



Changes Coming to the 2016 TNI Laboratory Accreditation Standard

September 24, 2026
IAS ELAP Symposium
Brea, CA

Jerry Parr – The NELAC Institute



Standards Development Process

- ❑ A **Notice of Intent** requests comment on a new standard or proposed changes to an existing one.
- ❑ Standards development must meet the requirements of OMB A-119:
 - Balance, Openness, Due Process, Consensus, Appeals
- ❑ Committee considers previous comments and Standard Interpretation Requests (SIRs) and develops a Draft Standard.
- ❑ Draft Standard goes through as many revisions as are necessary to achieve acceptance by the Expert Committee and no additional persuasive comments.
- ❑ Meetings of any sort may be held to request comment.



TNI COMMITTEE OPERATION

- ☐ 5-15 Members representing stakeholder interests
 - Accreditation Body
 - Laboratory
 - Other (PT Provider, Consultant, Vendor, etc.)
- ☐ Committee must have balanced representation
- ☐ No more than 2 members from one organization
- ☐ May serve 2 3-year terms
- ☐ Develop standards by consensus
- ☐ Associate members may fully participate but do not vote

Consensus: General agreement, but not necessarily unanimity.





Thank You California!

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Socorro Baldonado
Clifford Baldrige
Hei Man Barrio
Carlita Barton
Steve Boggs
Kenneth Brown
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Prasanth Ramakrishnan
Bill Ray
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Lily Sanchez
Nicole Van Aken
Marie Wu
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BE THE
change
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the world

-MAHATMA GANDHI



EXPERT COMMITTEES

Asbestos (3A, 3L, 10)	EL Volume 1, Module 3
Chemistry (6A, 7L, 20)	EL Volume 1, Module 4
Field Activities (4A, 4L, 30)	FSMO Standards, Volumes 1 and 2
Microbiology (4A, 6L, 40)	EL Volume 1, Module 5
Proficiency Testing (PT) (5A, 3L, 50)	EL Volume 1, Module 1 (Laboratory), EL Volume 2, Module 2 (AB), EL Volume 3 (PT Provider), EL Volume 4 (PT Provider AB)
Radiochemistry (2A, 4L, 20)	EL Volume 1, Module 6
Laboratory Accreditation Body (4A, 3L, 30)	EL Volume 2, Module 1
Quality Management Systems (6A, 5L, 20)	EL Volume 1, Module 2
Whole Effluent Toxicity (3A, 5L, 30)	EL Volume 1, Module 7



PT Standards – Volume 4

- ❑ General Requirements for an Accreditation Body of Environmental Proficiency Test Providers
 - Total rewrite of the standard consistent with ISO 17011
 - Other changes include:
 - PTPA to PTP AB
 - PT Provider must be accredited to ISO 17034 (Reference Material Producer)
 - Annual report from PTAB to TNI
 - Many other minor changes for clarity
 - Draft posted July 31 for 60 days
 - Comment period closes **September 29**
 - Committee will present Response to Comments on January 11 in Long Beach



PT Standards – Volume 3

- ❑ Volume 3 – General Requirements for Environmental Proficiency Test Providers
- ❑ Volume 3 is the next most ‘urgent’ revision
 - It is being reviewed to ensure consistency with Volume 4
 - Targeting November 2026 for posting of draft Module
 - Committee will present proposed changes and Response to Comments on January 11 in Long Beach





PT Standards Volumes 1, Module 1 and Volume 2, Module 2

- ❑ Volume 1, Module 1 – Management and Technical Requirements for Laboratories performing Environmental Testing: Proficiency Testing
- ❑ Volume 2, Module 2 – General Requirements for Accreditation Bodies Accrediting Environmental Laboratories: Proficiency Testing
- ❑ Volumes 1 & 2 will have minor changes to align with Volumes 3 & 4
 - Draft language to be presented January 14 , 2027 in Long Beach
 - May include a 1 PT option for in-state laboratories
 - TNI-2 becomes TNI-1?

PT Committee now meeting twice monthly to meet these goals.



Module 2 – Quality Management Systems: Overview

Total rewrite with many significant changes.

