Mentoring Session: Topics in the New TNI Laboratory Accreditation Standards

Changing from the 2003 nelac Standard

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TNI's NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)

Changing from the 2003 nelac Standard

Full Day Workshop Friday 8:30am – 3:00pm
Registration – $95

This Session's Topics:

- ☀ Changes in ISO 17025
- ☀ Demonstration of Capability *and* Method Validation

Refresher:
What is the ISO 17025 Standard

![The NELAC Institute logo]

ISO/IEC 17025 is the main standard used by testing and calibration laboratories. Originally known as ISO/IEC Guide 25
The standard was first published in 1999 and the revised standard became effective in May 2005.

The ISO/IEC 17025 standard itself comprises five elements that are Scope, Normative References, Terms and Definitions, Management Requirements and Technical Requirements.

The Two Main Sections in ISO/IEC 17025:

Management Requirements which are primarily related to the operation and effectiveness of the quality management system within the laboratory.

and **Technical requirements which includes factors that determine the correctness and reliability of the tests performed in the laboratory.**

Changes in ISO/IEC 17025 are incorporated in the 2009 TNI Standard

Although laboratories meeting the TNI requirements are fully compliant with the requirements of ISO 17025, a NELAC accredited laboratory cannot claim it is an ISO 17025 accredited laboratory.

GLOBAL CHANGES IN ISO 17025

- Quality System changed to Management System
- Client changed to Customer

OTHER CHANGES TO ISO 17025

☀️ Many minor editorial changes

☀️ New sections on organization and laboratory management

☀️ New section on quality improvement

☀️ New language on evaluating QC results

See Comparison Table in Handout

TNI Standard
Volume 1
Environmental Laboratory Sector

ISO 17025 Changes

Volume 1 Contents:

Module 1: Proficiency Testing
Module 2: Quality Systems General Requirements
Module 3: Quality Systems for Asbestos Testing
Module 4: Quality Systems for Chemical Testing
Module 5: Quality Systems for Microbiological Testing Module 6: Quality Systems for Radiochemical Testing
Module 7: Quality Systems for Toxicity Testing

Module 2 contains the General Requirements that applies to all laboratories

- ☀ **Much, but not all of nelac Chapter 5**
- ☀ **Updated to 2005 version of 17025**
- ☀ **ISO 17025 language clearly identified and not modified**
- ☀ **Personnel requirements from Chapter 4 incorporate ISO 17025 language**

4.0 MANAGEMENT REQUIREMENTS
4.1 Organization *(ISO/IEC17025:2005(E), Clause 4.1)*

4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

4.1 Organization

☀ 4.1.5 (k) ensure personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

☀ 4.1.6 ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

ISO 17025 Change

4.2 Management System

☀ Implementation of the management system and to continually improving its effectiveness.

☀ Importance of meeting customer requirements as well as statutory and regulatory requirements.

☀ Ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.

ISO 17025 Change

4.7 Service to Customer

☀️ Customer feedback required
- ➤ Recommended in older version of 17025
- ➤ Not in 2003 NELAC

ISO 17025 Change

Other ISO Changes

- Many *Notes* are now included
  - Notes provide clarification of the text, examples and guidance.
  - "They do not contain requirements and do not form an integral part of this Standard."
- ISO 17025 language has been reproduced faithfully in the TNI Standard

Two Notes Follow 4.7.1

4.7 Service to the Client *(ISO/IEC 17025:2005(E), Clause 4.7)*

4.7.1 The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

NOTE 1: Such cooperation may include:

a)   providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

NOTE 2: Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

4.10 Improvement (New)

☀ The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

ISO 17025 Change

4.11 Corrective Action

☀ Required changes to be documented and implemented.

☀ Not stated in earlier version, but clearly implied.

A top ten common deficiency

ISO 17025 Change

4.14 Internal Audits

☀ Follow-up required to verify corrective actions implemented

☀ A top ten common deficiency

ISO 17025 Change

5.9 Assuring Quality of Results

☀ Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. (5.9.2)

☀ *This should not be something new!*

ISO 17025 Change

5.2 PERSONNEL

☀ Detailed NELAC requirements relating to personnel requirements deleted, but ISO *appropriate education, training, experience and/or demonstrated skills* maintains requirement

What Next?

☀ Purchase the TNI Standard

☀ Read the TNI Standard

☀ The ISO 17025 is clearly identified as discussed

☀ Do not be intimidated by change

☀ Do not compare the 2003 **nelac** Standard item for item to the TNI Standard

Questions…

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Break Time

10:00 am – 10:30 am