





The New TNI Laboratory Accreditation Standard



TNI's NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)

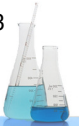
Changing from the 2003  Standard






This Workshop


- Presents major changes required for laboratories to comply with the TNI standard.
- Presents changes to PT program and on-site assessments
- Briefly presents changes to requirements for Accreditation Bodies
- Does not substitute for reading the standards
- Assumes VERY GOOD familiarity with 2003 NELAC Standard






AGENDA

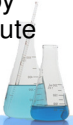
- 8:15 Background and Implementation Schedule
- 8:45 Proficiency Testing Requirements
 - > 9:30 Break
- 10:00 Quality Systems: General Requirements
 - > 12:00 Lunch Break
- 1:00 Quality Systems: Technical Requirements
- 2:00 Accreditation Body Requirements
- 2:30 Interpretations and Action Plan
- 3:00 Questions and Answers




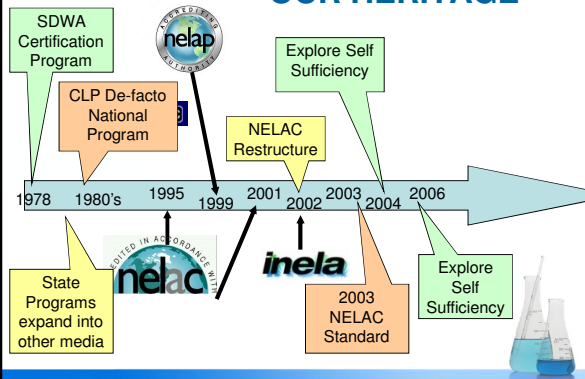
The New TNI Laboratory Accreditation Standard

 **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).




 **OUR HERITAGE**



Timeline events:

- 1978: SDWA Certification Program
- 1980's: CLP De-facto National Program
- 1995: State Programs expand into other media
- 1999: nelap logo
- 2001: nelac logo
- 2002: NELAC Restructure
- 2003: 2003 NELAC Standard
- 2004: inela logo
- 2006: Explore Self Sufficiency




The Magic Box

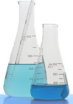



INELA NELAC TNI

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 **WHAT DOES TNI PROVIDE?**


- Infrastructure for stakeholders
- Consensus building for establishing requirements for:
 - Organizations that accredit
 - Organizations that are accredited
 - Proficiency testing programs
- Recognition of organizations that operate accreditation programs
- Assistance to members and others




 **CONSENSUS**

- Federal policy on use of voluntary consensus standards: OMB A-119
- *Federal Agencies must use voluntary consensus standards except where inconsistent with law or otherwise impractical*
- Policy applies to all Federal government, including test procedures



 **CONSENSUS STANDARDS ORGANIZATIONS**

- Must meet requirements of OMB A-119
 - Balance of interest
 - Openness
 - Due process
 - Consensus
 - Appeals process
- May become accredited by ANSI



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TECHNICAL ASSISTANCE

- Quality Manual Template
- Small Laboratory Advocacy Group
- Consultant Listing
- Accreditation Roadmap
- Training Courses
- Assessment Forum
- Mentoring Sessions






SMALL LABORATORY ADVOCACY GROUP




The screenshot shows the TNI Bulletin Board interface. It includes a search bar, a list of topics, and statistics. The statistics section shows: Total posts 33 - Total topics 29 - Total members 35 - Our newest member ACMS.





WHAT DOES TNI NOT DO?

- Accredite laboratories
- Resolve disputes between laboratories and their Accreditation Bodies
- Interpret questions on methods



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TNI CORE PROGRAMS


- Consensus Standards Development Program
- National Environmental Laboratory Accreditation Program (NELAP)
- National Environmental Field Activities Program (NEFAP)
- Proficiency Testing Program






NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)



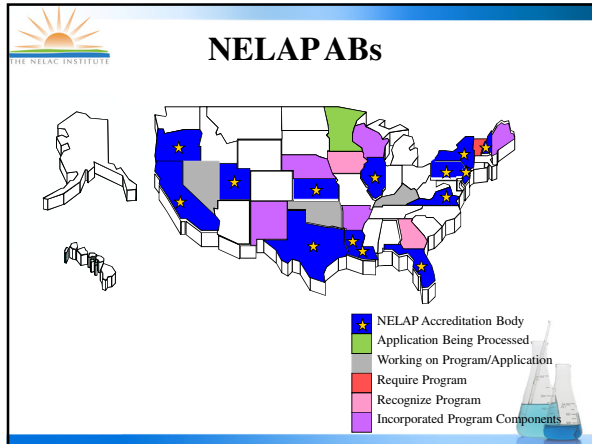


FUNDAMENTAL CONCEPTS

- TNI develops consensus standards that are voluntarily adopted by states agencies designated as accreditation bodies (ABs).
- State ABs grant accreditation, which is **unconditionally recognized**, by other participating ABs.
- Laboratories can voluntarily apply to any approved NELAP AB, if their home state does not participate.



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2003 nelac STANDARD


- One **Big** Document = One Standard
 - Constitution and Bylaws
 - Chapter 1: Program Policy & Structure
 - Chapter 2: Proficiency Testing
 - Chapter 3: On-Site Assessment
 - Chapter 4: Accreditation Process
 - Chapter 5: Quality Systems
 - Chapter 6: Accrediting Authority

The 2003 nelac STANDARD

- Uses ISO 17025 quality system approach,
- Adds specificity to improve clarity and help with consistency for environmental testing,
- Requires conformance to EPA mandated methods, but otherwise allows flexibility in meeting requirements,
- Represents best professional practice,
- Allows for multiple Accreditation Bodies to implement consistently,
- Appropriate level of proficiency testing, and
- Includes data integrity component missing from 17025.


□ **nelac 2003 is the best accreditation program for environmental laboratories currently in use.**


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 **The 2003 nelac STANDARD**


- Refers to an organization that no longer exists,
- Hard to find all the laboratory requirements,
- Written by chemists for chemists,
- Some language could be improved,
- Not a true consensus standard,
- Does not incorporate ISO 17011 for Accreditation Bodies, and
- Muddled and outdated version of ISO 17025.


□ **New TNI Standards corrects these weaknesses**




 **THE NEW TNI NELAP STANDARDS**

- Developed by consensus
- Ensured key elements were retained.
- Removed redundant language
- Removed non-essential requirements
- Considered the following goals:
 - Easy to use and understand;
 - Easy to grow and expand;
 - Easy to revise and implement; and
 - Applicable to all laboratories.