- ☐ Scope
- ☐ ISO 17025:2005 → ISO 17025:2017
- ☐ Terms and definitions
- ☐ Data integrity in one section
- ☐ Requirements from Volume 2
- ☐ Annex C: Non-Mandatory information on Technical Specialist
- ☐ Draft posted May 26, 2026 closing **September 26**

These changes were all covered in the 2025 ELAP Symposium



Changes since October 2026

- ☐ Final revisions to Technical Specialist
- ☐ Incorporation of language from Volume 2
- ☐ Annex C



Technical Specialist Background

- ❑ The Educational and Experience requirements for a Technical Manager have been problematic since the inception of NELAP.
 - Individuals possessing the required experienced education and experience are not always competent.
 - Individuals who do not have the required experienced education and experience are sometimes very competent.
 - This issue is particularly problematic in rural areas.
 - The exceptions for “legacy” individuals is fading away as individuals retire.
 - This is one of 2 exceptions in the California regulations
- ❑ Everyone agrees individuals should be qualified.



Technical Specialist (nee Technical Manager)

- ☐ Cross-organizational effort over 5 years
 - Competency Task Force
 - Expert Committees
 - Accreditation Council
- ☐ Exceptions will still exist
- ☐ No current Technical Manager will be disqualified
- ☐ New options for meeting educational requirements
 - TNI-1 becomes TNI-0?



Technical Specialist Overview

- ☐ Required for every field of accreditation held by the laboratory.
 - Understanding of quality management systems
 - Supervisory role NOT required
 - Key authority in a specific area of responsibility
 - May be filled by multiple people
- ☐ May be responsible at more than one location.
- ☐ Coursework records must be maintained.
- ☐ Minimum education and experience required.
 - TNI credential can be use as an alternative for meeting some educational requirements.



Technical Specialist Duties

- ❑ The laboratory must have a Technical Specialist(s) to provide technical guidance to laboratory personnel for all work associated with the laboratory's scope of accreditation
- ❑ The laboratory must clearly define its technical structure and how Technical Specialist responsibilities align with the laboratory's scope
- ❑ A laboratory may have one or more Technical Specialists that may also hold additional primary job responsibilities



Technical Specialist Requirements - 1

5.6.3 The laboratory must have a Technical Specialist(s) (however named) to **provide technical guidance** to laboratory personnel for all work associated with the laboratory's scope of accreditation. The **laboratory must clearly define its technical structure and how Technical Specialist responsibilities align with the laboratory's scope**. A laboratory may have one or more Technical Specialists that may also hold additional primary job responsibilities. **Annex C** provides examples of how a laboratory may define this structure.



Technical Specialist Requirements - 2

5.6.3.1 Technical Specialist(s) must:

a) **ensure laboratory activities** related to the generation of analytical data and test results, including but not limited to method development and validation, procedure development, sample preparation, instrument calibration, sample analysis, quality control, and data reduction, **comply with the laboratory's quality management system and with relevant regulatory requirements** for which the data will be used and

b) **have the authority** to halt work, repeat work, withhold reports, and resume work as part **of the management of nonconforming work**, as defined in 7.10.

5.6.4 A Technical Specialist may be **appointed across multiple laboratories**, subject to **approval by the primary accrediting body**. Requests for approval **must include a plan** outlining how the Technical Specialist will meet the requirements in section 5.6.3 across multiple locations. Records of the accrediting body's approval, including the approved plan, must be retained.





Technical Specialist Requirements - 3

5.6.5 If a Technical Specialist is **unable to fulfill** the duties in sections 5.6.3 a) and b) for fifteen **(15) consecutive calendar days**,

5.6.5.1 a designated **alternate must be appointed** per the procedure in 5.5.1 **and assume the responsibilities** of the technical specialist or

5.6.5.2 **work** in that area of responsibility **must be halted or subcontracted** to another qualified laboratory.

5.6.6 The designated alternate is **not required to meet the same qualification requirements** of a Technical Specialist but **must meet the requirements the laboratory defines** in the procedure described in 5.5.1.





Technical Specialist Requirements - 4

5.6.7 When a **designated alternate assumes** the responsibilities of a Technical Specialist, the laboratory must **notify the primary accreditation body within sixty (60) days** if a qualified Technical Specialist does not resume the responsibilities. The notification must be in writing for accreditation body approval and **must include a plan with a timeline for appointing a qualified Technical Specialist**. If approval is not granted the laboratory accreditation may be suspended.

5.6.8 Where staffing is limited, the Technical Specialist and the Quality Specialist may be the same person.





Technical Specialist Qualifications - 1

6.2.2.1 Technical Specialist (however named) Qualifications

The laboratory shall retain a record showing that each Technical Specialist meets the requirements of 6.2.2.2 or exceptions of 6.2.2.3. Where coursework is required, the **laboratory must retain records that show courses were successfully completed** (e.g., certificate, letter, transcript).





