



OELA 2024 Environmental Laboratory Conference

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**Future Changes to the TNI National Environmental Laboratory
Accreditation Program (NELAP) Standard**

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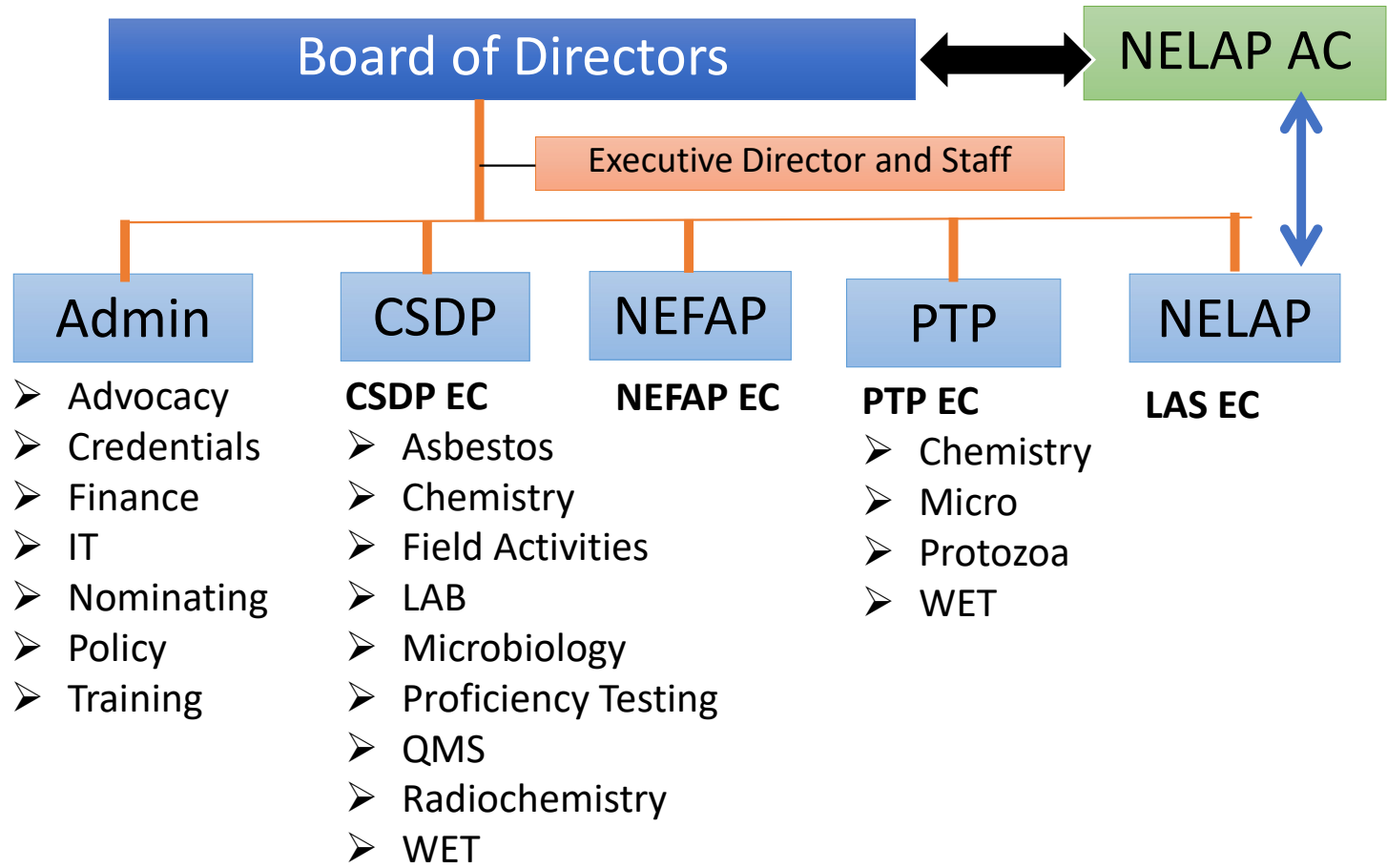
Agenda

