



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



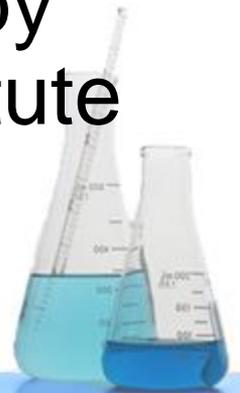
AGENDA

- 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



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

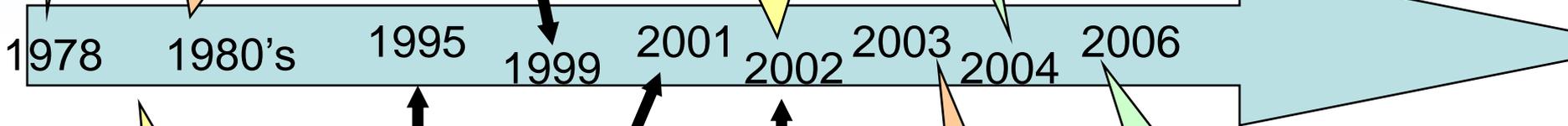
SDWA
Certification
Program



CLP De-facto
National
Program

Explore Self
Sufficiency

NELAC
Restructure



State
Programs
expand into
other media



inela

2003
NELAC
Standard

Explore
Self
Sufficiency



The Magic Box



<https://www.uber.com>

INELA NELAC TNI



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





TECHNICAL ASSISTANCE

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





SMALL LABORATORY ADVOCACY GROUP

The NELAC Institute <http://www.nelac-institute.org/board/>



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WHAT DOES TNI NOT DO?

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





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)



