



**The State of National Accreditation
December 4, 2023**

The NELAC Institute (TNI) is a 501(c)(3) non-profit 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. The organization is managed by a Board of Directors and is governed by organizational bylaws. TNI's vision is a true national accreditation program, whereby all entities involved in the generation of environmental measurement data within the United States are accredited to one uniform, rigorous, and robust program that has been implemented consistently nationwide and focuses on the technical competence of the entity pursuing accreditation. TNI believes such a program will improve the quality and reliability of environmental data used by federal and state agencies.

To support this mission, TNI operates the following programs and related activities:

1. Consensus Standards Development Program (CSDP)
2. National Environmental Laboratory Accreditation Program (NELAP)
3. National Environmental Field Activities Program (NEFAP)
4. Proficiency Testing Program (PTP)
5. Other Activities

1. Consensus Standards Development Program

- TNI develops standards using a consensus process consistent with OMB Circular A-119 and currently has nine Expert Committees actively developing and revising standards (Asbestos, Chemistry, Field Activities, Laboratory Accreditation Body, Microbiology, Quality Management System, Proficiency Testing, Radiochemistry, and Whole Effluent Toxicity).
- TNI's National Environmental Laboratory Accreditation Program (NELAP) adopted and currently implements the 2016 Environmental Laboratory Sector (ELS) Standard which was based on the 2005 version of ISO/IEC 17025 (laboratories) and the 2004 version of ISO/IEC 17011 (Accreditation Body [AB] operations). This standard provides enhanced requirements for all aspects of laboratory accreditation, including recognition of ABs and approval of Proficiency Test (PT) providers.
- TNI's National Environmental Field Activities Program (NEFAP) adopted and currently implements the 2014 Field Sampling and Measurement Organization (FSMO) Standard which was based on the 2005 version of ISO/IEC 17025 (sampling and field testing) and the 2004 version of ISO/IEC 17011 (AB operations). This standard provides heightened requirements for all aspects of FSMO accreditation.

- TNI Expert Committees operating as consensus bodies are in the process of reviewing and proposing needed changes to the field and laboratory Standards based upon developments within the environmental testing industry. Both the ELS and FSMO standards are being updated to incorporate the 2017 version of ISO/IEC 17011 into AB modules and the 2017 version of ISO/IEC 17025 into the laboratory/FSMO modules. Once all modules have been revised, each of the complete standards will be proposed for adoption by the relevant program. TNI anticipates these new standards will be available late in 2024.
- The Stationary Source Audit Sample Program (SSAS) lost the remaining Audit Sample provider as of the end of March, 2022, and ceased reporting returned results from Audit Samples on December 31st, 2022. As EPA declined to modify any aspect of the program, the SSAS Committee and its operations ceased functioning as of December 31st, 2022.
- TNI's Proficiency Testing Program (PTP) adopted standards for proficiency testing (PT) providers and their accreditors based on the 2010 version of ISO/IEC 17043. ISO/IEC released a 2023 version of this standard in May of 2023 so TNI will soon begin efforts to update the PT standards to this version.