- ❑ TNI and the Standards Development Process
- ❑ Revisions to the 2016 Standard underway
 - 4 Volumes and 9 Modules
- ❑ Implementation





The NELAC Institute





INTERRELATIONSHIPS OF KEY LABORATORY PROGRAMS

Consensus Standards Development

- Laboratory Standards
- AB Standards
- PT Standards

NELAP

- Adopt standards for use
- Recognize ABs
- Implement Standards

Educational Delivery System

- Develop Training and other Tools and Templates to assist labs and ABs with implementation

PT Program

- Implement PT Standards
- Recognize PT Provider Accreditors
- Establish PT Program Details





Standards Development in TNI

- ❑ Conforms to OMB A-119 and ANSI Essential Requirements.
 - Balance of interest
 - Openness
 - Due process
 - Consensus
 - Appeals process





Standards Development Process

- ❑ A Notice of Intent is published on the TNI website.
- ❑ Expert Committees develop language during in-person and virtual meetings and publish draft standard for comment.
- ❑ Any TNI member or member of the public may provide comment.
 - Persuasive comments require revision of Draft Standard
 - Non-persuasive comments require development of a Response to Comments document.
- ❑ Draft Standard goes through as many revisions as are necessary to achieve acceptance by the Expert Committee and no additional persuasive comments.





Providing Comments

Persuasive

- The verification of the MDL using blanks is in conflict with the EPA procedure, specifically by not allowing the use of the 99th percentile.
- The requirements for checking calibration error for ion selective electrodes are not appropriate.

Non-persuasive

- I do not think my lab has to calculate an MDL based on blanks.
- I do not have to calibrate an ion selective electrode.





Voting and Associate Members

- ❑ Per OMB A-119 and ANSI, consensus bodies must have a balance of stakeholder interests. For TNI this is:
 - Accreditation Body
 - Accredited Organization (e.g. Laboratory or FSMO)
 - Other (e.g. Consultant, Regulator, PT Provider)
- ❑ Expert Committee Voting members are the only ones that vote to adopt a standard.
- ❑ Associate members can fully participate in the process.





Approval and Implementation

- ❑ The process of revise – committee approval – public comment continues until there are no persuasive comments. The Standard is then approved.
- ❑ A final review among the Consensus Standards Development Chairs and the Accreditation Council searches for conflict across standards.
- ❑ Standard then provided to other TNI groups.
 - Laboratory Accreditation System Executive Committee (review for suitability)
 - NELAP Accreditation Council (AC)
 - Proficiency Testing Executive Committee
- ❑ NELAP AC adopts standard for use in the program with an effective date for Volumes 1 and 2; PTP EC adopts and sets date for Volumes 3 and 4.





New TNI Accreditation Standards (2025?)

Environmental Sector

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: Toxicological Testing

Volume 2 Accreditation Body Requirements

- Module 1: Accreditation Body Requirements
- Module 2: Proficiency Testing
- ~~Module 3: On-Site Assessment~~

Volume 3 Proficiency Testing Provider Requirements

Volume 4 Proficiency Testing Provider Accreditors





Status of PT Standards

- All Volumes/Modules are being revised.
- Potential substantive change for V1M1 (laboratory requirements)
 - Allow 1 PT sample/year for laboratories only doing in-state work.
- No substantive changes for V2M2 (AB requirements).
- Volume 3 (PT Provider)
 - Update to ISO/IEC 17043:2023
 - Reference Guide 30 (reference materials and 13528 (statistical methods)
 - Clarification on supplemental PTs
- Volume 4 (PT Provider Accreditor)
 - Minor edits





V1M2 – Quality Management Systems

- ISO 17025:2005 → ISO 17025:2017
- Definitions
 - What are: Procedures, Policies, Documents, Systems...
- Data Integrity
- Calibration of Support equipment
- Other Changes
- Technical Manager → Technical Specialist