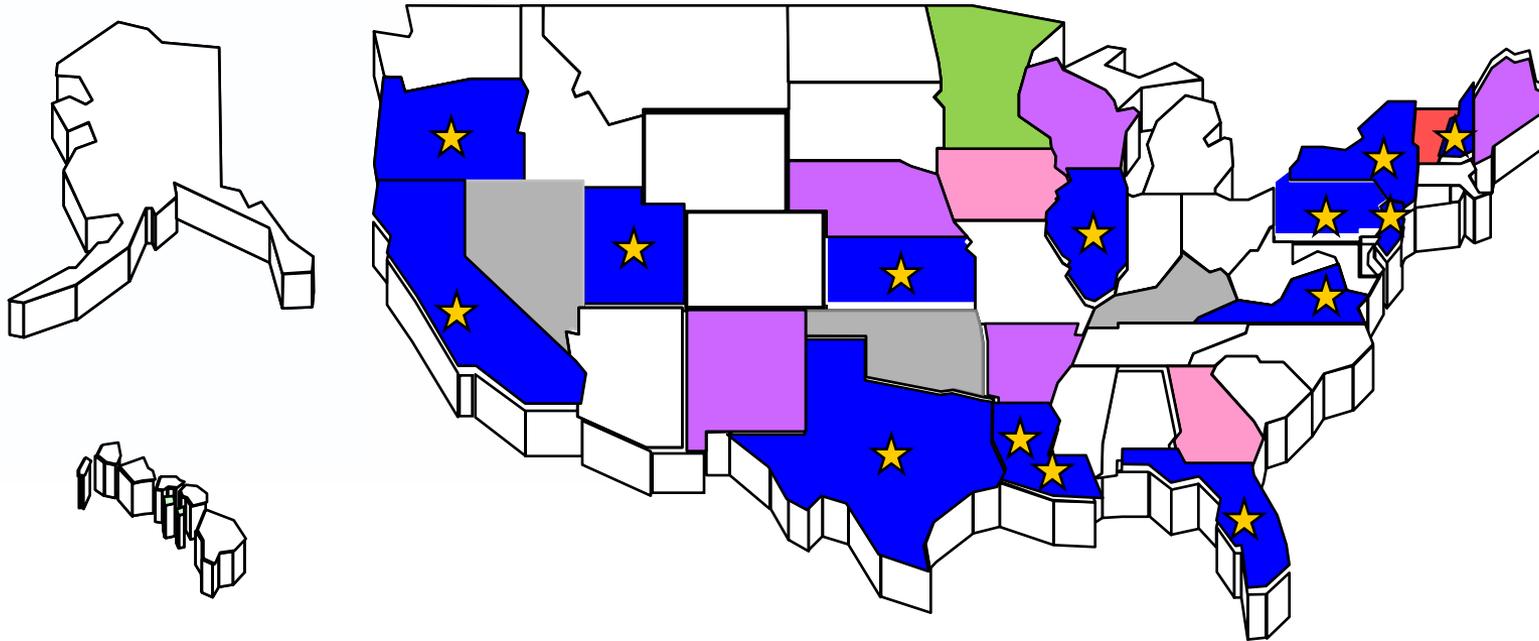


FUNDAMENTAL CONCEPTS

- 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.



NELAP ABs



-  NELAP Accreditation Body
-  Application Being Processed
-  Working on Program/Application
-  Require Program
-  Recognize Program
-  Incorporated Program Components





2003 STANDARD

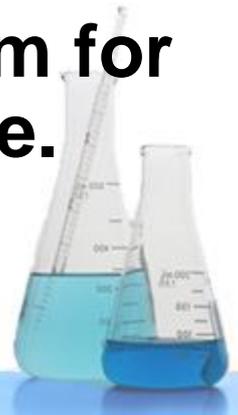
- One **Big** Document = One Standard
 - Constitution and Bylaws
 - Chapter 1: Program Policy & Structure
 - Chapter 2: Proficiency Testing
 - Chapter 3: On-Site Assessment
 - Chapter 4: Accreditation Process
 - Chapter 5: Quality Systems
 - Chapter 6: Accrediting Authority





The 2003 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.
-  **2003 is the best accreditation program for environmental laboratories currently in use.**





The 2003 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



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  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.





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

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TNI Standards

Open All Close All

- ▶ 2003 NELAC Standard
- ▶ TNI Standards
- ▶ Sale Of TNI Standards
- ▶ Consensus Standards Development Process
- ▶ Adoption and Implementation of TNI Standards

news

Nominations for 2010 Board of Directors
16 February 2010

(Updated) Workshops on Implementing the New TNI Standards Planned In 2010
11 February 2010

New PT Subcommittee being formed for the development of a PT Table for NEFAP
9 February 2010

Final Program for TNI Forum Chicago Published
22 January 2010

FAQ for Stationary Source Audit Sample Program now available
20 January 2010

Fields of Proficiency Testing Table for Non-Potable Water Updated
13 January 2010

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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

- **This is a significant new requirement**

Deleted or relaxed requirement

- This is a good change





DISCUSSION BOARD

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ISO 17025 ACCREDITATION

- 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
- Why? TNI is not recognized by ILAC
 - International Laboratory Accreditation Cooperation



PROFICIENCY TESTING





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

*Same as 2003 



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



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



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.



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





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



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.