Technical Specialist Qualifications - 2

6.2.2.2 A Technical Specialist must **meet one combination of education and experience qualifications** listed below, where **experience is in the area of responsibility**. In addition, areas of responsibility in TNI **Asbestos and Radiochemistry Technical Modules require a relevant technical course**. Information on relevant technical courses and examples of experience can be found in **Annex C**.

- a) a master's or doctoral degree in a STEM (science, technology, engineering, or mathematics) field and one (1) year of experience,
- b) a bachelor's degree in a STEM field and two (2) years of experience,
- c) an associate's degree in a STEM field and three (3) years of experience, or
- d) four (4) college level STEM courses and four (4) years of experience. **A TNI credential applicable to the areas of the Technical Specialist responsibilities can be substituted for the college level STEM courses.** Vendor courses with certificates and a minimum of 3 CEUs may be considered equivalent to a college level STEM course.



6.2.2.3 EDUCATION/EXPERIENCE EXEMPTION

- a) Any person who was **formerly recognized** based on requirements or exceptions in previous revisions of this Standard **will continue to be eligible** for the **same areas of responsibility at any accredited laboratory**. Appropriate records must be available to show previous recognition.
- b) Any person who is an 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 has **two (2) years of laboratory experience is eligible** as Technical Specialist at facilities **where the treatment plant operator's certificate is recognized** and for the scope covered by that certificate.
- c) An **accrediting body may provide an exemption** other than those listed in a) and b). The laboratory must receive the **exemption from each of its accrediting bodies**. The laboratory must retain the record of the exemption for the same time period as required for the data generated during the employment of that technical specialist.



Requirements from Volume 2

- ❑ Volume 2 is the standard for Accreditation Bodies
- ❑ Section 8.1, *Obligations of the CAB*, contains requirements for laboratories relating to:
 - Meeting the requirements of the standard
 - Cooperating with their AB
 - Providing documents and records
 - Claim accreditation appropriately
 - Paying fees
- ❑ These requirements have been reworded and incorporated into a new sections 4.3-4.5.



Meeting the Requirements

4.3 If more stringent standards or requirements are included in a mandated method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed.

4.4 The laboratory must comply with requirements outlined in applicable Technical Modules.



Cooperation with ABs

4.5.1 A laboratory accredited or seeking accreditation to this Standard must commit to meeting the requirements of this Standard, as well as applicable requirements of the accreditation body from whom it seeks accreditation. It must **cooperate** with the accreditation body to verify its fulfillment of the requirements including providing access to laboratory facilities, personnel, equipment, documents, records, and witnessing of laboratory activities upon request. Items identified in this document must be available upon request.

4.5.2 The laboratory must provide access to accreditation body assessment teams to assess the laboratory's performance when carrying out laboratory activities at the client's site.



Claiming Accreditation

4.5.3 The laboratory must only claim accreditation for the fields of accreditation granted on its approved scope and must comply with the accreditation body's policy for the use of the accreditation symbol. The laboratory must comply with any requirements from their accreditation body concerning accreditation claims and references to its accreditation in communication media.

4.5.4 The laboratory must inform the accreditation body of significant changes relevant to its accreditation and to assist in the investigation and resolution of any accreditation-related complaints referred to it by the accreditation body.



Claiming Accreditation and Fees

4.5.5 The laboratory must not use its accreditation in such a way that brings the accreditation body into disrepute. The laboratory must not make misleading statements about its accreditation or that imply endorsement of individuals, products, or services by the accreditation body.

4.5.6 The laboratory must inform affected clients of suspension, reduction or withdrawal of its accreditation in a timely way and must immediately discontinue referencing that accreditation.

4.5.7 The laboratory must pay fees as determined by the accreditation body.



ANNEX C – Implementation Examples

- ❑ Annex C is an Informative Annex to Volume 1 Module 2
 - Not required
- ❑ It includes:
 - Prohibited Actions for Data Integrity training
 - Laboratory Structure for Technical Specialist responsibilities
 - Relevant technical course types for Technical Specialist education requirements
 - Examples of experience for Technical Specialist



C.3.1 EXAMPLES OF LABORATORY STRUCTURE

□ Lab 1:

- One TS responsible for entire Scope

□ Lab 2:

- Wet Chemistry Manual TS
- Wet Chemistry Instrument TS
- Metals TS
- Organics TS
- Radiochemistry Prep TS
- Radiochemistry Counts TS
- Microbiology TS

□ Lab 3:

- Inorganic Non-Metals TS
- Inorganic Metals TS
- Microbiology TS
- SVOA TS
- VOA TS
- Organic Prep TS
- WET TS

□ Lab 4, etc.:

- Asbestos TS
- Chemistry TS
- Microbiology TS
- Radiochemistry TS
- WET TS



C.3.3 EXAMPLES OF EXPERIENCE

□ Examples of Experience

- Hands on analysis
- Data validation and review
- QA oversight
- Training classes
- Credentials
- Similar work in another industry

□ NOTE: Experience does not have to be:

- requiring a DOC for every method that is within the Technical Specialists scope of work.
- having run every method that is within the Technical Specialists scope of work. The Technical Specialist's capabilities are a combination of education and experience.
- exclusively bench level.



