NELAC TNI 2016

Environmental Testing Laboratories

AN EXECUTIVE OVERVIEW

PERRY JOHNSON CONSULTING, INC.

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FOREWORD

The National Environmental Laboratory Accreditation Conference (NELAC) was established on February 16, 1995 by State and Federal officials as an accreditation standard setting organization. The primary objective of NELAC was to develop and adopt laboratory accreditation standards to support a National Environmental Laboratory Accreditation Program (NELAP). NELAC was established as a voluntary program for States because of the absence of existing Congressional authority to establish a Federal accreditation program. The USEPA's initial intentions were an eventual transition to a fiscally self-sufficient program.

Initially, eleven (11) states received recognition as NELAP accrediting authorities. The goal of NELAP was to unify existing State and Federal accreditation standards through a cooperative process between various states and other governmental agencies. Standards approval authority was limited to representatives of State and Federal agencies.

Two significant events hastened the transition to self-sufficiency. The National Technology Transfer and Advancement Act (NTTAA) of 1996, which is mandatory for Federal agencies, increased the reliance of Federal agencies on "voluntary consensus standards." Federal agencies were directed to adopt private sector standards, wherever possible, in lieu of creating proprietary, non-consensus standards. The revised OMB Circular A-119 of February 1998 established policies on Federal use and development of voluntary consensus standards and on conformity assessment activities.

NELAC did not meet the OMB Circular A-119 definition of a voluntary consensus organization. In 2002, they amended their Constitution and By-Laws to change the function of the conference to a standards adoption body only, receiving and considering standards that have been developed by standards development organizations that use a consensus process as defined in OMB Circular A-119. NELAP was unaffected by this change.

In 2001, the Institute for National Environmental Laboratory Accreditation (INELA) was formed with a mission of developing OMB A-119 compliant consensus standards for NELAC and other organizations to use. Standards development transitioned from NELAC to INELA in 2002 when the NELAC Constitution and By-Laws were amended.

In 2005, the USEPA initiated a five-year plan to transition NELAC into a self-sufficient program. This was accomplished on November 6, 2006 when The NELAC Institute (TNI) was created which recombined accreditation standards development and laboratory accreditation within the same organization.

The activities of NELAC and NELAP were systematically transitioned into TNI. NELAC remained an active conference until all previously existing functions were transitioned. NELAP was transitioned to TNI late in 2007 and now exists as a Board of accreditation bodies within the organization. Their objective is to establish and implement a program for the accreditation of environmental laboratories including the formal recognition of accreditation bodies, the adoption of acceptance limits for proficiency testing, and the adoption of the laboratory accreditation system developed by the Laboratory Accreditation System Committee (LASC). To ensure that the program is implemented effectively and to address the needs of the stakeholder community, the NELAP Board is expected to work in cooperation with other key committees within TNI.

In January 2008 NELAC officially discontinued operations following the successful transition of all program elements to TNI.

The NELAC Institute (TNI) 2016 standard is the national basis for accrediting environmental testing laboratories. It applies to both freestanding laboratories, as well as laboratories which are part of a larger facility.

Environmental testing laboratories accredited to TNI 2016 will find national acceptance of their testing results, efficiency in their operations and improved customer satisfaction.

The effects of TNI 2016 management system and competency requirements are already being felt by many laboratories around the country, with greater influence in the near future. While implementing a management system is time-consuming and sometimes difficult, accredited laboratories will be considered to have higher standards and better-quality results.

This guide was created to aid those environmental testing laboratories that are about to embark upon the TNI 2016 journey. It will help smooth out the bumps as it explains the general requirements of TNI 2016. Since achieving TNI 2016 accreditation is a lengthy and detailed process, it is strongly suggested that laboratories seeking accreditation retain the services of a reputable consulting firm.

PERRY JOHNSON CONSULTING, INC.
June 2020

THE USERS OF THIS GUIDE

This guide will be useful to lab managers and other personnel in labs that meet any of the following criteria:

- Independent testing laboratories
- Testing laboratories housed in corporate facilities

WHAT IS TNI 2016?

TNI Standard, *Management and Technical Requirements for Laboratories Performing Environmental Analysis,* released in 2003, is the national standard for establishing testing laboratory quality management systems and recognizing laboratory technical competence through accreditation. TNI Standard was been through two additional revisions in 2009 and again in 2016.