EVALUATION OF RESULTS

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

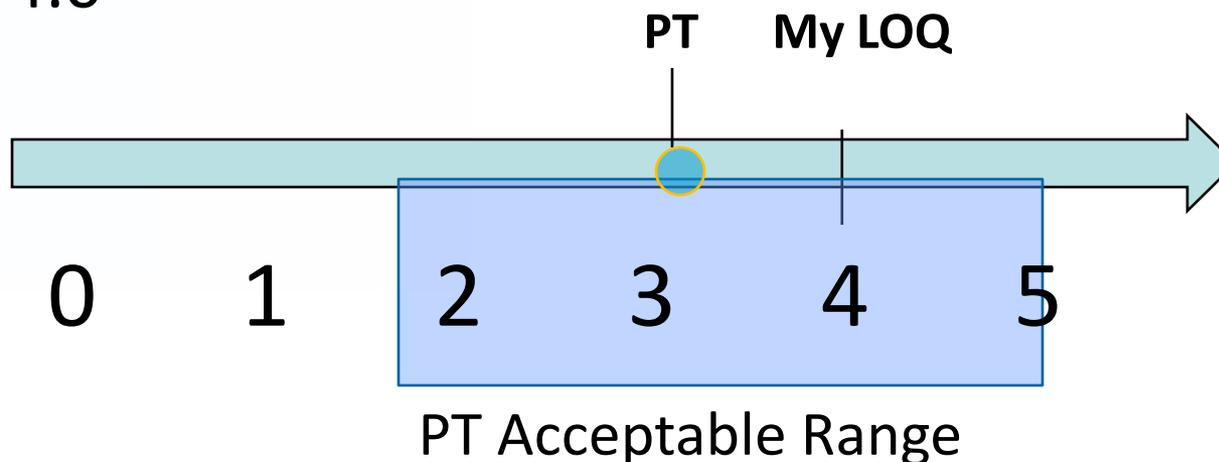


Evaluation of Results

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

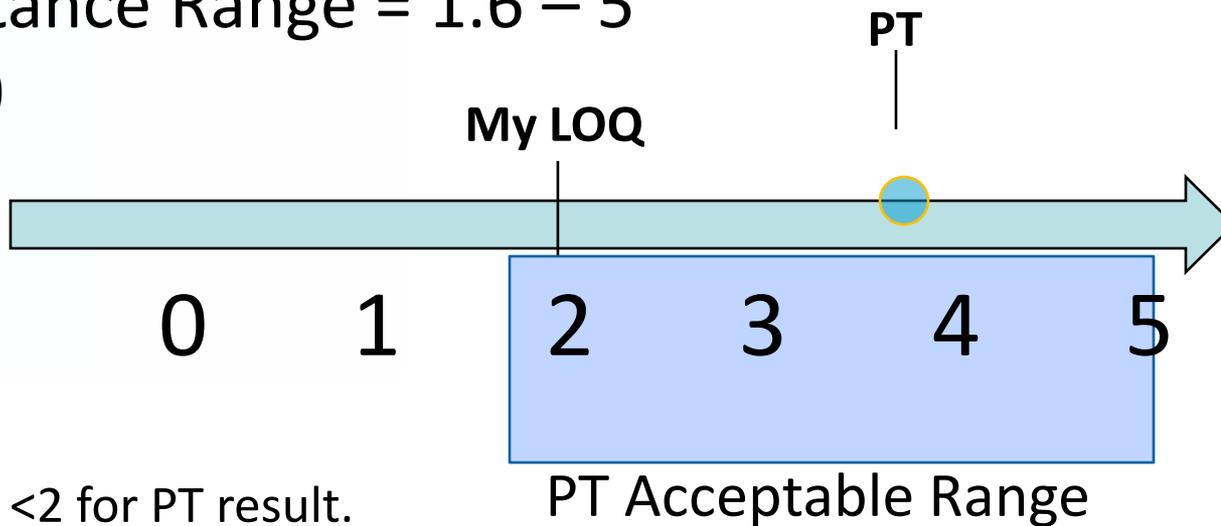


Evaluation of Results

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





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 than 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.



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.**



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



7.0 COMPLAINTS

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





SUSPENSION AND REVOCACTION

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



QUALITY SYSTEMS





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





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



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



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

- 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



4.7 Service to Customer

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

ISO 17025 Change



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

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



4.14 Internal Audits

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



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



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).



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.



NEW DEFINITIONS

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



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!





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



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”



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



SAMPLE HANDLING



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.”



5.2 PERSONNEL

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





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



DATA INTEGRITY

NELAC

- 5.4.2.6 Data Integrity Procedures
- 5.5.2.7 Data Integrity Training

TNI

- 4.2.8.1 Management requirements
- 4.16 Data Integrity Investigations
- 5.2.7 Data Integrity Training

Comparable language
with equal intent



5.3 ACCOMODATIONS

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



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.



