Summary of Program

NELAP is a national program for the accreditation of environmental laboratories where state governmental agencies serve as Accreditation Bodies. States, which apply to TNI's NELAP Board to become an accreditation body, may select to operate an accreditation program which covers all of the EPA regulatory programs or as few as one. For example, many states may select to only accredit laboratories for chemistry and microbiology under the drinking water program. Other states may select to operate a comprehensive program, which includes all types of analyses for all types of media (i.e., hazardous waste, waste water, drinking water, air, soil, etc.) under the five EPA regulatory programs. There is no requirement that a state incorporate any particular portion of the possible scope into its program. The scope of accreditation, the type of laboratory included under the state's program, including the regulatory or voluntary nature of the program itself, the assessment of fees, and the use of third party assessors are all options of the state.

A NELAP Accreditation Body will accept by recognition, the accreditation status of a laboratory issued by another NELAP Accreditation Body (this is called secondary accreditation). Each Accreditation Body must adopt and adhere to this principle as a condition of membership in NELAP. In accepting the accreditation status of a laboratory through recognition, the Accreditation Body assumes accreditation responsibilities as a secondary accreditation body.

Laboratories who are accredited under this program

- must implement a **quality system** based on ISO/IEC 17025,
- conduct periodic analyses of **proficiency test** samples, and
- undergo an independent **assessment** of their facility every two years.

Quality System Requirements

NELAP-accredited laboratories must implement a quality system based on ISO/IEC 17025, Competence of Testing and Calibration Laboratories, as defined in the NELAP-approved accreditation standard.

The quality system requirements include both management and technical requirements and address the following activities:

Management Requirements

- Organization
- Quality System
- Document Control
- Review of Contracts
- Subcontracting
- Purchasing
- Service
- Complaints
- Control of Non-conforming Work
- Corrective Action
- Preventative Action
- Records Control
- Internal Audits
- Management Reviews

Technical Requirements

- Personnel
- Facility
- Test Methods
- Equipment and Calibration
- Traceability
- Sampling
- Sample Handling
- Quality Control
- Reporting Results

Proficiency Testing

The TNI Proficiency Testing (PT) program is an integral part of NELAP. Laboratories are required to participate in regular proficiency testing programs as an on-going demonstration of their competence. Proficiency Testing is defined as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. The TNI PT program consists of:

- A PT Expert Committee that establishes the requirement for proficiency testing.
- A PT Executive Committee who manages the implementation of the program.
- A PT Provider Accreditor that accredits organizations as PT Providers.
- Private and public sector PT Providers that manufacture and provide PT samples and evaluate the results.
- Fields of Proficiency Testing (FoPTs) – the matrices, analytes, concentration ranges, and acceptance limits adopted for the PT program.

Participating laboratories must analyze two PT samples per year for each FoPT for which it is accredited and maintain an acceptable performance by passing two out of every three samples it analyzes.

On-Site Assessment

The accreditation process involves a thorough independent evaluation, called an on-site assessment, of all the elements of a laboratory that contribute to the production of accurate and reliable test data.

The assessment can take one to several days, and involves the use of specialist technical assessors who evaluate the specific types of testing or measurement being performed. The assessment evaluates factors relevant to a laboratory's ability to produce reliable and authentic data, including factors such as the:

- technical competence of staff,
- validity and appropriateness of test methods ,
- traceability of measurements and calibrations to national standards ,
- suitability, calibration and maintenance of test equipment,
- testing environment,
- sampling, handling and transportation of test items, and
- quality assurance of test and calibration data.

At the end of the assessment a detailed report is presented to the laboratory, highlighting any areas that require attention and corrective action prior to the laboratory being recommended for accreditation. Once accredited, the laboratory is re-evaluated every two years to ensure its continued compliance with requirements, and to check that its standard of operation is being maintained.

TNI Standards

Accreditation standards are developed by TNI's Expert Committees using a consensus process that includes the elements of openness, balance, due process, and consensus as established by Circular A-119 published by the US Office of Management and Budget. Standards have been developed that are widely applicable, and will therefore promote a uniform national program of environmental laboratory accreditation. These standards are modular, allowing their assembly into a series of volumes, each specifically designed for a stakeholder group (Laboratories; Accreditation Bodies; Proficiency Test Providers; and Proficiency Test Provider Oversight Bodies). The standards that have been developed for NELAP are summarized in Table 1.

Table 1. TNI Accreditation Standards

Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis

- Module 1 - Proficiency Testing
- Module 2 - Quality Systems: General Requirements
- Module 3 - Asbestos Testing

Module 4 – Chemical Testing
Module 5 – Microbiological Testing
Module 6 – Radiochemical Testing
Module 7 – Toxicity Testing

Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories

Module 1 – General Requirements
Module 2 – Proficiency Testing
Module 3 – On-site Assessment

Volume 3: General Requirements for Environmental Proficiency Test Providers

Volume 4: General Requirements for an Accreditor of Environmental Proficiency Test Providers

Accreditation Process

A laboratory seeking accreditation must apply to its home state Accreditation Body for accreditation. However, if the Accreditation Body does not offer accreditation for testing in conformance with a particular field of accreditation (matrix-method/technology-analyte/analyte group), laboratories may obtain primary accreditation for that particular field of accreditation from any other NELAP Accreditation Body.

Laboratory accreditation is available to any laboratory from the private sector, state or federal government, municipality, university or company. Within the NELAP program, fields of accreditation for which accreditation is granted are 1) Drinking Water, 2) Non-Potable Water (to include all aqueous samples that are not public drinking water), 3) Solid and Chemical Materials (to include soils, sediments, other solids and non-aqueous liquids), 4) Biological Tissues and 5) Air and Emissions. Within these broad categories, laboratories may be accredited to perform the following types of testing: asbestos, chemical, microbiological, radiochemical, and toxicity.

Each field of accreditation is associated with a specific scope of accreditation. The scope of accreditation is a document issued to a laboratory that lists the methods for which the laboratory is accredited, including analytes.