 **THE NEW NELAP STANDARDS**

- Four Small Volumes = Four Standards
 - Volume 1: Requirements for Laboratories
 - + 7 Modules
 - Volume 2: Requirements for Accreditation Bodies
 - + 3 Modules
 - Volume 3: Requirements for PT Providers
 - Volume 4: Requirements for a PT Provider Accreditor




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VOLUME 1

- Everything a lab needs to know
 - Proficiency testing (Module 1)
 - Personnel requirements (Module 2)
 - Quality systems (Module 2)
 - Technical requirements (Modules 3-7)
- Volumes 2, 3, and 4
 - Interesting reading, for maybe QA Manager
 - Do not provide to lab staff






BENEFITS OF NEW LABORATORY STANDARDS

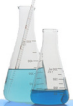
- Removal of outdated **nelac** language
- Incorporation of ISO 17011
- Incorporation of current version of ISO 17025
- Volume/Modular approach simplifies understanding
- Improved clarity on Technical Requirements
- True consensus standard!!!






STATUS OF STANDARDS

- All Standards have been approved for adoption into NELAP.
- TNI NELAP Standards will replace the 2003 **nelac** Standard on July 1, 2011.
- All laboratories must be in compliance with the requirements by July 1, 2011.
- Laboratories will be inspected on their normal 2-year cycle, and thus may not be assessed to the new standard until June 30, 2013.





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PROGRAM IMPLEMENTATION


- 2010 Training and outreach
- 2010 Guidance, checklists, etc.
- 2010 New Quality Manual template
- July 1, 2011 Replace NELAC 2003.





LABORATORY IMPLEMENTATION

- Read the new standard
- Begin adding in a few new requirements to be in compliance
July 1, 2011
- Stop PTRL reporting
- Consider removing obsolete NELAC requirements





THE NEW STANDARDS


The NELAC Institute Member Page



NEWS
Nominations for 2010 Board of Directors
16 February 2010
Updated Workshops on Qualifying the New TNI Standards Planned in 2010
31 February 2010
New PT Subcommittee being formed for the development of a PT Table for NELAP
9 February 2010
Final Program for TNI Forum Chicago Published
22 January 2010
FAQ for Stationary Source Audit Sample Program now available
29 January 2010
Fields of Proficiency Testing Table for Non-Potable Water Updated
11 January 2010
Recent Site Updates


http://nelac-institute.org/standards.php

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FINAL VERSION

- November 2009
 - Editorial changes
 - Tentative Interim Amendments (TIA)
 - Copies automatically provided to previous buyers of ISO version






PURCHASE OF STANDARDS


Standard	Single Use	Network Use
Volume 1	\$50	\$90
Volume 2	\$65	\$75
Volume 3	Free	Free
Volume 4	Free	Free



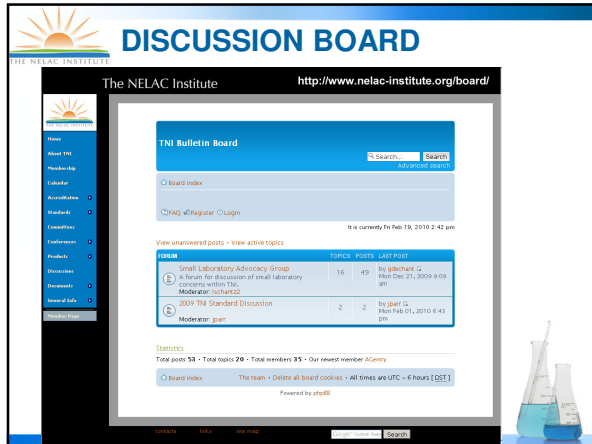


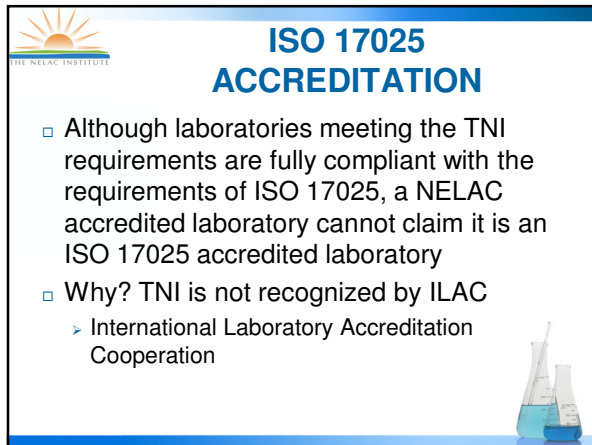
CHANGES TO STANDARD

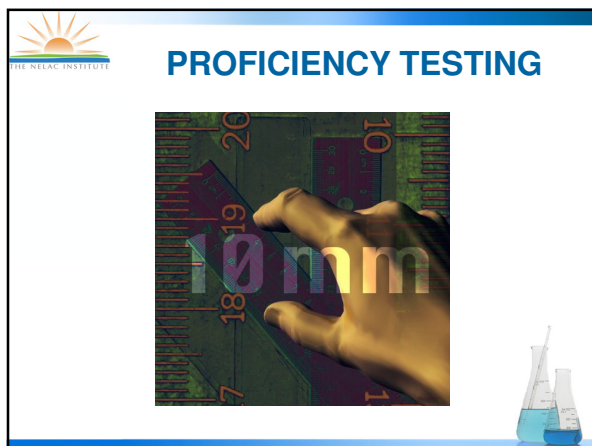
New Requirement	Deleted or relaxed requirement
□ This is a significant new requirement	□ This is a good change




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PT STANDARDS


- Volume 1: Laboratory Requirements
 - Module 1: Proficiency Testing
- Volume 2: Accreditation Body Requirements
 - Module 2: Proficiency Testing
- Volume 3: Proficiency Testing Provider Requirements
- Volume 4: Proficiency Testing Oversight






VOLUME 1: MODULE 1

- The laboratory requirements
 - 1.0 SCOPE AND APPLICABILITY
 - 2.0 REFERENCES
 - 3.0 TERMS AND DEFINITIONS
 - 4.0 REQUIREMENTS FOR ACCREDITATION
 - 5.0 SAMPLE HANDLING, ANALYSIS & REPORTING
 - 6.0 CORRECTIVE ACTION
 - 7.0 COMPLAINT RESOLUTION
 - 8.0 REINSTATEMENT AFTER SUSPENSION OR REVOCATION







