



November 2, 2012

Dr. Michael Shapiro
Deputy Assistant Administrator, Office of Water
U.S. Environmental Protection Agency
Ariel Rios Building (MD 4101M)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Dr. Shapiro:

On behalf of the members of the Environmental Laboratory Accreditation Board (ELAB or Board), I am writing to you as the Chair of the U.S. Environmental Protection Agency's (EPA's) Forum on Environmental Measurements (FEM) to make you aware of concerns regarding the state of national environmental accreditation.

The stakeholder community ELAB represents is concerned that the existing economic climate will hamper the continued progress of the National Environmental Laboratory Accreditation Program (commonly known as NELAP), negatively affecting its use in states not currently participating and potentially delaying or stopping expanded implementation. In response to stakeholders' concerns, the Board chose to conduct an assessment of the state of the national accreditation program. The objective of this assessment was to determine whether the stakeholder community's concerns were issues on which ELAB could make recommendations to the Agency to help resolve.

Since the early 1990s, EPA has taken an active role in, and been integral to, improving the state of national accreditation. ELAB respectfully submits the attached document, which includes: an outline of the process ELAB followed for its assessment, summary of the findings, and recommendations that, if implemented, could help the continued and ongoing improvement of a national accreditation program. We are hopeful that the Agency, through the FEM, can take steps to support some or all of these recommendations.

We would also like to request a face-to-face meeting to discuss our recommendations, suggest potential steps to move these recommendations forward, and answer any questions. Please have someone on your staff contact me (ashields@lawrenceks.org; 785-832-7817) or Lara Phelps (phelps.lara@epa.gov; 919-541-5544), ELAB's Designated Federal Officer, at your earliest convenience to coordinate a meeting date and time.

Sincerely,

A handwritten signature in cursive script that reads "Aurora Shields".

Aurora Shields
Chair, Environmental Laboratory Advisory Board

Attachment

CC: Lara Phelps
ELAB Members

Introduction

The Environmental Laboratory Advisory Board (ELAB or Board) was requested to assess the state of the national environmental laboratory accreditation by the stakeholder community represented by the Board members. ELAB historically has provided advice and recommendations to the U.S. Environmental Protection Agency (EPA) regarding national accreditation from the inception of the National Environmental Laboratory Accreditation Program (NELAP), and in response to the stakeholders' request, the Board chose to limit its assessment to NELAP. The stakeholder community represented by ELAB has expressed concerns that the existing economic climate will hamper the continued progress of NELAP, negatively affecting its use in states not currently participating and potentially delaying or stopping expanded implementation or recognition.

The objective of this process was to determine whether the stakeholder community's concerns regarding national accreditation pertained to issues that could be categorized as recommendations, which ELAB then could present to the Agency. Although many of the concerns were beyond the scope of the Agency's control, several important issues emerged that EPA should be aware of and act on.

Since the early 1990s, EPA has taken great interest in communicating with the environmental laboratory community about issues related to national accreditation. The laboratory community, states and EPA were extensively involved in supporting the development of the national program. EPA has taken an active role in this process and has been integral to promoting and improving the "health" of the national accreditation program. The Agency's efforts have included support to consensus standard organizations, participation in development, support for training, establishment of accreditation requirements in contractual agreements, accreditation of EPA laboratories, establishment of a national system for a proficiency study program that is accepted and well used nationally, acceptance of NELAP equivalence for drinking water certification, and harmonization of the drinking water manual for laboratory certification with consensus standards.

ELAB's Review of the Health of NELAP and Findings

During ELAB's review of the current health of NELAP, responses from the stakeholder community represented by individual ELAB members indicated strong sentiment for EPA to initiate discussions with the laboratory community on further advancement and implementation of the existing national accreditation program. Two primary themes were common to all stakeholders: (1) a need to continue the implementation and improvement efforts of the existing national laboratory accreditation system and (2) the recognition that EPA involvement and leadership is essential to the program's long-term success.

The stakeholder community as a whole indicated that although data quality needs are a national concern, laboratory accreditation and data quality assurance requirements vary widely among programs as well as among states. This results in a fragmented laboratory

qualification system that negatively affects interlaboratory data comparability and significantly increases accreditation costs and effort for all involved parties.