This standard was developed by the National Environmental Laboratory Accreditation Conference (NELAC).

TNI 2016 ACCREDITATION _____

TNI 2016 accreditation is a thorough process requiring diligence by laboratories.

TNI 2016 technical requirements serve as criteria for on-site assessments similar to ISO/IEC 17025 audits. These assessments are performed by a third-party accreditation body, which is primarily interested in the laboratory's ability to perform specific environmental tests.

Accreditation can be a valuable tool, demonstrating that a laboratory operates an efficient QMS and is competent to perform environmental testing, leading to improved credibility, fewer customer complaints and a strong competitive edge.

5 KEY STEPS TO ACHIEVING TNI 2016 ACCREDITATION

Before an environmental laboratory can be considered for accreditation, several preliminary steps MUST be taken:

Step 1: The first step is to implement a management system that meets all TNI 2016 management and technical requirements.

Step 2: A Quality Manual MUST be created which stipulates the laboratory's policies, procedures, and technical practices. This document plays a vital role in the accreditation process. Because the manual is the principal document used during an assessment, it MUST be a true reflection of the laboratory's management system. In addition, the laboratory will be required to have Standard Operating Procedures governing Tests performed.

Step 3: The laboratory MUST have at least two sets of passing Proficiency Test results for every Field of Proficiency Testing (FoPT) the lab wants to be accredited for.

The most time efficient and cost-effective way of achieving Steps 1-3 is to have Perry Johnson Consulting, Inc. (PJC) apply its unique Streamlined approach to implementing TNI 2016. Our approach is broken down into 4 phases:

Phase 1: We first conduct a Gap Analysis. We compare your current management system to the TNI 2016 requirements; identify any nonconformities and recommend actions to correct them.

Phase 2: While you are working on the corrective actions, we will be completing phase 2, which is writing your Quality Manual. The manual we will create will contain your policies, procedures, and technical practices and will be written in the correct format required by TNI 2016. This will ensure you meet all documentation requirements of TNI 2016.

Phase 3: **During Phase 3, PJC will provide "hands-on" training of your employees on what they are responsible for within your TNI 2016 management system. We will also coach your people on what to expect during an audit.**

Phase 4: **During the final Phase, PJC will conduct the required full system Internal Audit making sure your laboratory and staff have completed at least two sets of passing Proficiency Test results for every FoPT you want to be accredited for. Once this is completed you ARE READY for a successful Accreditation Audit.**

Step 4: Select an Accreditation Body (AB). If the AB is within your home state, you MUST apply to your home state as your primary AB. If your state does not cover all your Fields of Testing (FoT), then you must find an additional AB9s) that covers your desired FoT.

Step 5: Complete the Application with AB9s) and coordinate scheduling of your on-site assessments.

To receive a quote for implementation, please contact us at **1-888-248-0256** or email chayden@pjcinc.com.

Once the services of a recognized accreditation body have been obtained, a formal application must be filed. When all of the paperwork has been submitted, the accreditation body audits the laboratory's quality manual and related documentation. If the accreditation body's auditors find documentation gaps, they may ask the laboratory to implement corrective action before scheduling the assessment. The laboratory may request a preassessment to improve the chances of a successful assessment.

After the accreditation body has verified that the manual and other documentation is a satisfactory reflection of the laboratory's management system and meets all TNI 2016 requirements, and has determined the tests to possibly witness, an on-site assessment of the laboratory is scheduled.

During the assessment, the accreditation body conducts an entry briefing with laboratory management; audits the management system to verify that it is fully operational and conforms to all TNI 2016 elements, including documentation; interviews technical staff; witnesses selected environmental tests; and examines equipment and calibration records.

The purpose of the assessment is to ensure that the laboratory conforms to all TNI 2016 requirements and can competently perform the types of environmental tests within its Field of Testing. Auditors may also provide advice, based on observations or in response to questions, to help the laboratory improve its performance.

Afterward, the accreditation body reports its findings in an assessment report. If any major or minor nonconformities were found, the laboratory must take corrective action to remedy the cause of the nonconformity.