3.0 Terms and Definitions

□ Accreditation Body*	□ Proficiency Testing Provider
□ Accreditation Field of Proficiency Testing*	□ Accreditor (PTPA)*
□ Analysis Date	□ PT Sample
□ Experimental Field of Proficiency Testing	□ PT Study
□ Field of Accreditation*	□ PT Study Closing Date
□ Field of Proficiency Testing*	□ PT Study Opening Date
□ Primary Accreditation Body*	□ Revocation*
□ Proficiency Testing (PT)*	□ Study
□ PT Program*	□ Supplemental PT Study
□ Proficiency Testing Provider (PTP)*	□ Suspension*
	□ TNI PT Board


V1M1 *Same as 2003 nelac




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 **4.1 Initial Accreditation**


- “Successfully analyze” 2 PT samples
 - Within 18 months of application
 - **Last analysis must be within 6 months of application date**
 - At least 15 calendar days apart
- Provision to obtain from non-accredited PT provider
 - Highly unlikely this will ever be used




V1M1

 **4.2 – Continued Accreditation**


- 2 TNI compliant PTs per year
 - **At least 5 and no more than 7 months apart**
 - Corrective Action PTs must be analyzed at least 15 days apart.
- Successfully analyze 2 of the last 3
- Provision to obtain from non-accredited provider
 - Highly unlikely this will ever be used
- Provision for experimental PTs
 - Highly unlikely this will ever be used




V1M1

 **4.2 Corrective Action PTs**


- Not required
- If done, must be **at least 15 days after** original analysis date
 - Not PT study closing date
- Section 6.1 requires sample to be from a different lot.




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 **5.1 PT SAMPLE ANALYSIS**


- Process as routine sample
- Test only per technology not method, except drinking water
- No sharing of information
- No sharing of PT samples between labs




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 **ROUTINE ANALYSIS OF PT SAMPLES**


- Scheduled as normal samples
- Diluted or prepared according to instructions
- Analysis by “normal” chemist
- No additional QC
- No extra analyses
- Document any exceptions



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 **5.2 LOQ REPORTING**

- [Report PT data based on documented Limit of Quantitation \(LOQ\) or low point in curve.](#)
 - [Use LOQ for methods like ICP](#)
 - [Use low calibration point for methods with a calibration curve](#)
- This allows the laboratories to analyze and report the PT samples in the same manner as their normal samples.
 - Removes issue of reporting to the PTRL.





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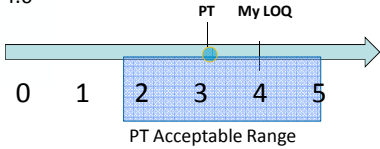
 **EVALUATION OF RESULTS**

- See Volume 3, Section 10.3
- If the laboratory reports < LOQ and the LOQ value is greater than the lower acceptance limit, the reported < LOQ is evaluated as 'Acceptable'

V1M1 


 **Evaluation of Results**


PT true value = 3.2
 PT Acceptance Range = 1.8 – 5.1
 LOQ = 4.0



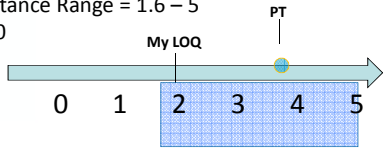
The Lab reports "<4"

Since LOQ value is greater than the lower acceptance limit, 1.8, the statement <4 is true.

Acceptable 


 **Evaluation of Results**

PT true value = 3.8
 PT Acceptance Range = 1.6 – 5
 LOQ = 2.0




Lab Reports <2 for PT result.

Even if the PT true value is greater than the LOQ, the LOQ value is greater than the lower acceptance limit, so the PT could be less than my LOQ – It still fits within the range.


Acceptable 


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LOQ REPORTING


- No change for most laboratories
- May be a change for labs that had reported results less than LOQ that were greater than PTRL
- For these few labs, continue current practice until July 1, 2011






5.2 PT Reporting


- 5.2.1 (a) for instruments that employ multi-point calibration
- 5.2.1 (b) for instruments such as ICP that employ standardization with 0 and a single-point
- What about Micro, Radiochemistry, and WET?






PT Reporting


- A Tentative Interim Amendment will be processed in 2010 for volume 3 to address reporting for Micro, Radiochemistry, and WET
- Change will require laboratories to follow instructions provided by PT Provider.




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 **5.3 RECORDS**


- PT records 5 years
 - [No statement about regulatory programs that have longer retention.](#)
- Reporting forms used must be retained.
 - **Includes copy of on-line data entry summary or similar documentation.**

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 **6.0 CORRECTIVE ACTION**

- Handling “Not Acceptable” results
- Actions required
 - **Notify PTP that it is a corrective action sample**
 - [At least 15 days between analyses. not closing date](#)
 - [Analyte does not have to be present](#)
 - Analyzed like other samples


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 **7.0 COMPLAINTS**

- Submit to PT Provider; if not resolved to the PT Provider Accreditor
 - [TNI has no direct role in this dispute](#)

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 **SUSPENSION AND REVOCATION**


Suspension


- the laboratory receives an unacceptable score in 2 out of the last 3
- the laboratory does not provide a corrective action report to the Primary AB within 30 days of request

Revocation

- the laboratory does not participate in the PT program
- the laboratory submits results for PT samples that were generated by another laboratory


Volume 2 Module 2



 **8.0 REINSTATEMENT**

- Suspension – lab must meet requirements of continued accreditation
 - Pass 2 out of last 3
- Revocation - lab must meet requirements of initial accreditation
 - Pass 2, at least 15 days apart


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 **QUALITY SYSTEMS**




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 **TNI NELAP STANDARDS**


- Volume 1: Laboratory Requirements
 - Module 2: Quality Systems General Requirements
- **nelac** Chapter 5
 - Reorganized, simplified, updated
 - Without the appendices



 **QUALITY SYSTEM REQUIREMENTS**


- 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
 - 17025 language clearly identified and not modified
 - Personnel requirements from **nelac** Chapter 4
- Modules 3 through 7 are Technical Requirements for different types of labs
 - Method Selection, Validation and DOC
 - Instrument Calibration
 - Quality Control
 - Sample Handling




 **INCORPORATION OF ISO LANGUAGE**

- 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.”
- 17025 language reproduced faithfully
 - Shown in italics

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CALIBRATION LABORATORIES


- ISO 17025 applies to all types of laboratories, including “calibration laboratories”
- Calibration laboratories provide calibration certificates for reference materials (e.g., a 1 gram weight)
- The words “calibration tests” and “calibration certificates” can generally be ignored.






