



November 5, 2015

Ms. Lara Phelps, Executive Director  
Forum on Environmental Measurement  
United States Environmental Protection Agency  
Office of the Science Advisor  
109 T.W. Alexander Drive (E243-05)  
Research Triangle Park, NC 27709

Dear Ms. Phelps:

The NELAC Institute (TNI) is a 501(c)3 organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. TNI has over 900 members including state and federal officials, commercial and municipal laboratories and sampling organizations, as well as suppliers and consultants. TNI provides resources for both sampling and measurement organizations and the accreditation bodies.

In October 2013, The NELAC Institute (TNI) shared with the Forum on Environmental Measurement (FEM) a report on the progress we had made towards accomplishing our mutual goal of the generation of environmental data that is of a known and documented quality. We have continued to make significant advancements in the areas of standards development, expansion of the National Environmental Laboratory Accreditation Program (NELAP), Field Sampling and Measurement Organization (FSMO) accreditation, proficiency testing, and educational delivery and outreach, and the United States Environmental Protection Agency (EPA) has been a valuable partner in these efforts. On behalf of TNI, I would like to share this second biennial report with the members of the FEM to update you on our progress.

Please let us know if you would like any additional information or for us to meet with you to provide more detail. We appreciate the strong relationship we have enjoyed with the EPA in the past, and we look forward to our continued collaboration in the future.

Sincerely,

A handwritten signature in black ink that reads "Sharon K. Mertens". The signature is written in a cursive style.

Sharon Mertens, Chair  
TNI Board of Directors  
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## TNI ACCOMPLISHMENTS AND OBJECTIVES

### Summary

Over the past two years, TNI has continued to make significant advancements in the areas of standards development, expansion of the National Environmental Laboratory Accreditation Program (NELAP), Field Sampling and Measurement Organization (FSMO) accreditation, proficiency testing, and educational delivery and outreach, and the United States Environmental Protection Agency (EPA) has been a valuable partner in these efforts. Significant accomplishments and activities since our last report are summarized by program.

### Consensus Standards Development

Two volumes of TNI's Environmental Laboratory Sector Standard (ELSS) provide requirements for laboratories and laboratory accreditation bodies. Two volumes for proficiency testing standards related to all types of measurement are designed for proficiency test (PT) providers, and PT provider accreditors. These four volumes are all classified as American National Standards by the American National Standards Institute. Two additional volumes provide requirements for Field Sampling and Measurement Organizations (FSMOs) and their accreditation bodies. These two volumes are in the process for recognition as American National Standards.

In our ongoing interest in continuous improvement, further standards development is underway. **A new calibration standard for laboratory quality systems has been completed, and a quality systems standard for detection and quantitation is nearing completion. An update of the PT requirements is also almost complete. Development of updates to the quality system standards for microbiology, radiochemistry, and chemistry is underway.** TNI has established requirements for quality and management systems of FSMOs and their accreditors to improve the quality of data collection, and the standards have been updated. Lastly, the Office of Air has formally recognized TNI's Stationary Source Audit Sample Program. This program uses three approved TNI standards, two of which were recently updated.

### National Environmental Laboratory Accreditation Program

**TNI's National Environmental Laboratory Accreditation Program (NELAP) now has 13 states with 14 Accreditation Bodies (ABs)** (Louisiana has two ABs). California, one of the original NELAP states, withdrew from NELAP in early 2014 due to insurmountable managerial issues. NELAP's Accreditation Council (AC) worked with California's NELAP-accredited labs during that transition out

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of the program to ensure continuity and has continued to provide information and advice to California's Environmental Laboratory Accreditation Program as it reassembles in an entirely different agency. In light of this reorganization, we are optimistic that California will reapply to be a NELAP AB within a few years. We are also expecting an application from the Oklahoma Department of Environmental Quality by the end of October.

**Additionally, 28 of the remaining 35 states with laboratory accreditation programs utilize some aspect of the TNI standards or recognize NELAP accreditation as equivalent to their in-state programs.** Even more states utilize the Field of Proficiency Testing (FoPT) tables developed by TNI, and virtually all states require labs to obtain PT studies from providers accredited by TNI. **The Department of Energy and the Department of Defense use the TNI Standard as the basis for their accreditation programs as well.**

EPA Region 2 provides a liaison with the NELAP AC and coordinates EPA participation in the evaluations of NELAP ABs, as some regions choose to continue in that role. For the 2014-2016 round of evaluations, NELAP implemented the use of a third party contractor to serve as Lead Evaluator (LE,) which was the Agency's recommendation for adapting to the shift in EPA's participation in the evaluation teams. After the previous EPA representative retired earlier this year, the Laboratory Accreditation System Executive Committee (LASEC), which is the "balanced" committee that manages NELAP, worked with EPA's liaison to TNI to help us identify the replacement representative to the LASEC, Karen Costa, who is the Region 3 Lab Director.