5.5.13 DAILY CHECK



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.



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**



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



REPORTING UNITS

nelac 5.5.10.2

- 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;

TNI

- 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).



REPORTING QC FAILURES



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;



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;



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



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

- 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

Where's D.5
(Air)?

It's in
V1M4
Chemical



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



Demonstration of Capability

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

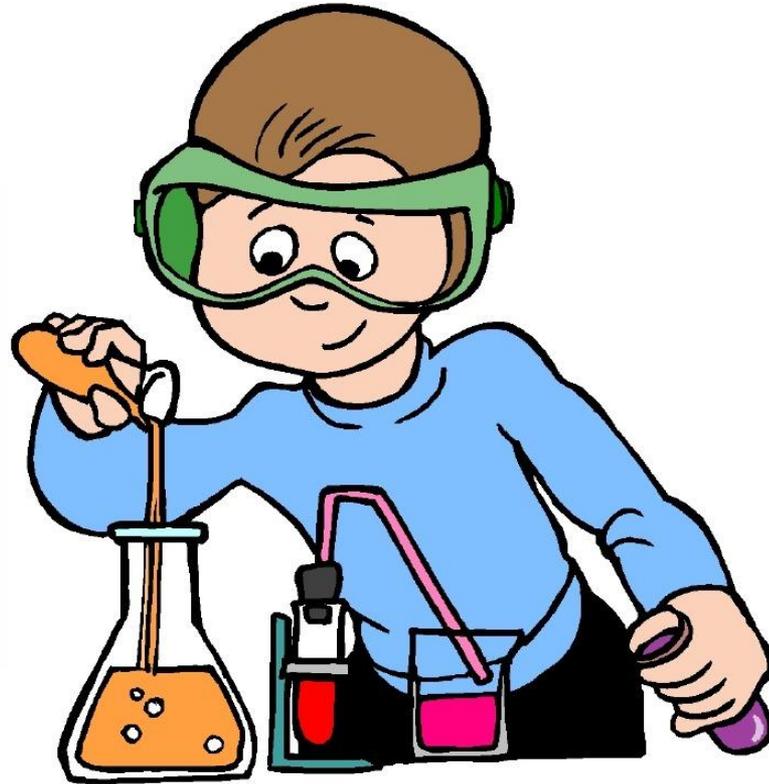




Technical Requirements

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





Module 4: Chemistry



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



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



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



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



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.



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



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



ISO and TNI

ISO 5.4.5.1

- 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)

- 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

- The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use....

TNI 1.5 (b)

- The laboratory shall validate non-reference methods, laboratory-designed/developed methods, reference methods used outside their published scope, and amplifications and modifications of reference 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.



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



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





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



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”



1.5.3 PRECISION AND BIAS

Reference Methods

- Initial DOC, or
- Alternate procedure

Non-Reference Methods

- Evaluate precision and bias across the analytical range
 - e.g., Triplicates analyzed at multiple concentrations
 - EPA Tier 1, 2, or 3 ATP procedure
- Same as  C.3.3(b)



ISO and TNI

ISO 5.4.5.3

- 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.

TNI ???



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



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**





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?