Very few new requirements!






SUMMARY OF CHANGES

- ISO 17025 Changes
- Removal of some redundant language
- Increased clarity
- Removal of some non-essential language




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GLOBAL CHANGES IN ISO 17025

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




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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



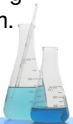
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4.1 Organization


- 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




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 **4.2 Management System**

- 4.2.2 (e) and 4.2.3 Commitment to compliance and **to continually improving its effectiveness.**
- 4.2.4 Importance of meeting customer and regulatory requirements
- 4.2.7 Ensure the integrity of the management system is maintained when changes to the management system are planned and implemented.


ISO 17025 Change


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 **4.7 Service to Customer**

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


ISO 17025 Change

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 **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

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 **4.11 Corrective Action**


- 4.11.3 Required changes to be documented and **implemented**. (Increased emphasis)
- **A top ten common deficiency**




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 **4.14 Internal Audits**

- Follow-up required to verify corrective actions implemented
- **A top ten common deficiency**




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 **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




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CHANGES BY TNI


- Reorganized, but no substantive change in requirements
- Increased flexibility
- Editorial to improve clarity and intent
- Incorporation of personnel requirements from **nelac** Chapter 4
- Removal of some redundant language
- Removal of **non-essential requirements**






3.0 DEFINITIONS


- 78 definitions from **nelac** removed, relocated, or not changed
 - Many are administrative or moved to other modules
 - Many related to the old non-existent NELAC
- 5 definitions added






NEW DEFINITIONS

- **Analytical Uncertainty:** A subset of Measurement Uncertainty that includes all laboratory activities performed as part of the analysis.
- **Bias:** The systematic or persistent distortion of a measurement process, which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).




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 **NEW DEFINITIONS**


- **Matrix Duplicate:** A replicate matrix prepared in the laboratory and analyzed to obtain a measure of precision
- **Method:** A body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification), systematically presented in the order in which they are to be executed.




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 **NEW DEFINITIONS**

- **Sampling:** Activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure




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 **4.2.8 QUALITY MANUAL**


- 4.2.8.3 The quality manual shall contain:
 - a) Document title;
 - b) 8 other items
- 4.2.8.4 The quality manual shall contain or reference:
 - a) All maintenance, calibration and verification procedures used by the laboratory in conducting tests
 - b) 19 other items

[Requirements for contents of Title Page removed!](#)




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QUALITY MANUAL

- New TNI Template for later this year
- Will be organized according to V2, M2
- Will be priced like existing template with discount for TNI members




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METHODS AND 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"




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5.2.6 PERSONNEL

- Technical Director requirements from NELAC Chapter 4, but TD renamed Technical Manager
- NELAC 4.1.1 (grandfather clause) moved to 5.2.6 (c)
- NELAC 4.1.1.1 (duties) moved to 4.1.7.2



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SAMPLE HANDLING


nelac 5.4.12.2.5

- All records pertaining to:
 - a) sample preservation including appropriateness of sample container and compliance with holding time requirement;
 - b) sample identification, receipt, acceptance or rejection and log-in;
 - c) sample storage and tracking including shipping receipts, sample transmittal forms, (chain of custody form); and
 - d) documented procedures for the receipt and retention of samples, including all provisions necessary to protect the integrity of samples.

TNI 4.13.3

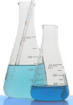
- The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.






4.13.3 ANALYTICAL RECORDS

- NELAC 5.4.12.2.5.2 and 5.4.12.2.5.3 combined into one subsection listing information needed to reconstruct the analytical data
- Some items from NELAC not specifically listed (e.g., archived SOPs), but still covered under the phrase “all information necessary.”




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5.2 PERSONNEL

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




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 **DEMONSTRATION OF CAPABILITY**

- NELAC 5.5.2.6 and Appendix C
- Not in Module 2
- DOC is contained in Modules 3-7 and varies based on the scientific discipline
- Note: Work Cells eliminated entirely




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 **DATA INTEGRITY**

NELAC	TNI
□ 5.4.2.6 Data Integrity Procedures	□ 4.2.8.1 Management requirements
□ 5.5.2.7 Data Integrity Training	□ 4.16 Data Integrity Investigations
	□ 5.2.7 Data Integrity Training


Comparable language with equal intent



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 **5.3 ACCOMODATIONS**

- NELAC 5.5.3.6 unencumbered work area language deleted
- 5.3.4 and 5.3.5 keep the requirement



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 **5.5.13 SUPPORT EQUIPMENT**


nelac 5.5.5.2.1


- “Prior to use on each *working day*...”
- Who or what is working?
 - The analyst, the sample, or the equipment?

TNI 5.5.13

- “On each day the equipment is used...”
- What does “being used” mean?
 - Interacting with samples, e.g.,
 - Stored, incubated, extracted

No change in intent by authors, but maybe a change in perception by readers.

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
 **5.5.13 DAILY CHECK**


nelac 5.5.5.2.1

- ...shall be checked in the expected use range, with NIST traceable references where commercially available.
- The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.


TNI 5.5.13.1

- ...shall be checked and documented.
- The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.




 **5.5.5 EQUIPMENT RECORDS**


- [Removed requirements for date received, placed in service and condition when received!!!](#)
- This was never in ISO 17025.