Major nonconformities directly affect the integrity of environmental test results, can have several related minor nonconformities, or are repeat nonconformities from previous assessments. Examples include a laboratory's inability to perform a test or type of test for which it seeks accreditation; and a laboratory's management system which does not conform to a clause or section of TNI 2016, is not adequately documented or is not completely operational. Minor nonconformities do not directly affect the integrity of environmental test results.

At the end of the assessment, the Lead Auditor prepares a report of findings, identifying nonconformities which the laboratory must resolve in order to achieve TNI 2016 accreditation.

The accreditation body auditors hold an exit briefing with the laboratory's top management, going over findings and presenting a deficiency report which lists nonconformities. The laboratory's authorized representative or designee is asked to sign the deficiency report to attest that it has been reviewed. This does not indicate concurrence with any deficiency findings.

The laboratory is requested to respond within one month after the exit briefing with either corrective action or why it does not believe a deficiency exists. The corrective action response must include a copy of the objective evidence, such as calibration certificates, laboratory procedures, paid invoices, packaging slips and training records, to indicate that corrective actions have been implemented and completed.

If the laboratory disagrees with deficiency findings, it is requested to explain the reasons for this disagreement. A laboratory that fails to respond in writing within four months after the exit briefing is treated as a new accreditation applicant.

TNI 2016 REQUIREMENTS

Module 1: Proficiency Testing Requirements

This module lays out the requirements for the proficiency tests that must be conducted. This includes the sample handling, preparation, analysis, reporting and record retention requirements. In addition, it establishes the proficiency testing study frequency requirements for both the initial accreditation and continued accreditation. This module also lays out the requirements for corrective actions, complaint resolution and reinstatement after suspension or revocation.

Module 2: Quality Systems General Requirements

This module breaks down all the requirements for the quality management system that must be implemented at the laboratory. This is based on the requirements of the ISO/IEC 17025 standard with additional requirements specific to environmental testing laboratories. This includes areas relative to corrective actions, internal audits, management reviews, customer satisfaction, document control, record control, contracting, purchasing, complaints, nonconforming work, data integrity among others. The technical requirements cover the personnel, environmental conditions, method selection and validation, calibrations, measurement traceability, sample collection, handling of samples and test items, quality assurance and reporting results.

Module 3: Quality Systems for Asbestos Testing

This module is specific for those labs performing tests on asbestos samples. This includes the requirements for method selection, method validation, demonstration of capability, calibrations, quality control, test variability/reproducibility, analytical sensitivity, quality of standards and reagents, data acceptance/rejection criteria, and constant and consistent test conditions sample and sampling requirements.

Module 4: Quality Systems for Chemical Testing

This module applies to laboratories conducting environmental tests involving chemical measurements. This includes method selection, method validation, demonstration of capability, calibrations, quality control, data acceptance/rejection criteria, and sample handling.

Module 5: Quality Systems for Microbiological Testing

This module applies to laboratories performing microbiological analysis of environmental samples. This includes requirements for method selection, method validation, demonstration of capability, calibration and continuing calibration, quality control, data acceptance/rejection criteria, and sample handling.

Module 6: Quality Systems for Radiochemical Testing

This module applies to laboratories conducting environmental tests involving radiochemical measurements. This includes requirements for method selection, method validation, demonstration of capability, instrument set-up, calibration, performance checks, background measurements, quality control for radiochemistry, data evaluation and reporting, and sample handling.

Module 7: Quality Systems for Toxicity Testing

This module applies to laboratories measuring the toxicity and/or bioaccumulation of contaminants in effluents, receiving waters, sediments, elutriates, leachates and soils. This includes requirements for method selection, method validation, demonstration of capability, quality control, data acceptance/rejection criteria, and sample handling.

CONCLUSION

As accreditation typically takes 12 to 18 months to complete, laboratories are advised to start moving now. Accreditation should not be put on the back burner. Laboratories shouldn't delay accreditation, but should take full advantage of the competitive edge such status carries.

There are many benefits to be derived from implementing a well-structured laboratory management system such as TNI 2016, and the accreditation process is rigorous and timely. For this reason, not to mention the high rate of failure that afflicts laboratories seeking accreditation for the first time, it's a good idea to seek the services of an outside professional consulting firm.

A competent quality consultant can walk your laboratory through TNI 2016 requirements and identify any problems that may halt the accreditation process.