Objectives of 17025 Revision

- ❑ Align structure and content with other recently revised ISO standards
 - Other 17000-series documents
 - ISO 9001
- ❑ Focus on outcomes rather than prescriptive requirements
 - Less variety in terms used to describe required documentation
 - Elimination of some favorite terms (e.g., quality manual, quality manager, subcontracting, etc.)
 - More flexibility for laboratories
- ❑ Requirements for information systems/records more reflective of current technologies





Organization of ISO/IEC 17025 (and TNI Module 2)

2005

1. Scope
2. Normative references
3. Terms and definitions
4. **Management requirements**
5. **Technical requirements**

2017

1. Scope
2. Normative references
3. Terms and definitions
4. **General requirements**
5. **Structural requirements**
6. **Resource requirements**
7. **Process requirements**
8. **Management requirements**





ISO 17025:2005 → ISO 17025:2017

□ Workgroup Efforts

- Compared 17025:2005 language to 17025:2017
- TNI kept some language from 2005 to 17025:2017
- Important to note that things that are 'missing' haven't been removed as requirements – they are stated elsewhere



Definitions

- ❑ Annual, Quarterly, Customer, Procedure, Corrective Action
 - We couldn't define 'Support Equipment', so we added clarifying (we hope) language
 - We had proposed language for Duplicate and Replicate, but they were very unpopular
- ❑ Standardizing the use of Policy → Procedure → Process
 - Replacing terms like 'instructions', 'measures', 'systems'
 - ISO language reviewed for its use of procedure, and it doesn't seem problematic with our definition
- ❑ Information that is procedural in nature is being removed from many definitions.





Language Workgroup

- SOPs
 - Clarifying Method vs. Administrative requirements
 - List of items isn't a required format
- Unique identification of a sample – breakthrough!
- Clarify the meaning of 'undue delay' in 17025:2017 as it relates to implementing corrective actions





Containers - Unique or Traceable?

“All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date.”

- We’ve written a ‘how to comply’ requirement
- The requirement is for traceability

BECOMES

“The laboratory shall maintain records for [the preparation of reagents] that include an unequivocal link to the products used, mass, volumes, and/or quantities used, date of preparation, expiration date, and preparer's initials.”





Data Integrity in One Section



A Data Integrity System



1. Data Integrity Procedures



2. Data Integrity Training



3. Periodic In-depth Data Monitoring



4. Data Integrity Investigation





Calibration of Support Equipment

- New table summarizing requirements

Equipment	Activity	Frequency
Balances	Verify the range of use	Daily Before Use





Technical Specialist (nee Technical Manager)

- Cross-organizational effort
 - Competency Task Force
 - Expert Committees
 - Accreditation Council
- Exceptions will still exist
- No current Technical Manager will be disqualified
- Educational requirements relaxed
- Each Technical Module can specify additional requirements





Technical Specialist

- Must have a working knowledge of relevant TNI Standard requirements
- Must have responsibility and authority for the management of nonconforming work
- Must serve as the responsible individual regarding all processes involved in generating data from an analytical discipline
- May be responsible at more than one location.
- Coursework records must be maintained.
- TNI credential can be use as an alternative.





Technical Specialist

REQUIREMENTS

- bachelor's, master's or doctoral degree and one (1) year of experience,
- four (4) college level STEM (science, technology, engineering, math) courses and three (3) years of experience,
- be a full-time employee of a drinking water or sewage treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility and have two (2) years of experience, **OR**
- TNI technical specialist credential for each analytical discipline and one (1) year of experience





Analytical Discipline

- ❑ “Simple” – Preparation, Inorganic Nonmetals, Inorganic Metals, Organic Analysis, Microbiology, Toxicity, Radiochemistry
- ❑ “Complex” – Inorganic Nonmetals becomes UV/VIS, Titrimetric, Gravimetric, Ion Chromatography, ISE, Autoanalyzer Techniques, Turbidimetry, Electrometric determinations, Dissolved Oxygen Depletion, Combustion, Luminescence Sensors





Analytical Discipline

- ❑ Joint effort of many TNI committees including all technical committees, QMS, and Credentials
- ❑ Special session on February 3, 2025 in Jacksonville, FL to present plan.
- ❑ Thoughts and comments encouraged.