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 **5.6.4 STANDARDS & REAGENTS**


- [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
- **Traceability of reagents**




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 **5.10.2 REPORTING**


- Not required to be included
 - Date of issue
 - Name or number of subcontractor on the report, (subcontract results must be identified)
 - Certification that the results meet all requirements or provide reasons and/or justification if they do not.
- ["Report cannot be reproduced except in full" is now a Note](#)



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 **REPORTING UNITS**

<p>nelac 5.5.10.2</p> <ul style="list-style-type: none">□ the environmental test results with, where appropriate, the units of measurement, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as ug/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;	<p>TNI</p> <ul style="list-style-type: none">□ 5.10.2 (i) the test or calibration results with, where appropriate, the units of measurement;□ 5.10.11 Results that are reported on a basis other than as received (e. g., dry weight).
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 **REPORTING QC FAILURES**

nelac 5.5.20.3.1


- deviations from (such as failed quality control), additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions and any non-standard conditions that may have affected the quality of results, including the use and definitions of data qualifiers;

TNI 5.10.3

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;



V1M2


 **REPORTING: NON-COMPLIANCE**

nelac 5.5.10.3.1


- where quality system requirements are not met, a statement of compliance/non-compliance with requirements and/or specifications, including identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature;

TNI 5.10.3.1

- where relevant, a statement of compliance/non-compliance with requirements and/or specifications;



V1M2

 **REPORTING: UNCERTAINTY**

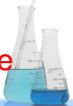
nelac 5.5.10.3.1

- where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed when a client's instruction so requires;

TNI 5.10.3.1


- where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, **or when the uncertainty affects compliance to a specification limit;**

ISO 17025 Change





V1M2

The New TNI Laboratory Accreditation Standard


 **TNI NELAP STANDARDS**


- Volume 1 Laboratory Requirements
 - Module 3: Asbestos
 - Module 4: Chemical
 - Module 5: Microbiological
 - Module 6: Radiochemical
 - Module 7: Toxicological



 **TECHNICAL MODULES 3-7**

- Combination of Requirements from NELAC 2003, Chapter 5 and Appendices C and D
- Format consistent in all Technical Modules
- All requirements related to the scientific discipline
 - Asbestos, Chemical, etc




 **TECHNICAL MODULES**


Where's D.5 (Air)?

It's in V1M4 Chemical


- Asbestos
 - V1M3, Formerly D.6
- Chemical
 - V1M4, Formerly D.1
- Microbiology
 - V1M5, Formerly D.3
- Radiochemical
 - V1M6, Formerly D.4
- Toxicity
 - V1M7, Formerly D.2





The New TNI Laboratory Accreditation Standard


 **TECHNICAL MODULE
KEY ELEMENTS**


- 1.4 Method Selection
- 1.5 Method Validation
- 1.6 Demonstration of Capability
- 1.7 Technical Requirements
 - Calibration
 - Quality Control
 - Data Acceptance/Rejection
 - Sample Handling




 **MODULE 3: ASBESTOS**




No significant changes from 




 **Method Selection &
Validation**


- Section 1.4 Method Selection
 - ISO 5.4.4; Standard Method changed to Reference Method
 - Plus confusing language on parameter/method combination from Module 4
- Section 1.5 Method Validation
 - ISO 5.4.5.1 (other ISO language not included)
 - Participate in PT program




The New TNI Laboratory Accreditation Standard


 **Demonstration of Capability**



- Initial
 - Same as Module 4, 1.6.1 and 1.6.2
- Ongoing
 - Same as Module 4, 1.6.3




 **Technical Requirements**


- Section 1.7
 - Virtually identical to **nelac** D.6




 
Module 4: Chemistry




The New TNI Laboratory Accreditation Standard

 **TECHNICAL MODULE
KEY ELEMENTS**


- 1.4 Method Selection
- 1.5 Method Validation
- 1.6 Demonstration of Capability
- 1.7 Technical Requirements
 - Calibration
 - Quality Control
 - Data Acceptance/Rejection
 - Sample Handling




 **METHODS AND
METHOD VALIDATION**

- Module 2, Section 5.4
 - 5.4.1 General
 - 5.4.2 Selection of Methods
 - 5.4.3 Laboratory Developed Methods
 - ~~5.4.4 Non-Standard Methods~~
 - ~~5.4.5 Method Validation~~
- Modules 3-6
 - 1.4 Method Selection: ISO 5.4.4 plus
 - 1.5 Method Validation: ISO 5.4.5 plus
- Module 7 (WET) uses simplified language


ISO 17025 language



V1M3-M6


 **1.4 Method Selection**

- Language from ISO 5.4.4 (use of non-standard methods) with some twists
- Standard Method renamed Reference Method
- Reference Method is a method issued by organization recognized as competent to do so.
 - This is the classical definition



V1M3-M6

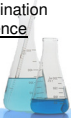
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 **ISO and TNI**

ISO 5.4.4


TNI 1.4

- A reference method is a method issued by an organization generally recognized as competent to do so. When a laboratory is required to analyze a parameter by a specified method due to a regulatory requirement, the parameter/method combination is recognized as a reference method....




 **1.4 METHOD SELECTION**


- Allows the adding of analytes to reference method
- Method must be identified as modified



V1M4


 **REFERENCE METHOD**

- If there is not a regulatory requirement for the parameter/method combination, the parameter/method combination is recognized as a reference method if it can be analyzed by another similar reference method of the same matrix and technology.”
- The inclusion of the parameter in the method shall meet all required calibration requirements and the quality control requirements of the method to which the parameter is being added. If no QC exists in the method, the laboratory shall adhere to the requirements outlined in the similar method.
- Example, Acetone by 624




V1M3-M6


The New TNI Laboratory Accreditation Standard

 **REFERENCE METHOD**

- Parameter must meet all QC requirements in method
- If no QC in method, must meet QC in “the similar” method
- Method must be identified as modified

So, if you follow the QC requirements of Method 624, then acetone by 624 can be considered a Reference Method.


V1M3-M6 


 **ISO 1.5.4**

- When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.


TNI 1.4

- When it is necessary to use methods not covered by reference methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the environmental test. The method developed shall have been validated appropriately before use.




 **SO WHAT DOES THIS ALL MEAN?**

- Alternate method validation options for Reference Methods and Non-Reference Methods in 1.5.3 (Evaluation of Precision and Bias)
- Applies to Chemistry and Radiochemistry only
- Language exists in other modules


V1M3-M6 

The New TNI Laboratory Accreditation Standard




1.5 METHOD VALIDATION

- Retains 2 sections from ISO 17025
 - Definition of validation (except M4)
 - All methods require validation (except M7)
- Adds language about PT samples
- Does not contain ISO section on assessing data for intended use
- Each module has additional details on validation





V1M3-M7



ISO and TNI


ISO 5.4.5.1 <ul style="list-style-type: none">□ Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.	TNI 1.5 (a) <ul style="list-style-type: none">□ a) The laboratory shall validate reference methods via the procedures specified in Sections 1.5.2 and 1.5.3.
--	---