2. National Environmental Laboratory Accreditation Program (NELAP)

- Fourteen states are now NELAP-recognized ABs with over 1200 laboratories accredited to a total of nearly 5000 methods covering over 3600 different analytes. These methods and analytes encompass virtually all of EPA's regulatory programs.
- TNI has updated and streamlined its process for providing Standard Interpretation Requests (SIRs) and Implementation Guidance. The SIRs are publicly available on the TNI website, but Implementation Guidance (best practice documents) are available only to TNI members. Additionally, we now ensure that all submitted questions and the approved responses are considered for incorporation into revised Standards as they are developed.
- Many non-NELAP state programs incorporate or recognize accreditation to the NELAP standard
 - California has now fully implemented its accreditation program using the TNI ELS Standard, with two changes that will keep it separate from NELAP for the time being, but it fully recognizes labs accredited by NELAP. TNI has actively supported California's efforts in this regard. TNI has actively worked with California to support the state's efforts to revise its Environmental Laboratory Accreditation Program rules to incorporate TNI's quality management system requirements. CA uses NGAB assessments for laboratories performing "sophisticated technologies" but then makes accreditation decisions based on those assessments.
 - Two additional states, Nevada and Kentucky, are actively considering whether to implement the TNI EL Standard and join NELAP.
 - On May 25, 2023, Ohio revised their regulation for their Voluntary Accreditation Program to allow any laboratories accredited to the TNI Standard, whether by NELAP or one of the Non-governmental Accreditation Bodies recognized by TNI to accredit to that Standard while concurrently dismantling their state program.
 - Additionally, another 35 states with laboratory accreditation programs utilize some aspect of the TNI Standard or recognize NELAP accreditation as equivalent to their own state programs.
 - The Department of Energy and the Department of Defense use the TNI Standard as the basis for their accreditation programs.

- Separate from NELAP, TNI recognizes four Non-Governmental Accreditation Bodies (NGABs) to accredit laboratories and FSMOs to the TNI ELS standards. NGAB accreditations are accepted by some non-NELAP states, and also meet the requirements for accreditation as set forth by EPA for its grants and contracts. Additionally, NGAB assessors work as third party assessors for certain NELAP states as well as for California, essentially serving as contract assessors while the state itself reviews assessment report and grants accreditations.

3. **National Environmental Field Activities Program (NEFAP)**

- NEFAP is a unique, voluntary program that accredits organizations collecting field samples and obtaining field measurements to a quality management system created for the complexity and variety of FSMOs.
- NEFAP is the only accreditation program specifically designed for the field industry and is implemented by those wanting to demonstrate their competency and proficiency.
- TNI's first *Environmental Field Sampling and Measurement Conclave* took place as a virtual meeting from June 6-8, 2023. The Conclave featured 21 presentations by various industry experts supporting the critical aspects of field sampling and measurement. It provided an opportunity for FSMOs, laboratories and other interested parties to learn more about field sampling techniques, regulations, and appropriate field practices that help ensure data collected in the field is accurate and reliable while raising awareness to the industry of TNI's quality system standard and accreditation program for FSMOs.
- TNI recognizes three NGABs to accredit to the 2014 TNI FSMO Standard.

4. **Proficiency Testing (PT) Program**

TNI's PT Program is utilized across the country, by the EPA Discharge Monitoring Report-Quality Assurance (DMRQA) program for wastewater testing and by the EPA drinking water program. TNI recognizes PT providers manufacture samples for drinking water, non-potable water, and solid and chemical materials. The TNI Proficiency Testing Program Executive Committee (PTPEC) that provides program oversight consists of representatives from EPA, TNI, state specific accrediting agencies, PT Providers, non- governmental accreditation bodies, laboratories, and other stakeholders.

TNI's PT Program has responded to regulatory drivers and the needs of the environmental laboratory community by:

- Updating the Drinking Water Radiochemistry Fields of Proficiency Testing (FoPT) Table.
- Completing updates to a Position Paper that can be utilized to advocate the advantages of participation in the TNI PT Program.
- Continuing to work with non-governmental accreditation bodies for recognition as PT Provider Accreditors.
- Completing and updating SOPs to document procedures used by the PTPEC and other stakeholders for activities related to the TNI PT Program.
- Developing concentration ranges and acceptance limits for Polyfluoroalkyl Substances (PFAS) in drinking water.

The PTPEC is continuing to provide oversight and respond to the environmental laboratory community on issues related to the PT Program through:

- Updating the Whole Effluent Toxicity Testing (WETT) non-potable water FoPT Table to include more meaningful data evaluation criteria.
- Preparing to address a request for addition of radiochemistry FoPTs in non-potable water and solid and chemical materials.
- Continuing to evaluate the value of expanding the PT Program to include sample preparation methods.
- Continuing to work with other stakeholders to streamline LAMS.
- Identifying and providing training on the PT program as needed.