Modules 3-7

- ❑ Technical Modules are formatted similarly
- ❑ Consistent and Revised Numbering
 - 1 Introduction
 - 2 Scope
 - 3 Terms and Definitions
 - 4 **Technical Specialist**
 - 5 Method Selection
 - 6 Method Validation **& Verification**
 - 7 Demonstration of Capability
 - 8 Technical Requirements
- 1.1 Introduction
- 1.2 Scope
- 1.3 Terms and Definitions
- 1.4 Method Selection
- 1.5 Method Validation
- 1.6 Demonstration of Capability
- 1.7 Technical Requirements





Asbestos Module

- Module re-written from a technology standpoint.
- Public Comment on the revised Module 3 opened in February '23.
- No persuasive comments were received, the Module is final effective July, 2023.
 - “Final” means approved by the CSDP, not adopted into NELAP.
- Final review for any potential conflicts in the Module is the final step before completion.
- A webinar will be made regarding the changes.





Technical Specialist - Asbestos

- ❑ Transmission Electron Microscope
 - Bachelor's Degree in a scientific discipline
 - Course in use of the instrument
 - 1 year of experience
- ❑ Polarized Light Microscope
 - Associate Degree or 2 years of college study in a scientific discipline
 - Coursework in polarized light microscopy
 - 1 year of experience
- ❑ Phase Contrast Microscope
 - Associate Degree or 2 years of college study in a scientific discipline
 - NIOSH 582 (or equivalent) course in phase contrast microscopy
 - 1 year of experience





Changes to the Chemistry Module

- ❑ Method Selection, Validation, and Verification
- ❑ Detection/Quantitation Limits
- ❑ Demonstration of Capability
- ❑ Calibration
- ❑ Extensive rewrite for clarify with little change in intent
 - Quality Control
 - Reagent Quality
 - Sample Handling
- ❑ Global Changes
 - Document/Record; Corrective Action/Correction
 - Removal of explanatory language





Method Selection, Validation and Verification

- ❑ Removed example from Method Selection
- ❑ Clear distinction of Validation of non-reference methods and Verification for reference methods.
 - Consistent with 7.2 of ISO/IEC 17025 and Module 2.
- ❑ Includes on-going verification of DL/LOQ and DOC.





Detection and Quantitation

- ❑ TNI 2016 Standard published before 2017 EPA MDL.
- ❑ Although TNI developed the MDL procedure and provided it to EPA, EPA made changes.
- ❑ Result: TNI and EPA language different.
- ❑ 2025 Standard: Remove all TNI language relative to detection limits and reference EPA procedure.
- ❑ DL verification not required if DL reporting is not done.
- ❑ No changes to LOQ section





Demonstration of Capability

- ❑ Initial DOC – Extensive rewrite for clarity with little change in intent.
- ❑ On-going Doc – Delete section
 - This became little more than an exercise
 - Training is the important part of this





Calibration

- ❑ Extensive rewrite for clarity with no change in intent
- ❑ An ISE exemption for calibration points will be included
- ❑ Note that the current exemption for the number of points needed in ICP comes AFTER the table that lists the required number of points in a calibration





Technical Specialist - Chemistry

- ❑ Chemical Testing
 - Bachelor's Degree in an assortment of science fields
 - 2 years of experience in the representative technology
- ❑ Chemical Testing – limited to inorganic, non-metals
 - Associate Degree in an assortment of science fields
 - 1 year of experience in the representative technology
- ❑ A Master's Degree may substitute for half of the required experience above





V1M5 Microbiology

□ Goals:

- To outline minimum requirements of Quality Systems for Microbiology Laboratory
- To make intent and requirements clear

□ Updates:

- Reorganized to improve readability
- Reworded to improve clarity





Changes to Sections 2.0, 3.0 and 4.0

- ❑ Section 2.0: Scope
 - Added language stating that records must be retained in accordance with V1M2 5.4.6.2
- ❑ Section 3.0: Terms and Definitions
 - Added definitions for Positive and Negative Culture Controls