ISO and TNI

ISO 5.4.5.2 <ul style="list-style-type: none">□ The laboratory shall validate non-<u>standard</u> methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of <u>standard</u> methods to confirm that the methods are fit for the intended use....	TNI 1.5 (b) <ul style="list-style-type: none">□ The laboratory shall validate non-<u>reference</u> methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of <u>reference</u> methods to confirm that the methods are fit for the intended use....In the absence of other specifications, the minimum requirements for method validation are given in Sections 1.5.2, 1.5.3 and 1.5.4.
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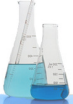


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METHOD VALIDATION

- Required for:
 - Reference methods
 - Non-reference methods
 - Laboratory-designed/developed methods,
 - Reference methods used outside their published scope, and
 - Amplifications and modifications of reference methods

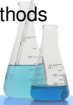


V1M3-M6




1.5 VALIDATION REQUIREMENTS

- Evaluation of
 - LOD, if reporting to LOD
 - LOQ
 - [Precision and bias](#)
 - Selectivity (not required for reference methods)
- Required for all methods:
 - Reference methods, non-reference methods, laboratory-developed methods, reference methods used outside their published scope, and amplifications and modifications of reference methods




V1M4




1.5.2 LIMIT OF DETECTION

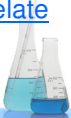
- Combination of NELAC C.3.1 and D.1.2.1
- No changes to requirements
 - Determine using any procedure if data reported to LOD
 - Verify by analysis of QC sample
 - Verify annually or change in method





The New TNI Laboratory Accreditation Standard


 **1.5.2 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"

V1M4 


 **1.5.3 PRECISION AND BIAS**

Reference Methods	Non-Reference Methods
<ul style="list-style-type: none">□ Initial DOC, or□ Alternate procedure	<ul style="list-style-type: none">□ Evaluate precision and bias across the analytical range<ul style="list-style-type: none">➢ e.g., Triplicates analyzed at multiple concentrations➢ EPA Tier 1, 2, or 3 ATP procedure□ Same as  C.3.3(b)


V1M4 

 **ISO and TNI**


ISO 5.4.5.3	TNI ???
<ul style="list-style-type: none">□ The range and accuracy of the values obtainable from validated methods (e.g. detection limit, selectivity, linearity, limit of repeatability, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample), as assessed for the intended use, shall be relevant to the customers' needs.	




The New TNI Laboratory Accreditation Standard


 **1.6.1 DOC: GENERAL**


- Initial DOC is required for all methods and analysts,
 - except for methods in place for one year before applying for accreditation.
- Initial DOC required if change in instrument, method or personnel
- Ongoing DOC is required.
- Records maintained

V1M3-M7 


 **1.6.2 INITIAL DOC**

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


V1M3-M7 

 **INITIAL DOC in 2003
NELAC**


- Contained in Section 5.5.4.2.2 and Appendix C
- Confusion on whether it applied to lab or analyst
- TNI standard clearly indicates every analyst must perform an initial DOC?




The New TNI Laboratory Accreditation Standard


 **1.6 ON-GOING DOC**

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




 **1.6 DOC**


- 4 replicates is one option, but not required
- [Form in NELAC Appendix C deleted](#), but requirements for documentation remain:
 - 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](#)



V1M4


 **1.6 ON-GOING DOC**

- Options from NELAC 5.5.2.6 still allowed:
 - Single-blind sample
 - Initial DOC
 - 4 LCS
- Another option added:
 - [a documented process of analyst review using QC samples. QC samples can be reviewed to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary](#)




V1M4


The New TNI Laboratory Accreditation Standard

 **1.7 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




V1M4

 **1.7 QUALITY CONTROL**


- No change from NELAC Appendix D.1
- Reorganized with evaluation criteria as a separate section
 - Method Blank
 - LCS
 - MS/MSD
 - MD
 - Surrogates
 - + For failed surrogates, must qualify data (was a "should")



V1M4

 **M4 LANGUAGE REMOVED**

- NELAC D.1.6 b
 - [Glassware cleaning and storage procedure](#)
 - [Cleaned to meet test sensitivity](#)
- Conscious decision of committee
 - Method blanks verify cleanliness



V1M4

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Is that chicken cooked to 178 degrees? Are you going to eat those sprouts? They're a haven for bacteria!

WHY MICROBIOLOGISTS HARDLY EVER GET A SECOND DINNER DATE.

Module 5: Microbiology

M5 Microbiology

- 1.4 Method Selection
- 1.5 Method Validation
 - Defines Accuracy, Precision and Selectivity
- 1.6 Demonstration of Capability
 - Use of 4 aliquots plus other techniques
- 1.7 Technical Requirements
 - Comparable to NELAC


V1M5

1.5 METHOD VALIDATION


- **In order to demonstrate proficiency prior to first use**
 - Analysis of one pure reference culture,
 - Analysis of a minimum of ten spiked samples whose matrix is representative of those normally submitted to the laboratory,
 - Verify responses in 10 samples
- **If no reference method, validate to demonstrate method can meet intended use**


V1M5

The New TNI Laboratory Accreditation Standard


 **1.6 INITIAL DOC**


- Much more detail
 - One acceptable approach described
 - Other approaches acceptable
- Acceptable approach
 - 4 aliquots; calculate recovery and SD, or
 - For P/A tests, assess against criteria
 - For qualitative tests, blind study with blank, negative and positive

V1M5 


 **1.6 ON-GOING DOC**

- Acceptable approaches
 - One spike sample, or
 - One duplicate set of analyses, or
 - One PT sample, or
 - Analyst review of QC samples




 **1.7.5 SAMPLE PRESERVATION**


- Thermal preservation not required if analysis begins within 15 minutes of collection or samples refrigerated within 15 minutes
- Chlorine residual check requirement revised
 - Increased clarity and intent

V1M5 


The New TNI Laboratory Accreditation Standard

 **CHLORINE CHECK**

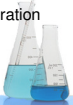
- Samples from known chlorinated sources (such as wastewater effluent), unknown sources where chlorine usage is suspected (such a new client or a new source) and all potable water sources (including source water) shall be checked for absence of chlorine residual.





V1M5

 **CHLORINE CHECK**


- Laboratories that receive samples from potable water sources (including source water) that have a demonstrated history of acceptable preservation may check a sample from each source at a frequency of once per month if:
 - > the sample containers are from their laboratory;
 - > sufficient sodium thiosulfate was added to neutralize at minimum 5 mg/l of chlorine for drinking water and 15 mg/l of chlorine for wastewater samples;
 - > one container from each batch is checked to ensure efficacy of the sodium thiosulfate and the check is documented;
 - > chlorine residual is checked in the field and actual concentration is documented with sample submission.