The stakeholder community also believes that EPA has the responsibility to ensure that data used in environmental programs are of adequate and known quality (usability, comparability, etc.). The community also believes that EPA has the responsibility to establish requirements at the national level that will fortify data quality. Improved data quality only can be achieved by specifying data quality objectives, publishing/approving methods with specified control criteria, and setting criteria for laboratories to demonstrate competency that universally apply to the data-generation community.

The stakeholder community also indicated that the data-generation process could be simplified if EPA consolidated the data-generation process across program offices by employing a common approach to data quality assurance, certification and methodology rather than developing replicate processes with similar but different characteristics for each program office involved in data generation. There is a very engaged community of technical experts ready to provide assistance to consolidate these processes. Throughout the process of gathering information, an overwhelming number of respondents made comments regarding EPA's role in NELAP and the desire to see solid EPA leadership support for the program.

There are many existing federal regulations that support nationally driven accreditation, participation in development of private sector conformity assessment standards, third party accreditation, and NELAP. Several examples follow.

- *The Code of Federal Regulations (CFR), Title 15: Commerce and Foreign Trade, Parts 287.4 and 287.5, "Responsibilities of Federal Agencies" and "Responsibilities of an Agency Standards Executive", respectively:*
 - 15 CFR 287.4 (c), (e), and (g) and 15 CFR 287.5 (e) promote the involvement and support of government agencies in conformity assessment and recommend working with the private sector.
 - 15 CFR 287.4 (g) specifically mentions and supports NELAP.
 - 15 CFR 287.4 (e) and (f) support third-party assessment and sharing of resources.
 - 15 CFR 287.4 (d) and (j) support EPA involvement in developing standards with the private sector.
- *The Office of Management and Budget (OMB) Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and on Conformity Assessment Activities":* This circular was designed to improve the internal management of the Executive Branch and directs agencies to use voluntary consensus standards in lieu of government unique standards, except where inconsistent with the law or otherwise impractical.

- *U.S. Code (USC): Title 7 – Agriculture, Chapter 6a – National Laboratory Accreditation, § 138a – National Laboratory Accreditation Program: 7 USC § 138a* provides a directive for a national laboratory accreditation program to be developed for laboratories analyzing agricultural products.

These sources confirm that EPA must be engaged in national accreditation and consensus standards development. Although a program exists for certification of laboratories analyzing drinking water, the governing standards— contained in EPA’s *Manual for the Certification of Laboratories Analyzing Drinking Water: Criteria and Procedures Quality Assurance*—are not specified as a requirement in any federal document, therefore disqualifying the manual as a national standard. Additionally, the drinking water certification program only covers drinking water, which leaves the other programs vulnerable to incompetence resulting from the absence of a comprehensive, mandated federal program. The absence of programs that consistently address data quality issues in air, surface and wastewater, and solid and hazardous waste complicates the data assessment and evaluation process, which is the foundation for determining the need for future regulations and ongoing compliance.

Historically, EPA has selectively supported and collaborated with many consensus standards organizations and third-party accreditation organizations. This is underscored by the support of numerous methods developed and published by AOAC International and ASTM International and methods published in *Standard Methods for the Examination of Water and Wastewater* (a joint publication of the American Public Health Association, American Water Works Association and Water Environment Federation). Also underscoring this point is the requirement in several existing EPA program regulations to use the National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program, American Industrial Hygiene Association and similar organizations as accrediting bodies. Similar to these organizations, The NELAC Institute (TNI) also is supported by large stakeholder groups within the environmental laboratory community.

Recommendations

- *EPA must emphasize that data from all programs be of known and verifiable quality and take an active role in providing information on how to accomplish this.* State regulatory programs take their lead from EPA policy. For some EPA programs, the states perceive (rightly or wrongly) that EPA is interested in numbers, and the need to maintain the integrity of the numbers, but not the quality or usability of the data these numbers represent. As a result, these programs tend to view issues dealing with data quality as minor concerns. A stronger emphasis by EPA on data of known and verifiable quality will result in a trickle-down effect within the community. Although EPA grant and direct funding programs emphasize data quality, planning and quality management, how these concepts are to be achieved is not actively communicated within the regulatory process.

