The TNI Standard – Then and Now

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INTRODUCTION

NELAC Standard (RIP) 2003
TNI Standard – 2009
TNI Standard – 2015 (?)

INTRODUCTION

about me

1st Meeting – 1999

Joined Quality Systems – 2004

Chair 2008-10; 2012-present

2003 NELAC Standard

- First National Standard
- Good, but room for improvement

2003 NELAC Standard

- Not consensus driven
- One Big Document

2009 TNI Standard

- Consensus driven
- Volume and Module based

2009 TNI Standard

Four Volumes = Four Standards

Volume 1: Requirements for Laboratories

7 Modules (155 pages in all)

Volume 2: Requirements for Accreditation Bodies

3 Modules (70 pages)

Volume 3: Requirements for PT Providers

Volume 4: Requirements for a PT Provider Accreditor

2009 TNI Standard

Environmental Laboratory Requirements:

(Module 1): Proficiency testing (12 pages)

(Module 2): Personnel requirements & Quality system (40 pages)

(Modules 3-7) Technical requirements

- M3: Asbestos (14 pages)
- M4: Chemistry (14 pages)
- M5: Microbiology (10 pages)
- M6: Radiochemistry (14 pages)
- M7: Toxicity testing (8 pages)

Changes?

Items not required in the TNI Standard that were in the 2003 NELAC Standard

5.5.5.2.1.e	syringe attestation
D.1.6. b	glassware cleaning
D.2.1.3.	recommendation deleted
D.6.3.2. b	fiber counting course
D.6.6.1.3. b	recommendation deleted

Changes?

Items removed from the 2003 NELAC Standard

5.4.10.6. b	report data only if QC is ok
5.5.5.2.1. f	autoclave documentation
D.1.2.1. c	LOD related to LOQ
D.2.5. b	data plotting
D.2.8. h	expected chronic value

Additions / New Items

Management System = Quality System

Addition of section on Improvement (4.10)

General – There is a consistent layout between the Technical Modules, such that sections contain the same items (i.e., 1.6 is always Demonstration of Capability).

Module Structure

1. Introduction
2. Scope
3. Terms and Definitions
4. Method Selection
5. Method Validation

   Validation of Methods, Limit of Detection and Limit of Quantitation, Evaluation of Precision and Bias, and Evaluation of Selectivity
6. Demonstration of Capability (DOC)

   General, Initial DOC, and Ongoing DOC
7. Technical Requirements

   Calibration, Quality Control for the specific Module, Data Acceptance / Rejection Criteria, Sample Handling

Additions / New Items

ISO/IEC 17025:2005 Structure

Placement of additional NELAC Requirements was made at the end of all ISO language, where we resumed the numbering from that point. KEY –*ISO language is presented in Italics*

Clarifications

Quality Manual requirements were pulled from all over the Standard and put into two sections:

M2 4.2.8.3 – This is what MUST be in the Quality Manual

M2 4.2.8.4 – This is what MAY be in the Quality Manual or exist elsewhere.

We tried to remove prescriptive language where ever we found it. If there is more than one way to accomplish the requirements of the Standard, we tried to leave it open. Thus, ongoing DOC (for example) doesn't have to follow the same requirements of initial DOC – the laboratory can determine how it wants to do this

Clarifications

- Calibration requirements for support equipment appear in the General Requirements section (Module 2)
- Calibration requirements specific to each discipline (Asbestos, Chemistry, Microbiology) are found in their respective Modules

ISO Requirements

- Ensure personnel are aware of how they fit in the management system. (4.1.5 (k))
- Ensure that communication takes place regarding the effectiveness of the management system.(4.1.6)
- Ensure the integrity of the management system is maintained when changes to the management system are planned and implemented. (4.2.7)
- Seek feedback, both positive and negative, from its customers to improve the management system, testing activities and customer service. (4.7.2)
- 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. (4.10)
- Analyze quality control data and, where they are found to be outside pre-defined criteria, take action to correct the problem and to prevent incorrect results from being reported. (5.9.2)

Methods & SOPs

NELAC 5.5.4.1.1 and 5.5.4.1.2 reformatted into TNI section 4.2.8.5, under records.

- Improved clarity and consistency
- Removal of "methods manual"
- Refers to LOD and LOQ instead of "detection limit"

Personnel

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

Records

Removed requirements for date received, placed in service and condition when received

Expiration dates for original containers not required unless provided by manufacturer

- Expiration dates for prepared reagents and standards must be on container
- NELAC allowed to be documented in quality manual or SOP

Limit of Detection

- Combination of NELAC C.3.1 and D.1.2.1
- No changes to requirements
  - Determine using any procedure if data reported to LOD
  - Verify by analysis of QC sample
  - Verify annually or change in method

Limit of Quantitation

- Combination of NELAC C.3.2 and D.1.2.2
- No changes to requirements
  - Determine using any documented procedure
  - Verify by analysis of QC sample
  - Verify annually or change in method
  - LOQ must be greater than LOD
- Removed: "must have procedures to relate LOD to LOQ"

Initial DOC

- Prior to using method
- Change in instrument type, personnel or method
- If method not performed by an analyst within 12 months

Ongoing DOC

- Procedure needed
- Analyst demonstrates on-going capability
  - Meets QC requirements
  - Document other approaches to DOC if not per method, lab SOP, regulation, client specifications

Ongoing DOC

- 4 replicates is one option, but not required
- Form in NELAC Appendix C deleted, but requirements for documentation remain:
  - a) analyst(s);
  - b) matrix;
  - c) analyte(s);
  - d) identification of method(s) performed;
  - e) identification of laboratory-specific SOP;
  - f) date(s) of analysis; and
  - g) summary of analyses
- Not required to be in personnel file

Calibration

- Initial Calibration
  - Comparable to NELAC 5.5.5.2.2.1
  - Low standard must be at or below LOQ
  - Minimum number of points changed to 3
- Continuing Calibration
  - Virtually identical to NELAC 5.5.5.10

Then / Now

- 2003 became 2009
- 2009 becomes 2015
  - Quality Systems Committee subdivided
  - Each Module becomes a Committee
  - No more Chemists writing Microbiology!

Clarification

Revisions to the 2009 TNI Standard were almost exclusively clarification

Chemistry Committee has done a great deal of work on LOD and Calibration – those are more than clarifications

Clarification

Global Changes

- "Parameter" was changed to "Analyte"
- Any Notes were either eliminated or had the "NOTE" removed – this makes them requirements
- ISO Notes, also not enforceable, were reviewed to see if they needed to become requirements

Clarification

- Change ISO citation from ISO/IEC 17025:2005(E) to ISO/IEC 17025:2005
- Definitions
  - *Analyte (revised)*
  - *Data Integrity (revised)*
  - *Parameter (deleted)*
  - *Physical parameter (added)*
  - *Reference Method (revised)*

Clarification

Module 2

- 5.4.4 Non Standard Methods – added ISO Text
- 5.4.5 Validation of Methods – added ISO Text
  - 5.4.5.4 *(TNI additional requirements) – revised for clarity)*

Clarification

Modules 3-7

- 1.4 Method Selection – deleted majority of text and referred to Module 2
- 1.5 Method Validation – deleted majority of text and referred to Module 2
- 1.6.1 Added clarifying language to indicate that DOCs are related to individual competency.
- 1.6.3.1 Revised for clarity – *on-going DOC are meant to be continuous rather than singular events.*

Thank You

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