requirements for training assessors and facilitating opportunities for information exchange.
- Having the capability to expand the scope of accreditation programs to include emerging contaminants, field sampling activities, and additional environmental media as needed in the future.
- Reducing the amount of effort needed to define project expectations and requirements. With an ever increasing number of laboratories and states participating in NELAP, baseline expectations for environmental projects will become more constant resulting in more efficient communications regarding Data Quality Objectives and project deliverables.
- Making possible the "secondary uses of data" – combining data from multiple sources for the purpose of broader examinations of environmental conditions – by providing documentation of data quality and the purpose for which it was generated/

Laboratories benefit because adherence to NELAP standards would:

- Replace redundant and often contradictory inspections with comprehensive standardized inspections, and thus lowers laboratory costs;
- Improve acceptability of data to regulators and customers due to documentation of data quality;
- Significantly reduce the substantial indirect costs associated with conflicting program requirements, especially for those laboratories that works across two or more EPA programs.
- Establish credibility of data; and
- Improve acceptability of data to regulatory agencies.

An independent survey of the effectiveness of the NELAP program was conducted in 2008. This survey was sent to over 1000 laboratories of all sizes and types. The program received high scores in most categories and had notable positive results in the following categories:

- 74% of the respondents believe the cost to implement and maintain the program is justified.
- 80% of the respondents believe all laboratories should be accredited.
- Over 80% of the respondents believe the program improved the laboratory's quality system, data defensibility, and data quality.

Participating ABs benefit from NELAP by:

- Saving the resources and efforts that would be incurred in creating local or state accreditation standards.
- Reducing the number of on-site assessments to perform through the reciprocal recognition of accredited laboratories.
- Having access to a global accreditation database, uniform curricula for training assessors, and a national forum for exchanging information.
- Appointing representatives to an accreditation council composed of peer accreditors.
- Receiving rigorous evaluations to confirm the quality of their operations.

## **Conclusion**

In summary, requiring laboratory accreditation based on a consensus national standard will ensure that environmental monitoring data are adequate for their intended purpose. EPA and others could then have confidence that the data generated by laboratories are accurate and reliable in order to make regulatory decisions. Using a NELAP accredited laboratory can help establish and assure this confidence.

If a laboratory is accredited to the NELAP standards, it means that the laboratory has demonstrated its competence to produce data that are accurate, traceable and reproducible -- critical components in governmental decision-making. The NELAP standard is presently the only environmental interpretive version of the international standard for laboratories.

Using a NELAP accredited laboratory benefits government and regulators by increasing confidence in data that are used to establish baselines for key analyses and decisions, and reducing uncertainties associated with decisions that affect the protection of human health and the environment. Using a NELAP accredited laboratory increases public confidence, because accreditation is a recognizable indication of competence, and it eliminates the need for multiple and sometimes redundant reviews and improves the efficiency of the assessment process, which reduces costs.

Using a NELAP accredited laboratory also increases confidence that decisions regarding multiple facilities are based on comparable data. Costs associated with laboratory problems, including re-testing, re-sampling, lost time and false positives/negatives, which can directly affect compliance with regulations, are minimized.