V1M5


MODULE 6: RADIOCHEMICAL




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 **M6 RADIOCHEMICAL**


- 1.4 Method Selection
- 1.5 Method Validation
 - Specific section on DW
 - Standard Method: MDA and Precision and bias
 - Non Standard Method: Intended use
- 1.6 Demonstration of Capability
- 1.7 Technical Requirements

V1M6 


 **1.5 PRECISION AND BIAS**

Reference Methods	Non-Reference Methods
□ Initial DOC	□ Documented procedure with example provided


V1M6 

 **1.7 CALIBRATION**


- Removed NELAC text (D.4.4(b))
 - [Verification of instrument calibration does not directly verify secondary calibrations, e.g., the mass efficiency curve or the quench curve](#)


V1M6 

The New TNI Laboratory Accreditation Standard


 **1.7 LCS**


- The activity of the laboratory control sample shall be:
 - at least ten (10) times the MDA, and
 - at a level comparable to that of routine samples when such information is available if the sample activities are expected to exceed ten times the MDA.
- Other clarifying changes

 V1M6

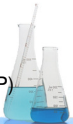
 **1.7 MATRIX SPIKES**

- The frequency of the analysis of matrix replicates and duplicates are as specified by the test method or may be determined as part of the contract review process
- NELAC 2003 required one per prep batch

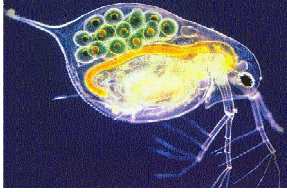

 V1M6

 **1.7 MEASUREMENT UNCERTAINTY**


- Each result shall be reported with its measurement uncertainty.
 - indicate whether the uncertainty is the combined standard uncertainty ("one sigma") or an expanded uncertainty; and
 - for expanded uncertainties, indicate the coverage factor (k) and optionally the approximate level of confidence.
- The procedures shall be documented and shall be consistent with
 - ISO Guide 98: 1995, Guide to the Expression of Uncertainty in Measurement (GUM)
 - Chapter 19 of the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP)


 V1M6

The New TNI Laboratory Accreditation Standard



MODULE 7: TOXICITY







M7 TOXICITY

- 1.4 Method Selection
- 1.5 Method Validation
 - Definition only
- 1.6 DOC
 - Initial or at least 1 per 12 months to remain qualified in method
 - On-going
- 1.7 Technical Requirements

V1M7






M7 1.7 QUALITY CONTROL

- Minimum number of standard reference toxicants (SRT) not specified as in the NELAC standard (5 for initial)
- SMSD now termed PMSD (percent minimum significant difference)

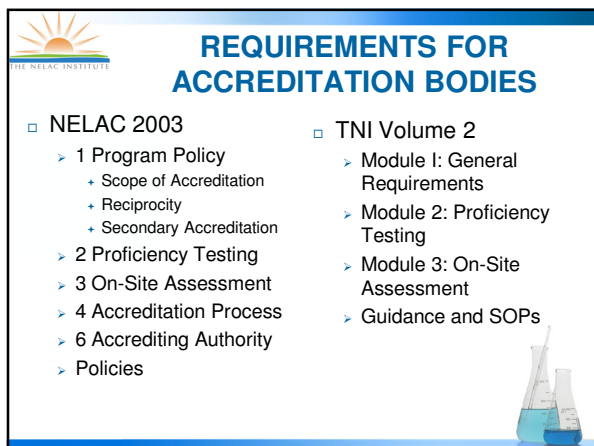
V1M7



The New TNI Laboratory Accreditation Standard








The New TNI Laboratory Accreditation Standard



BASIS OF NEW STANDARD


- ISO/IEC 17011:2004(E)
 - General requirements for accreditation bodies accrediting conformity assessment bodies
 - **Conformity Assessment Body (CAB) = Laboratory**






A Quality System for ABs


ISO 17011 <ul style="list-style-type: none">□ Registered legal entity□ Implement Quality System<ul style="list-style-type: none">➢ Document Control➢ Records➢ Corrective actions➢ Preventative Actions➢ Internal audits□ Qualified Personnel	ISO 17025 <ul style="list-style-type: none">□ Registered legal entity□ Implement Quality System<ul style="list-style-type: none">➢ Document Control➢ Records➢ Corrective actions➢ Preventative Actions➢ Internal audits□ Qualified Personnel
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Approval Programs

Accreditation Bodies <ul style="list-style-type: none">□ Conformance to 17011 plus TNI requirements verified by independent inspection of facilities, staff, and SOPs□ Inspection performed by NELAP Evaluation Team□ Shadow audit an independent check	Laboratories <ul style="list-style-type: none">□ Conformance to 17025 plus TNI requirements verified by independent inspection of facilities, staff, and SOPs□ Inspection performed by Accreditation Body□ Proficiency testing an independent check
--	--





The New TNI Laboratory Accreditation Standard



VOLUME 2 CONTENT

- Much of the detail from NELAC deleted
 - e.g., assessor training curriculum
- Requirements still exist
- Policies and SOPs will be developed to provide detail
 - e.g., assessor training curriculum







MODULE 1: GENERAL

1. Scope
2. Normative References
3. Terms & Definitions
4. Accreditation Body
5. Management
6. Human Resources
7. Accreditation Process
8. Responsibilities of the AB and CAB

V2M1







SCOPE, REFERENCES AND TERMS

- Clarify that CAB = laboratory
- Important terms
 - Accreditation is attestation of laboratory competence
 - Accreditation Body is the body that grants the accreditation
 - Laboratory assessment includes competence of entire operation, including personnel, test methods and validity of results
 - Field of accreditation defined as matrix, technology/method and analyte combination


V2M1




The New TNI Laboratory Accreditation Standard

 **7. ACCREDITATION PROCESS**


- General criteria for processes available
- Application process
- May subcontract the assessment, but not the accreditation decision
- Certificate
- Denial, suspension, withdrawal
- Assessment




V2M1

 **8. LAB RESPONSIBILITIES**


- Fulfill PT and Quality System requirements
- Allow AB to inspect operation
- Provide AB necessary documents
- Not misuse accreditation status
- Pay fees
- Notify AB of significant changes



V2M1


 **8. AB RESPONSIBILITIES**

- Make accreditation status publicly available
- Ensure laboratory fully conforms with requirements