NELAP adopted the 2009 TNI ELSS with a mid-2011 implementation date for laboratories, but with an immediate transition for the AB operations, so that all NELAP ABs are evaluated for conformance with Volume 2 of this standard, based on ISO/IEC 17011:2004. Five state ABs still officially accredit laboratories to the 2003 NELAC standard, but recognize conformance with the 2009 TNI Standard as acceptable. The remaining nine state ABs have fully transitioned to the 2009 TNI Standard. The individual modules of Volume 1 of the 2009 TNI ELSS, as well as the PT module of Volume 2, are nearing the end of a revision process, and we anticipate that these changes will be approved and adopted by the NELAP AC by the end of 2015, with a future implementation date established. It is likely that a rolling implementation will again be needed, as many states must accomplish rulemaking in order to implement a new standard.

TNI provides resources useful to stakeholders of the environmental laboratory community nationwide. **These include the Laboratory Accreditation Management System (LAMS) database ([www.nelac-institute.org/lams](http://www.nelac-institute.org/lams)), which contains method and analyte codes used by virtually all state programs. We are also developing a "generic application" that will allow laboratories to enter their information once and have it either transmitted electronically or printed in each AB's required format for manual signature and delivery.** This generic application is currently undergoing beta-testing. Because most NELAP-accredited labs are also certified in non-NELAP states, we will explore with the non-NELAP accreditation bodies whether they wish to utilize this application database.

Traditionally, laboratories have been accredited under NELAP by state agencies recognized by TNI as ABs. **In 2015 TNI implemented a program to recognize non-governmental Accreditation Bodies**

**(NGABs) to accredit laboratories to the TNI standard. We began accepting applications in August and plan to recognize the first group of NGABs in early 2016.**

### **National Environmental Field Activities Program (NEFAP)**

The National Environmental Field Activities Program (NEFAP) launched the accreditation of Field Measurement and Sampling Organizations (FSMOs) in 2012. The NEFAP Executive Committee implements the program, and its members represent all stakeholder groups (FSMOs, ABs and other). NEFAP is designed and developed specifically for those organizations planning and performing field activities. NEFAP standards and procedures are an objective way of demonstrating that an organization has an established management system and possesses the technical competence to perform field measurement and sampling services. Volume I: *General Requirements for Field Sampling and Measurement Organizations*, which outlines the minimum requirements for FSMOs, is based on the ISO/IEC 17025:2005 structure but includes additional requirements that specifically address challenges and circumstances unique to organizations that perform field activities. Volume II: *General Requirements for Accreditation Bodies (ABs) accrediting Field Sampling and Measurement Organizations* outlines the minimum requirements for ABs to become recognized by TNI to provide accreditation to FSMOs and is consistent with ISO/IEC 17011:2004. Volumes 1 and 2 of the Field Sampling and Measurement Organization standards were originally adopted in 2007 and updated by the TNI Field Activities Expert Committee through TNI's consensus standards development process. Revisions were finalized in January 2014 (effective date April 2016). Quality Management tools and guidance on scopes of accreditation have been developed to help FSMOs implement the standard and prepare for accreditation.

The NEFAP is a voluntary program and is not required by regulation. NEFAP accreditation may be required in contractual agreements or for work under programs or contracts in which the contracting organizations want to assure there is documented competency to a known standard. Awareness of the standard is slowly increasing and recently there has been discussion of requiring it to be followed for specific field activities associated with sample collection in the states of Oregon and Louisiana. There has also been discussion by various industrial organizations of requiring NEFAP accreditation in contracts to ensure competence.

**There are currently four ABs that are recognized and accepting applications from FSMOs and possibly an application from a fifth AB to come.** Participation from many stakeholders, including the air emissions testing community as well as compliance regulators, labs, data users, consultants and FSMOs, has increased as the program has gained momentum. Ten or more FSMOs have achieved accreditation or are in the process of accreditation. A focus team of advocates has been assembled to look for better ways to educate and communicate the benefits of the NEFAP Standard and to encourage organizations, private and government, to implement it.

## **Proficiency Testing (PT)**

NELAP, non-NELAP and NEFAP ABs rely heavily on the PT Program as a part of their accreditation programs. **There are currently two TNI approved PT Provider Accreditors (PTPAs) that perform ongoing monitoring of a total of seven accredited PT Providers to ensure conformance with the TNI Standard.**

The PT Program Executive Committee (PTPEC) has developed a process to manage the Fields of Proficiency Testing (FoPT) tables. The PTPEC reviews all proposals and requests for FoPT table editorial changes, modifications, additions, and renewals. The process ensures that table additions and deletions are supported by the user community. The committee has had three new requests submitted recently. Looking ahead, the PTPEC is considering updates to the FoPT table review process that will include looking at how often analytes need to be reviewed, how TNI will collect and store PT information used to develop the FoPT tables, and what types of follow-up evaluations are needed after limits are updated.