Modules 3-7 Global Changes

- ❑ Technical Modules are formatted similarly
- ❑ Consistent and Revised Numbering

1.0 Introduction

2.0 Scope

3.0 Terms and Definitions

4.0 Method Selection

5.0 Method Validation & Verification

6.0 Demonstration of Capability

7.0 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~~



Module 3 - Asbestos

- ❑ 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 (but see last bullet).
 - “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.
- ❑ The Committee is going to add an Annex regarding how to handle a referenced SRM that is no longer available



Module 4 - Chemistry

- ❑ Draft published August 15, 2025
- ❑ Focus was on these items:
 - Method Selection, Validation, and Verification
 - Detection/Quantitation Limits
 - Demonstration of Capability
 - Calibration
- ❑ Extensive rewrite for clarity with little change in intent
 - Quality Control, Reagent Quality, Sample Handling
- ❑ Global Changes
 - Document/Record; Corrective Action/Correction
 - Removal of explanatory language
- ❑ Informative Annex to be prepared to provide explanatory language on method verification and validation.



Module 4 – Response to Comments

- ☐ Over 500 comments were received.
- ☐ Committee began reviewing comments in November 2025.
- ☐ Discussion was held at the TNI Forum in January and August 2026.
- ☐ Many comments have already been ruled persuasive, so another Draft will be prepared.
- ☐ Goal is to have new draft published by early 2027.
- ☐ Update to be provided in Long Beach on January 13.

Committee now meeting twice per month to meet these goals.



Module 5 - Microbiology

- ☐ Reorganized to improve readability
- ☐ Reworded to improve clarity
- ☐ Draft Standard Revision 2 posted for review on June 1, 2026.
- ☐ Comment period closes **September 26, 2026**.
- ☐ Summary of changes available here: <https://nelac-institute.org/docs/standards/2026/DS-EL-V1M5-Summary%20of%20Changes.pdf>



Module 6 - Radiochemistry

- ☐ Public Comment on the revised Module 6 closed in April 2022.
- ☐ Few comments were received and none were ruled persuasive
- ☐ Response to Comment Document was posted January 2023.
- ☐ Final review for any potential conflicts in the Module is the final step before completion.
- ☐ Required courses for the Technical Specialist will be added to Annex C of Module 2.



Module 7 – Whole Effluent Toxicity

- ❑ The Committee wrote a Standard to address previous concerns of method requirements not being addressed
- ❑ Comments expressed a general concern that the Module looked like Guidance and not an enforceable document.
- ❑ Working to achieve consensus on terms.
- ❑ Revised draft expected by January.



Timeframes

- ❑ There is no driving factor for when this will be done
- ❑ Some ABs are limited in their ability to get new regulations written into their respective state codes
 - Incorporate by reference
 - Re-write with new language
- ❑ All Modules in Volume 1 must be completed so that all can be approved at one time.
- ❑ Once Volume 1 has been adopted by NELAP, there's still the lag of when every AB can use the revised Standards.
 - NELAP has a long history of a “rolling implementation.”



STANDARDS DEVELOPMENT AND IMPLEMENTATION

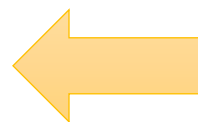
Expert Committees
develop language thru
consensus process



Programs review for
suitability for adoption



Programs adopt standard
with effective date



TNI develops “tools”
to assist labs and ABs



TNI Implementation Tools

- ☐ Detailed comparison document for the entire standard
- ☐ Detailed crosswalk for Module 2
- ☐ Training courses for laboratories and assessors
- ☐ New checklists
- ☐ Revised quality manual template
- ☐ Guidance documents on complex topics
- ☐ Credentialed Technical Specialists



SUMMARY

- ☐ Significant changes underway to ELV1 but a year or two from completion.
- ☐ We invite you to actively participate in our activities.
 - Provide persuasive comments on a draft standard.
 - Come to a TNI meeting and provide comments.
- ☐ Join TNI.
- ☐ Join a TNI committee and actively participate.
 - As a Voting Member
 - As an Associate



Questions?

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