- *EPA should provide leadership and support in making accreditation uniform from a requirements and implementation perspective. It is widely recognized that data representativeness and comparability is being affected negatively by the decentralization of the accreditation process under individual state programs. In the absence of stronger control, representativeness and comparability never will improve and will affect all environmental decisions based on data generated by accredited laboratories.*
- *EPA should create a vehicle that enables the Agency to team with state programs that have limited resources to develop rules that establish NELAP as the laboratory accreditation standard in their states.*
- *EPA should continue to aggressively support activities that promote continued training of the small laboratory community that enables small laboratories to participate in NELAP.*
- *EPA must incorporate requirements that specify the use of consensus developed standards for regulatory activities requiring laboratory accreditation when applicable.*
- *To assure successful implementation of a national accreditation program, EPA must convene a forum consisting of state interests and Agency regional and program offices to work together on a recognition system for the program.*
- *EPA should continue to support the National Environmental Monitoring Conference annually held in conjunction with the TNI Forum on National Accreditation.*
- *EPA should provide monetary grants for the development of a proficiency test (PT) database for managing PT data that includes automated tools for electronically loading data from PT providers and state certification programs. This database should include a function that automatically prepares and distributes notifications on an individual laboratory's certification status. A database of this type would resolve communication difficulties between states regarding certification change notifications for laboratories accredited in multiple states when an individual laboratory fails to meet minimum requirements. It also addresses the accreditation status communication problem that currently exists within EPA's drinking water program.*
- *EPA should consider an Agency-wide mandate to conform to the NELAP requirements for all compliance testing based on the directives given in 15 CFR 287, OMB Circular A-119 and 7 USC § 138a, following the established precedence by EPA in support of public and private organizations. ELAB contends that non-NELAP states, especially those without a laboratory accreditation program beyond drinking water, currently have no incentive to create other programs to protect air, water and soil. By taking a leading support position, EPA could create the model necessary for states to develop the additional programs that would protect all aspects of environmental compliance sampling and analysis by providing a consistent quality*

foundation for all laboratories that provide analytical support services for regulatory purposes. Under the current structure, laboratories can provide compliance data without the need to demonstrate any level of competence, with the exception of the drinking water program. A mandate of this type clearly meets the OMB Circular A-119 requirement regarding consensus standard use as follows: “Joint participation in the development of the consensus standard [TNI is a voluntary consensus standards development body], allow for collaboration in conformity assessment decisions, and embodies all EPA programs thus providing greater protection of public health and the environment.”

Economic Benefits to EPA

Advancing the implementation of a national accreditation program can result in economic benefits to the stakeholder community and EPA in the following ways:

- *Data:* Data of known quality has beneficial effects on data usability and comparability.
- *Resources:* Use of OMB Circular A-119-compliant standards enables the government sector and regulated community to provide input to the standards development process that meets their needs, promoting regulated community participation through an inclusion process. The use of consensus standards results in a more efficient use of resources currently used for creating and revising data and laboratory requirements.
- *PT programs:* EPA has taken a leading role in fostering collaboration between public and private sector experts to create a very successful, low-cost PT program that has been nationally accepted and implemented. For this effort, EPA provided staff support and an initial assistance grant. This program is now self-sufficient, providing for the oversight of PT provider accreditation bodies, accreditation of PT vendors, and the review of the PT studies. The program continues to improve.
- *Uniformity:* Pooling training and technical resources ultimately will reduce the cost to the community. Consistent interpretation and implementation of the laboratory accreditation standard and mandated methods improves through continued training, mentoring and forums.
- *Oversight:* EPA oversight of state programs beyond drinking water through a coordinated evaluation system to assess other programs would improve consistency across programs within the states.

Conclusion

ELAB believes that TNI provides a framework that can enable EPA and states to harmonize quality assurance requirements by employing a principal that specifies that laboratories must implement a quality management system to comply with state and federal regulations. TNI currently manages all aspects of several PT programs, including

the accreditation of PT providers. TNI also collaborates with other organizations to offer training, mentoring and forums to educate the stakeholder community and promote data consistency.

ELAB would like to discuss its findings with EPA and members of the stakeholder community to further elaborate on these recommendations. It is apparent that EPA leadership is needed to assure a uniform national approach to data quality, which can only be achieved by implementing and overseeing a system in which environmental data are generated by entities that have demonstrated competency under a uniform national standard. Without EPA leadership, it is unlikely that this objective will be achieved based on the input from this assessment.