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



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



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



1.7 QUALITY CONTROL

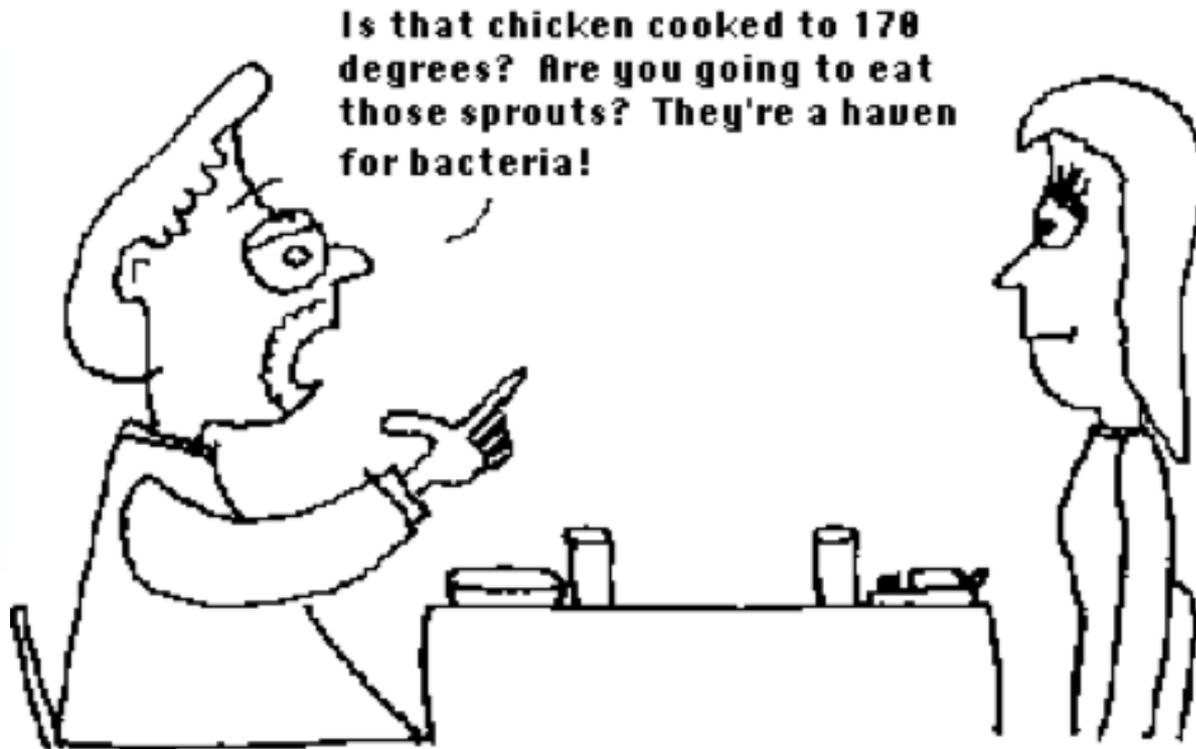
- No change from NELAC Appendix D.1
- Reorganized with evaluation criteria as a separate section
 - Method Blank
 - LCS
 - MS/MSD
 - MD
 - Surrogates
 - ✦ For failed surrogates, must qualify data (was a “should”)



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





**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



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**



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



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





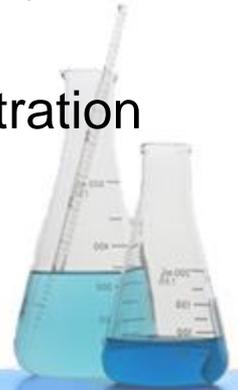
CHLORINE CHECK

- 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.



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.