5. Other Activities

- TNI recognizes the crucial importance of training that is accessible to anyone who wants to keep current or train for new jobs in environmental testing. To that end, TNI currently provides over 100 online and in-person training courses, available to the entire environmental laboratory community. TNI will develop even more classes each year going forward. In 2022 there were over 600 attendees participating in online live courses and recorded webcasts. A list of available courses can be viewed at TN's EDS webpage (<http://www.nelac-institute.org/content/eds-home.php>).
- In 2020, TNI initiated a new effort to show the value of accreditation relative to improving data quality and laboratory performance. This effort culminated into two White Papers:
 - The first of these, "Laboratory Accreditation Makes a Difference – Data You can Trust," redefined "quality" to include not just the analytical result but also confidence in the data as well as better laboratory operations and documented that implementing a Quality Management System helps ensure reliable data.
https://nelac-institute.org/docs/comm/advocacy/White%20Papers/WP-Value_101420.pdf
 - The second, "Having a Strong Quality Management Prevents Faulty Results," presented numerous actual cases studies affecting all types of laboratories (commercial, municipal, state, and federal) and all types of testing (environmental, forensic, clinical, and food) that the largest causes of data quality problems all result from a single root cause, the lack of a strong quality management system.
<https://nelac-institute.org/docs/comm/advocacy/White%20Papers/WP-Reliable.pdf>
- TNI provides resources useful to stakeholders of the environmental laboratory community nationwide. These include the Laboratory Accreditation Management System (LAMS) database (<https://lams.nelac-institute.org>), which contains method and analyte codes used by virtually all state programs as well as 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.
- TNI offers Quality Manual and SOP templates and a laboratory handbook for purchase usable by anyone, but particularly designed for small laboratories.
- In May 2021, TNI launched a mentoring initiative that is designed to help small laboratories implement a quality management system based on the TNI standard.

- TNI also created a Consumables Task Force to address issues surrounding laboratory consumables. The Task Force plans to develop guidance on this topic and potentially to create a consumables Standard.
- TNI is introducing a voluntary credentialing activity that will initially offer digital badges for certified personnel in twelve specialty areas of quality management systems as used in environmental laboratories – Quality Systems Specialist, Proficiency Testing (PT) Specialist, Data Integrity Specialist, Document Control and Records Specialist, Customer Service Specialist, Measurement Traceability Specialist, Internal Audit Specialist, Corrective Action Specialist, Method Validation Specialist, Sample Handling Specialist, Quality Control Specialist, and Data Review and Reporting Specialist. Each badge will require four hours of training and an examination. Once the individual badge certification activities are established, a Certified Environmental Quality Management Specialist credential will be offered. This “full credential” can be earned by either accumulating all twelve digital badges or by meeting specified education and experience requirements plus passing a comprehensive proctored examination on quality management system principles. TNI plans to launch this effort in January 2024. Additional roles will be added to the credentialing activity in the future, such as laboratory assessor and Technical Manager (Technical Specialist).
- TNI continues to hold two meetings every year to promote accreditation in general and provide technology outreach.
 - TNI’s winter meeting, the Forum on Environmental Accreditation, is designed to provide an update on TNI activities and allow TNI committees to meet in person to exchange ideas and share progress with the public. Presentations from these conferences can be found here: <https://www.nelac-institute.org/content/meetings-prev.php>
 - TNI’s summer meeting, the Environmental Measurement Symposium, combines TNI’s Forum on Environmental Accreditation with the National Environmental Monitoring Conference (NEMC), now in its 39th year. NEMC is the largest conference focused on environmental measurements in North America. A highlight of the Symposium is an update from EPA program offices covering drinking water, wastewater, and hazardous wastes. All presentations from NEMC are available for viewing after the conference here: <https://envirosymposium.group/>