The Proficiency Testing provisions of the Environmental Laboratory Sector Standard are undergoing revision via TNI's consensus standards development process. In particular, revisions being made to Volume 4 (General Requirements for an Accreditor of Environmental Proficiency Test Providers) will require the PTPEC to develop a number of SOPs to cover procedures formerly contained in Volume 4 of the Standard.

## **Educational Delivery System**

In 2011, TNI started a new process for providing training called the Educational Delivery System (EDS), a comprehensive training system that utilizes multiple face-to-face and web-based training venues. Training courses, workshops, forums, seminars, and on-demand webinar education materials are developed by TNI and its contracted training providers. TNI's training efforts are focused on improving the quality and consistency of laboratory assessments, assisting laboratory quality managers in understanding accreditation requirements, and providing technical training to laboratory analysts and field professionals. **Since the start of this effort, TNI has provided over 40 training events that have reached more than 2000 individuals. TNI's goal is to move much of this training on-line, and already many webinars have been recorded and are available for viewing as downloadable webcasts.** To see the current list of courses being provided, go to the TNI EDS webpage (<http://www.nelac-institute.org/content/eds-home.php>). TNI intends to expand training by developing partnerships with other organizations in the lab and field communities that are involved in training or that need training.

## **The Future of National Accreditation**

In response to communication between the Environmental Laboratory Advisory Board (ELAB) and Environmental Protection Agency's (EPA) Forum on Environmental Measurement (FEM) regarding the future of national environmental laboratory accreditation, The NELAC Institute (TNI) began a project in 2014 to review the status of national environmental laboratory accreditation to determine if a change in

approach was needed to expand the program. TNI collected input from states not currently participating in national accreditation (non-National Environmental Laboratory Accreditation Program [NELAP] states) as well as from accredited laboratories and other stakeholders in order to get their perceptions about national accreditation to determine what barriers and issues exist today. Using the input collected from stakeholders, TNI sponsored a workshop on August 8, 2014 to brainstorm solutions to the barriers and issues identified.

We found that barriers to national accreditation generally fell into three categories: technical issues related to the standards, the need for additional communication and outreach to stakeholders, and state/EPA roles and involvement. In evaluating the input received, it was evident that in several areas participants had outdated information or misperceptions about how TNI and national accreditation currently operate. Additionally, as one commenter correctly noted, a number of the issues and barriers identified are outside of TNI's ability to control. Of significant note was that there continues to be a perception by a number of states that EPA is not participating and supporting national accreditation. This perception exists in spite of EPA's monetary and other resource contributions to national accreditation efforts. We hope that TNI and EPA can continue to work together as partners to dispel this perception.

There were, however, a number of actions identified that TNI can pursue to promote and facilitate the expansion of national accreditation. The TNI Board of Directors has included objectives in its 2015-2020 strategic plan to address a number of the barriers and issues identified. **The objectives focus on continuing to promote acceptance of the TNI environmental laboratory standards by non-NELAP states and promoting third party accreditation as an alternative to states that do not have the resources to establish their own programs. TNI will also maintain and expand technical assistance to states and laboratories. TNI will expand outreach to non-NELAP states by offering complementary TNI memberships and a free introductory webinar.**

While some specific barriers to expansion of national accreditation were identified, responders also noted a number of positive aspects to the current program, including recognition of the TNI standard as a benchmark for laboratories, and TNI's conferences and training as a means to facilitate communication and compliance. It was also noted that many states have reaped benefits from the national accreditation program even though they do not participate as NELAP ABs. The full text of the report can be found on the TNI website at <http://nelac-institute.org/docs/news/TNI-Exploring-the-Future-Report-April-2015.pdf>

## **Outreach**

In keeping with TNI's vision for truly national environmental programs, we have a number of on-going outreach efforts in addition to our biannual meetings. These include having representatives at laboratory and trade organization meetings, and providing training and assistance with regulations such as EPA's latest Methods Update Rule. Also, to ease the somewhat intimidating task of developing documents from scratch, TNI offers Quality Manual and SOP templates for purchase by anyone, but particularly designed for small labs. **Continuing our efforts to support the laboratory community, TNI**

**embarked on a process to update EPA's 1979 *Handbook for Analytical Quality Control in Water and Wastewater Laboratories*. Our goal is to make this updated handbook a useful training tool for all environmental laboratories.**

Additionally, TNI has implemented a pilot project to reach out to non-NELAP states. Ambassadors to eight states have been appointed to help facilitate communication and to exchange information between TNI and these states. Our goal is to provide news and information about TNI resources to and to identify barriers to national accreditation, offering assistance where appropriate.