MODULE 6: RADIOCHEMICAL



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





1.5 PRECISION AND BIAS

Reference Methods

- Initial DOC

Non-Reference Methods

- Documented procedure with example provided



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



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



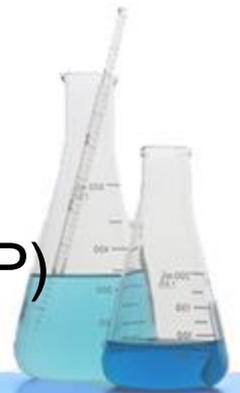
1.7 MATRIX SPIKES

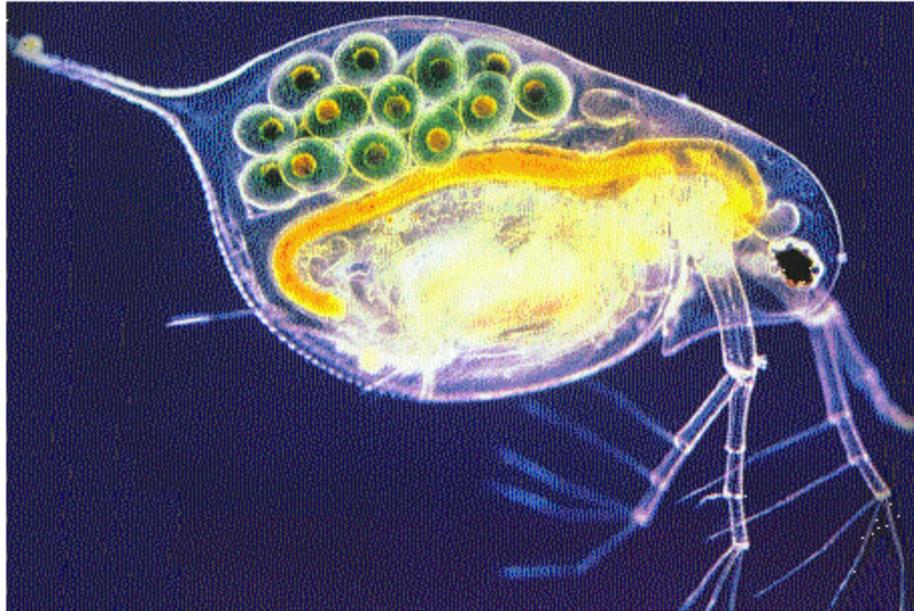
- The frequency of the analysis of matrix replicates and duplicates are as specified by the test method or may be determined as part of the contract review process
- NELAC 2003 required one per prep batch



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)





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





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)







TNI NELAP STANDARDS

- Volume 2 Accreditation Body Requirements
 - Module 1 – General Requirements
 - Module 3 – On-Site Assessment





REQUIREMENTS FOR ACCREDITATION BODIES

- NELAC 2003
 - 1 Program Policy
 - ✦ Scope of Accreditation
 - ✦ Reciprocity
 - ✦ Secondary Accreditation
 - 2 Proficiency Testing
 - 3 On-Site Assessment
 - 4 Accreditation Process
 - 6 Accrediting Authority
 - Policies
- TNI Volume 2
 - Module 1: General Requirements
 - Module 2: Proficiency Testing
 - Module 3: On-Site Assessment
 - Guidance and SOPs



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

- Registered legal entity
- Implement Quality System
 - Document Control
 - Records
 - Corrective actions
 - Preventative Actions
 - Internal audits
- Qualified Personnel

ISO 17025

- Registered legal entity
- Implement Quality System
 - Document Control
 - Records
 - Corrective actions
 - Preventative Actions
 - Internal audits
- Qualified Personnel





Approval Programs

Accreditation Bodies

- ❑ 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

- ❑ 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





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



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





7. ACCREDITATION PROCESS

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



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



8. AB RESPONSIBILITIES

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



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





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



TYPES OF ASSESSMENTS

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



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



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



4.3.5 CONSULTANCY

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





M3 5.0 FREQUENCY OF ASSESSMENTS

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





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!**



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





INTERPRETATIONS AND CLARIFICATIONS

- Official responses to requests
- Posted on the TNI website
 - <http://www.nelac-institute.org/interpret.php>
- Applicable to 2003 NELAC Standard
- Many also applicable to TNI Standards





Standards Interpretation Request

<http://www.nelac-institute.org/interpret-request.php>



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Member Page

Standards Interpretation

TNI has established an avenue for resolution of questions submitted electronically on interpretation of the 2003 NELAC Standard. The method for submittal is to complete the form below. Use of this entry form ensures that a question is automatically accepted, cataloged and emailed to the NELAP Board Chair, the LASC Chair and the TNI Program Administrator for review. A consensus of these three individuals shall determine who oversees the final disposition of the question. Timelines are defined for the NELAP Board Chair and LASC Chair to ensure a timely response to the question. Publication of the consensus resolution is then made to the affected parties via email and on the TNI web site. Please remember that any disputes between a laboratory and their AB regarding accreditation are to be handled through the appropriate appeals process established by applicable state laws and regulations. Your question should be clearly stated.