Changes to 7.3.1

2016 Standard V1M5

- Sterility checks
- Media checks
- Shelf life/expiration date
- Reagent water testing
- Dilution water testing
- Documentation

V1M5 Revised DS

- Sterility checks
- Media checks
- Dilution water testing
- Reagent water testing
- Documentation
- Shelf life/expiration date





Technical Specialist - Microbiology

- ❑ Microbiological Testing
 - Bachelor's Degree in an assortment of science fields
 - 1 college-level microbiology course
 - 2 years of experience in the representative technology (Masters or Doctors Degree can substitute for 1 year)
- ❑ Microbiological Testing – limited to 'simpler techniques'
 - Associate Degree or equivalent college education in an appropriate science field
 - 1 college-level microbiology course
 - 1 year of experience in the representative technology (Bachelor's, Masters, or Doctors Degree can substitute for 6 months)





Technical Specialist - Microbiology

- ❑ Microbiological Testing
 - ~~Bachelor's Degree in an assortment of science fields~~
 - 1 college-level microbiology course
 - ~~2 years of experience in the representative technology (Masters or Doctors Degree can substitute for 1 year)~~
- ❑ ~~Microbiological Testing – limited to 'simpler techniques'~~
 - ~~Associate Degree or equivalent college education in an appropriate science field~~
 - ~~1 college-level microbiology course~~
 - ~~1 year of experience in the representative technology (Bachelor's, Masters, or Doctors Degree can substitute for 6 months)~~





Module 6 - Radiochemistry

- Public Comment on the revised Module 6 closed in April '22
- Few comments were received, and none were ruled persuasive
- Response to Comment Document was posted January '23
- Final review for any potential conflicts in the Module is the final step before completion





Technical Specialist - Radiochemistry

- ❑ 8 college or equivalent technical courses, in any combination of chemistry, physics, or equivalent scientific discipline
- ❑ 1 college or equivalent technical course in radiochemistry for each technology (not to exceed 4 courses)
- ❑ 2 years of experience in the representative technology (Masters or Doctors Degree can substitute for 1 year)
- ❑ Required courses above may be substituted with additional years of experience working in an environmental radiochemical testing laboratory beyond the 2 years required





Module 7 – Whole Effluent Toxicity

- Demonstration of Capability is complete
- Essential Quality Control requirements have been completed
- Technical Requirements section is the last part under discussion





Technical Specialist – Whole Effluent Toxicity

- ❑ Bachelor's Degree in an assortment of science fields
- ❑ 4 college-level biological or environmental science courses
- ❑ 2 years of experience in toxicity testing of environmental samples representative of the analyses responsible
 - Masters or Doctors Degree can substitute for 1 year
 - Additional years of experience may be substituted for up to 2 of the courses. or of experience shall substitute for 1 course





V2M1: Accreditation Body

- Modules 1 (AB requirements) & 3 (on-site assessment) will be combined.
- Update to 2017 version of ISO/IEC 17011.
- Limited ability to conduct remote assessment.





STANDARDS DEVELOPMENT AND IMPLEMENTATION

Expert Committees develop language thru consensus process

February 2025?



LASEC reviews for suitability for NELAP

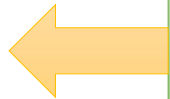
August 2025?



NELAP AC adopts standard into NELAP with effective date

TNI develops “tools” to assist labs and ABs

2025?



Adoption November 2025; effective 2027-28





TNI Implementation Tools

- Detailed comparison document
- Training courses for laboratories and assessors
- New checklists
- Revised quality manual template
- Guidance documents on complex topics







SUMMARY

- ❑ Significant changes underway but years from completion.
- ❑ We invite you to actively participate in our activities.
 - Provide persuasive comments on a draft standard
- ❑ Join TNI.
- ❑ Join a TNI committee.
 - As a Voting Member
 - As an Associate





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upcoming live training:
Environmental Laboratory Assessments - Basic Assessor Training: Austin, TX
Seminar by Marlene Moore, Starts Apr 21, 2020

