



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

FEB 19 2013

OFFICE OF WATER

Aurora Shields, Chair
Environmental Laboratory Advisory Board
City of Lawrence, Kansas
720 W 3rd Street
Lawrence, KS 66044

Dear Ms. Shields:

On behalf of the Forum on Environmental Measurements (FEM), I would like to once again thank the Environmental Laboratory Advisory Board (ELAB) for making us aware of concerns regarding the state of national environmental accreditation and further respond to the recommendations made.

As stated in my initial response on November 19, 2012, a small group of FEM Members convened to review ELAB's letter; participated in ELAB's December 19, 2012 monthly teleconference to ask a clarifying question; and discussed recommendations with the FEM Membership during the January 23, 2013, FEM Quarterly Meeting. Enclosed is a response by bullet to each recommendation.

The FEM will continue efforts to ensure the use of data of known and documented quality and support programs such as those for environmental accreditation to ensure organizations are doing their part to comply with data requirements. Although our budget is shrinking, we plan to fulfill funding commitments to this community that are already in place and hopefully new opportunities in the future.

We want to again thank you and the other members of ELAB for all the work you do to assist the Agency in improving environmental programs for organizations involved in environmental data activities. We look forward to the ongoing dialogue on this subject, as well. Please continue to send us your comments and suggestions, since ELAB serves as an important mechanism for the FEM to keep abreast of important issues facing the monitoring community and for receiving the community's input on our activities.

If you have any questions, please feel free to let me know 202-564-5700 or shapiro.mike@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Michael H. Shapiro".

Michael H. Shapiro
Chair, FEM

Enclosure

cc: Lara Phelps, OSA
FEM Membership (individual names can be provided)
STPC Membership (individual names can be provided)

Responses to ELAB Recommendations Regarding the State of National Accreditation

RECOMMENDATION: *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.

RESPONSE: The FEM agrees that it is extremely important for all programs to have data of known and documented quality and continues to establish guideline documents and policies to support this goal. Two documents were approved by the Science Technology Policy Council (STPC) in December 2012:

- A guidance document and policy statement for environmental sampling techniques that support the detection and recovery of microorganisms from the environment, which joins the six previous documents in this method validation series; and
- A policy for the competency of organizations performing environmental data operations under an assistance agreement or interagency agreement, which accompanies the policy already in place for acquisition agreements.

In addition to these documents, the FEM has convened a Data Management Team to catalogue the Agency's data networks for improved information availability and exchange.

RECOMMENDATION: *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.

RESPONSE: While the Agency only has two programs with the statutory authority to direct accreditation or certification requirements (i.e., the Office of Water and the Office of Pesticide Programs), each program has recognized existing accreditation and certification bodies to meet these requirements. By developing and establishing two Agency policies for the competency of organizations performing environmental data operations with Agency funding, the Agency has further encouraged bodies to become accredited or certified from an existing source, as well.

RECOMMENDATION: *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.*

RESPONSE: The FEM has provided funding through a cooperative agreement for the development of standards, guidance, training, and tools to benefit state, tribal, and local agencies in addition to the public and private sectors for several years. This vehicle is currently under award to The NELAC Institute (TNI). We will convey the additional need for state, tribal, and local agency support to set-up regulatory programs for accreditation or certification programs within their purview; however, it is

ultimately TNI's decision on how to prioritize and address this request based on the resources they have available from the Agency.

RECOMMENDATION: *EPA should continue to aggressively support activities that promote continued training of the small laboratory community that enables small laboratories to participate in NELAP.*

RESPONSE: EPA agrees that small businesses are extremely important and provide opportunities to ensure their competitive involvement in protecting human health and the environment. We are fortunate that funds in the cooperative agreement to TNI, previously mentioned, have been used to develop guidance and templates for the small laboratory community. Other efforts continue to encourage this important community's participation, as well.

RECOMMENDATION: *EPA must incorporate requirements that specify the use of consensus developed standards for regulatory activities requiring laboratory accreditation when applicable.*

RESPONSE: The National Technology Transfer and Advancement Act (NTTAA) ensure the use of consensus development standards by the Agency, when standards are available and meet the needs of areas being regulated by the Agency. In instances when funding and time have allowed, the Agency has written a solicitation for a consensus development organization to develop standards to meet regulatory need, as well.

RECOMMENDATION: *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.*

RESPONSE: As mentioned in a previous response above, the FEM has provided funding through a cooperative agreement for the development of standards, guidance, training, and tools to benefit state, tribal, and local agencies in addition to the public and private sectors for several years. This vehicle is currently under award to TNI, who convenes a Forum on Laboratory Accreditation twice per year with sessions available to foster and further such conversations between state interests and Agency regional and program offices. We will convey the additional need for state and Agency dialogue; however, it is ultimately TNI's decision on how to prioritize and address this request based on the resources they have available from the Agency.

RECOMMENDATION: *EPA should continue to support the national Environmental Monitoring Conference annually held in conjunction with the TNI Forum on National Accreditation.*

RESPONSE: The Agency is pleased to be a co-sponsor of the National Environmental Monitoring Conference, since its inception as the Waste Testing and Quality Assurance Conference over 25 years ago. Our current cooperative agreement, which is also with TNI, will be in place for another 3 years and we hope funding remains available for us to continue our support for such an important venue.

RECOMMENDATION: *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.*

RESPONSE: EPA provided over 1.2 million dollars for the development of a proficiency test (PT) database to be used by the National Environmental Laboratory Accreditation Conference (NELAC), which the community determined was not reasonable to maintain for the long term use of a dynamically changing program. A2LA has recently completed a new database and has made an offer to TNI to take over responsibility for maintaining the database for all PT providers.

RECOMMENDATION: *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.”

RESPONSE: The Agency only has the statutory authority to establish requirements for states to oversee programs for drinking water, asbestos, and lead. While EPA has encouraged or required certification, accreditation, or demonstration of competency through some policies, rules, and regulations, the Agency cannot require states to run additional programs or be more stringent than federal requirements dictate.