Please use this form to submit a request for standard interpretation to TNI.

Request for 2003 NELAC Standards Interpretation

Name *

First Last

Email *

Phone

 - -
(###) ### ####

Organization *

Address

Street Address

Address Line 2

City

State / Province / Region

Postal / Zip Code

Country

Are there others who should receive the TNI response as well?



The Interpretations

<http://www.nelac-institute.org/interpret.php>

The NELAC Institute

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2003 NELAC Standard Interpretations

[Open All](#) [Close All](#)

- ▶ Chapter 1 - Program Policy & Structure
- ▶ Chapter 2 - Proficiency Testing
- ▶ Chapter 3 - On-Site Assessment
- ▶ Chapter 4 - Accreditation Process
- ▼ Chapter 5 - Quality Systems

5.4.3.2.2 (b)
Frequency of Document Review (10/25/2008)

[View Request & Final Response Online](#)

5.4.12.2.2
Technical Records (12/19/2008)

[View Request & Final Response Online](#)

5.5.4.1.1
Standard Operating Procedures (SOPs) (10/25/2008)

[View Request & Final Response Online](#)

5.5.4.2.2
Demonstration of Capability (10/25/2008)

[View Request & Final Response Online](#)

STANDARDS INTERPRETATION REQUEST

Section: 5.4.3.2.2 (b)

REQUEST:

The above section requires documents to be reviewed "periodically". I have interpreted this to mean that NELAC wants the documents reviewed but requires the lab to establish the frequency. NELAC further supports this position by specifically requiring data integrity procedure to be reviewed annually (5.4.2.6). However, some assessors with whom I work take the position that since 5.4.14.1 requires labs to annually review the "suitability of procedures" and 5.4.13.1 requires labs to annually conduct audits on "all elements of the quality system" that these are inferred or indirect requirements to annually review all procedures. Since 5.4.3.2.2.b addresses the issue directly, I take the position that it prevails over any indirect or inferred interpretation of the standard. Agree? Disagree?

TNI FINAL RESPONSE:

(Quality Systems Expert Committee/NELAC Board, 10-25-08)

The Quality Systems Committee sees no conflict here. The internal audits must show compliance with the laboratories policies and procedures. This is a procedural review for compliance and suitability.

The periodic review of SOPs is set by the lab and does require that technical management review current procedures. This can be done with internal method audits. If the AB finds issues that would indicate that periodically has been stretched too long, then the AB could impose a finding that would require the timeframe be shortened.

Also, support procedures can be allowed to have longer periods between review, such as when changes are needed due to a change in laboratory practice.

news

Nominations for 2010 Board of Directors
16 February 2010

(Updated) Workshops on Implementing the New TNI Standards Planned In 2010
11 February 2010

[MOVE](#) [PRINT](#) [CLOSE](#)

Mon, Mar 1 1:30pm

Chemistry FoPT Call





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





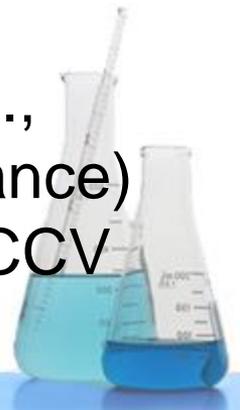
M4: 1.7.2 CONTINUING CALIBRATION

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.



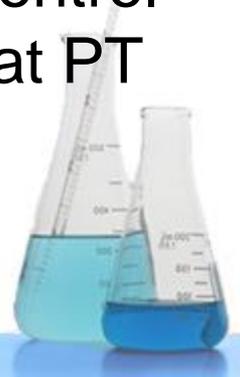
M4 1.7.4.2 LCS

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.*



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



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



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





Contact TNI

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