

TNI and the National Environmental Laboratory Accreditation Program

November 12, 2014

Note: This document was provided as a briefing package to Christine Sotelo of California ELAP on November 11, 2014.

Who is TNI?

- A 501(c)3 non-profit organization.
- A member organization managed by a Board of Directors.
- A voluntary consensus standards development organization accredited by the American National Standards Institute (ANSI).

The NELAC Institute – see attachment

National Environmental Laboratory Accreditation Program (NELAP)

- Purpose is to establish and implement a program for the accreditation of environmental laboratories.

Program components:

- The recognition of accreditation bodies,
- The adoption of acceptance limits for proficiency testing, and
- The adoption of consensus standards for use in the program.

NELAP

- 14 active Accreditation Bodies in 13 states
- Accredits nearly 1700 laboratories
 - US states and territories
 - Canadian provinces
 - US military lab in South Korea

The NELAP Accreditation Council

- Consistent with other international recognition programs, decisions to recognize ABs and enforce the program are performed by mutual recognition.
- This means, only those organizations that choose to participate as ABs may be involved in key decisions
 - Recognition of ABs
 - Enforcement
 - Standards adoption
 - Standards interpretation

NELAP Accreditation Council

- One representative and one alternate from each NELAP-recognized Accrediting Body.
- Each representative and alternate is officially appointed by the Accreditation Body to represent their state program.
- A chairperson is selected by the members of the Council.
- EPA designee as an Ex-Officio member
- Program administrator to help with administrative functions.

Council Duties

- Final authority for implementation of the program for the accreditation of environmental laboratories.
- Implements the policies and procedures that govern the operation of this program, and
- Responsible for ensuring the successful implementation of the program.

Authority

- The authority to administer an accreditation program comes from state statute and regulation.
- In accordance with ISO 17011, all accreditation decisions, including the handling of appeals, rest with the AB.
- EPA continues to have a key oversight function for drinking water.
- TNI provides the infrastructure to facilitate communication, consistency, and reciprocity.

Implementation

- NOT the role of TNI
- NELAP ABs adopt standards voluntarily:
 - Select scope of accreditation;
 - Select voluntary or mandatory nature of program;
 - Select types of laboratories to be accredited;
 - May use third party assessors; and
 - May assess fees.
- NELAP ABs must comply with the standards
 - Accept reciprocity;
 - Use trained assessors; and
 - Refrain from adding supplemental requirements.

The TNI Standard

- Strengths:
 - Uses ISO 17025 quality system approach,
 - Adds specificity to improve clarity and help with consistency for environmental testing,
 - Allows flexibility in meeting requirements,
 - Represents best professional practice
 - Allows for multiple Accreditation Bodies to implement consistently, and
 - Includes data integrity component missing from 17025.

Management Requirements

- Implement a quality system;
- Management requirements;
- Documents and records;
- Internal assessments; and
- System controls and improvements.

Comparable to ISO 9000, these requirements are good management practices to ensure analyses are performed in an orderly and structured way.

Technical Requirements

- Technical competence of staff;
- Validity and appropriateness of test methods;
- Traceability of measurements;
- Instrument calibration;
- Testing environment;
- Sampling, handling and transportation of samples;
- Quality assurance of test data; and
- Reporting.

These requirements focus on ensuring reliable and accurate data.

The Advantages of NELAP

- Uses a consensus standard that is widely recognized as the gold standard for environmental laboratory accreditation.
- Peer oversight to ensure all participating ABs are competent to operate accreditation programs.
- Utilizes TNI infrastructure (Assessor training, National database, Fields of Proficiency Testing, etc.) to leverage resources.
- NELAP-recognized ABs get to fully participate in the process.

Options for Non-NELAP States

- Apply to become a NELAP AB
- Develop and implement a non-NELAP state program
- Implement a drinking water only program (non-NELAP)
- Accept certifications from NELAP ABs
- Incorporate some or all of the TNI Standard into state program
- Enter into mutual recognition agreements with other non-NELAP states.
- Most use PTs from TNI-approved providers

Tools for Laboratories

TNI has also developed and maintains a number of resources in helping laboratories become accredited. These include:

- A Small Laboratory Handbook, a document that explains the TNI standard in plain English,
- A Quality Manual Template, a document that allows a laboratory to easily develop their own Quality Manual,

- A listing of consultants that assist laboratories in becoming accredited,
- An annual Mentor Session where information to help laboratories is shared,
- A Small Laboratory advocacy Group, where laboratories can share information and ask questions, and
- A series of downloadable webcasts (see the text box below) to help train laboratories on specific aspects of the TNI standard.

Webcasts Available from TNI

- Corrective Action Process and Root Cause Analysis
- Records and Record Keeping
- Theoretical and Practical Consideration for Establishing Sensitivity of Measurements
- Internal Audits and Management Review
- Ethics Training for the Environmental Professional
- Establishing a Data Integrity Plan
- Defining Organizational Responsibilities
- Method Selection and Validation
- Developing the Quality Manual as a Useful Management Tool
- Document and Document Control
- Implementing the 2009 TNI Standard

The NELAC Institute

<http://www.NELAC-Institute.org>

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