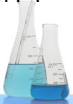
V2M1

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MODULE 2 - PT

- Specific requirements for accreditation bodies regarding PT
- Criteria is consistent with current NELAC
 - 2 samples per year; pass 2 out of last 3
 - **Evaluation of sample analysis process during on-site**
 - **Review results and evaluate data**
 - Suspend or revoke accreditation based on PT failures




V2M2




MODULE 3 – ON-SITE ASSESSMENT

1. Introduction, Scope and Applicability
2. References
3. Terms and Definitions
4. Human Resources
5. Frequency
6. Process
7. Changes in Laboratory Capability




V2M3




TYPES OF ASSESSMENTS

- Initial
- **Reassessment**
- **Surveillance**
- Follow-up
- **Extraordinary**




V2M3


The New TNI Laboratory Accreditation Standard

 **ASSESSMENT PROCESS**


- Assessors may not provide consultancy and must avoid any conflict of interest
- Initial assessment may be cancelled based on deficiencies identified in document review




V2M3

 **4.0 Human Resources**


- 4.1 Procedures for assigning assessors
- 4.2 Education and Training requirements
 - Passing score on general assessments and technical – each scientific discipline
- 4.3 Records of assessors
- 4.4 Professional conduct



V2M3


 **4.3.5 CONSULTANCY**

- *Assessment team members shall not have provided consultancy to the CAB which might compromise the accreditation process and decision.*




V2M3

The New TNI Laboratory Accreditation Standard




M3 5.0 FREQUENCY OF ASSESSMENTS

- Every 2 years ± 6 months
 - Unannounced allowed
- Initial assessments are announced



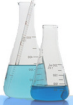
V2M3




M3 7.0 CHANGES IN CAB CAPABILITIES

- 30 day notice to AB of changes to:
 - Legal, commercial, ownership or organizational status
 - The organization, top management and key personnel*
 - Main policies
 - Resources and premises*
 - Scope of accreditation
 - Other such matters that may affect the ability to fulfill requirements for accreditation.*

*Talk to your AB!




V2M3



SUMMARY

- **Volume 1 Laboratory Requirements**
 - 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 Accreditation Body Requirements**
 - Module 1 – General Requirements
 - Module 2: Proficiency Testing
 - Module 3 – On-Site Assessment
- **Volume 3 Proficiency Testing Provider Requirements**
- **Volume 4 Proficiency Testing Oversight**




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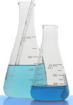
 **INTERPRETATION PROCESS**


- Complete on-line request form
 - www.nelac-institute.org/interpret-request.php
- Request sent to:
 - NELAP Board Chair, LASC Chair, TNI Staff
- Request then directed to:
 - LASC, Expert Committee, TAC, NELAP Board
- Preliminary opinion developed
- Opinion endorsed by NELAP Board
- Interpretation posted on website
- 4-6 week process




 **INTERPRETATION PROCESS**

- Process is NOT to be used to escalate a dispute between a laboratory and an Accreditation Body
- Some requests relate to method or EPA program interpretations
 - *Laboratories should attempt to reconcile all such interpretations with the applicable EPA Program*




 **CURRENT INTERPRETATIONS**

- 28 Completed in last 18 months
- 5 are from many years ago
- Most relate to the 2003 NELAC Standard
 - A few relate to method issues
- Most also apply to the TNI Standard



The New TNI Laboratory Accreditation Standard




M4: 1.7.2 CONTINUING CALIBRATION


Question

- A laboratory routinely will set up two consecutive CCVs. If the first CCV passes, the laboratory will not evaluate the second. However if the first CCV fails and the second one passes the laboratory will report all preceding and trailing samples as being acceptable.

Response

- Running a second CCV in a sequence is not the intent of the standard. This practice would require that the laboratory evaluate each of them on every occasion. There must be a form of corrective action (i.e., instrument maintenance) prior to the second CCV being evaluated.






M4 1.7.4.2 LCS


Question

- Can control limits include 0?

Response

- The laboratory would have to demonstrate how its data can meet all other aspects of the method and still generate control limits that include a 0% recovery. However, there is no restriction on control limits using 0 - look at PT criteria for soil.






M4 1.5 METHOD MODIFICATIONS

Question

- For Method 524.2, if DOC and MDL studies show that a 2 minutes desorb time achieves equal or greater method performance as the 4 minute desorb time, will this method modification meet requirements for drinking water volatile analysis

Response


- *The statement of "about 4 minutes" was to avoid issues with people demanding that desorb time be exactly 4.00000 minutes. It should be interpreted as times that could be rounded to 4, such as 3.5 to 4.4. It was not meant to allow drastically shorter times.*



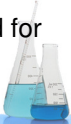
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 **Road to Accreditation**




 **REVIEW**

- A few minor changes in PT
- LOQ reporting in PT
- A few new requirements in ISO 17025
- A few new requirements in quality systems
- Several non-essential requirements deleted
- Interpretations and a Discussion Board for further clarification




 **COMING INTO COMPLIANCE: PT**


- Schedule 5 to 7 months
- **PT Reporting to LOQ**
- Document report to PT Provider
- Notify PT Provider of Corrective Action Sample




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 **COMING INTO COMPLIANCE: ISO**


- V1M2 4.7 Customer feedback
- V1M2 4.10 Continual improvement
- V1M2 4.11 Document corrective actions
- V1M2 4.14 Follow up internal audits
- V1M2 5.9 Assuring quality




 **COMING INTO COMPLIANCE: QS**

- V1M2 5.5.13 Support equipment: each day of use
- Maybe the DOC requirements
- Chlorine check for micro
- Specific items for radiochemistry and WET




 **COMING INTO COMPLIANCE: ASSESSMENT**


- V2M3 7.0 Notification of key changes




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 **ITEMS TO CONSIDER**

- Revise cover page of Quality Manual
- No documentation for when instrument received etc.
- Change SOP for expiration dates of reagents
- Quit using DOC form; don't file with personnel
- Implement easier system for continuing DOC
- Delete glassware cleaning SOP for chemistry
- etc.



 **ACTION PLAN**

- Obtain the new TNI Standards and **READ THEM**
- Implement new requirements that do not affect current NELAC accreditation
- Consider removing obsolete requirements
- Wait for further instructions on reporting on PT data
- Use your 2003 NELAC standard to prop up a wobbly table



 **SUMMARY**

- Major reorganization to simplify understanding
- Very few new requirements
- A lot of increased flexibility
- 15 months to prepare



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