

# Overview of TNI Standard Development Activities

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# Standards Development Process

- TNI writes consensus standards establishing requirements for:
  - Organizations that accredit (ABs)
  - Organizations that are accredited (Laboratories)
  - Proficiency testing (PT) Providers
- Expert Committees develop Standards during in-person and virtual meetings
- Any TNI member or member of the public may provide comment





# Standards Development Process

- Draft Standard goes through as many revisions as are necessary to achieve acceptance by the Expert Committee and no additional persuasive comments
- A Notice of Intent requests comment on the proposed changes
- Meetings of any sort may be held to request comment





# Consideration of Comments

- The following are considered during the development process:
  - Public comments
  - Comments from the previous standards development activity
  - Any comments that were previously placed on hold
  - Any pertinent SIRs





# Development of Draft Language

- Expert Committee, whether all or in part, writes language for the proposed Standard
- Expert Committee deliberates on the proposed changes
- Any negative votes cast by a member of the Expert Committee **MUST** be accompanied by explanatory language
- No other comment requires proposed language be submitted



# Public Comment Process

- When two-thirds of the Committee vote in favor of the Standard, it is posted for public comment
- In addition to the Standard being posted, there must be a Summary of Changes which includes a justification for those changes
- The Draft Standard is open for comment for 90 days



# Consideration of Comments

- The Expert Committee *MUST* rule comments persuasive, non-persuasive, or editorial
- Persuasive comments require that the Standards Development process continue
- A reason must be provided for any comments ruled non-persuasive
- Comments received are tracked to aid in providing feedback to the commenters and to those interested and published in a Response to Comments document



# Final Approval

- The process of revise – committee approval – public comment continues until there are no persuasive comments.
- A final review among the Consensus Standards Development Chairs and the Accreditation Council searches for conflict.
- Appeals are heard during this final review, if necessary.
- Standard then provided to other TNI groups for adoption.
  - NELAP Accreditation Council
  - Laboratory Accreditation System Executive Committee
  - Proficiency Testing Executive Committee
  - NEFAP Executive Committee



# TNI Standards

- Proficiency Testing Standards
- Environmental Laboratory Standard Volume 1 - Management and Technical Requirements for Laboratories Performing Environmental Analysis
- Environmental Laboratory Standard Volume 2 - General Requirements for Accreditation Bodies Accrediting Environmental Laboratories
- Field Activities Standard



# PT Standards

- Volume 4 General Requirements for an Accreditation Body of Environmental Proficiency Test Providers
  - Total rewrite of the standard consistent with ISO 17011
  - Posted for comment on the TNI website
  - Comments are due by 9/21/25
- Volume 3 is the next most 'urgent' revision due to ANSI requirements
  - It is being reviewed to ensure consistency with Volume 4
- Volumes 1 & 2 are under review and will have changes to align with Volumes 3 & 4



# Module 2 – Quality Systems

- ISO 17025:2005 → ISO 17025:2017
- Fine-tuning terms and definitions
- Technical Specialist



# Module 2 – Quality Systems

## ISO 17025:2005 → ISO 17025:2017

- Crosswalk
  - 17025:2005 language compared to 17025:2017
  - TNI added language compared to 17025:2017
- Most of what was in 17025:2005 is addressed in 17025:2017; some of what wasn't kept, we've decided to keep
  - Important to note that things that are 'missing' haven't been removed as requirements – they are stated elsewhere



# Module 2 – Quality Systems

## Definitions/Terms

- Rely on ISO definitions where they exist
- Annual, Contract, Correction, Corrective Action, Customer, Document, Quarterly, Record, Test Item
- 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



# Module 2 – Quality Systems

## Definitions/Terms

- Definitions/terms used in multiple Modules are being reviewed for need
- Definitions/terms used in multiple Volumes are being reviewed for consistency





# Module 2 – Quality Systems

## Technical Specialist

- Formerly 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



# Module 2 – Quality Systems

## Technical Specialist

- Required for every field of accreditation held by the laboratory
  - Working knowledge of the TNI Standards
  - Supervisory role NOT required
  - Key authority in a specific area of responsibility
- May be responsible at more than one location
- Coursework documents must be maintained
- “Technology” used in Accreditation, Proficiency Testing, Assessor qualifications
- LAMS has 116 technologies listed



# Module 2 – Quality Systems

## Technical Specialist

- ‘Analytical Discipline’ as a possible way to characterize a person’s abilities, based on knowledge in certain areas
- “Simple” breakdown – Inorganic Nonmetals, Inorganic Metals, Organic Analysis, Asbestos, Microbiology, Toxicity, Radiochemistry
- Problematic in defining what it is, other than those groups
- This is an ongoing effort, involving many people from many different perspectives
- We need to consider how all of this relates to Emerging Technology so that we can deal with the ‘unknown’



# Module 2 – Quality Systems

- The Committee has reviewed the entirety of this draft and taken previous suggestions into consideration
- Annex C will have implementation aids – this is a new concept where information that is non-mandatory but may be helpful in terms of compliance is appended to the Module
- Technical Specialist still needs to be resolved



# 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
- Final review for any potential conflicts in the Module is the final step before completion
- A webinar will be made regarding the changes



# Module 4 - Chemistry

- Entire Module open for revision
- Draft is done, but awaiting the vote of all members of the Committee
- Focus was on these items:
  - Detection/Quantitation Limits
  - Calibration Points
  - Relative Error
  - Demonstration of Capability





# Module 5 - Microbiology

- Draft Standard Rev 2 was posted for review on April 10, 2025
- Comment period ended June 9, 2025
- Committee is currently working through 132 comments
- Committee comments were made to draw attention to items that they felt needed to be looked at
- Many of the comments were redundant, indicating language that needs revision



# 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



# Module 7 – Whole Effluent Toxicity

- Draft Standard was posted for review on February 26, 2025
- Comment period ended May 27, 2025
- Committee is currently working through 74 comments, many of which dealt with definitions
- The Committee wrote a Standard to address previous concerns of method requirements not being addressed
- Comments expressed a concern of Guidance and format





# Laboratory Accreditation Body

- Volume 2 - General Requirements for Accreditation Bodies Accrediting Environmental Laboratories Modules 1 & 3 will be combined
- Comments received through the June '23 comment period have all been reviewed
- The Committee is now performing a complete review to make sure that there are no consistency errors
- The ISO term CAB (Conformity Assessment Body) is being replaced with laboratory





# ISO 17011:2017 and Remote Assessments

- Updates the Module from 17011:2004 to 17011:2017
- ISO terms were alphabetized
- ISO section number references removed (the TNI numbering matches them)
- Added clarity regarding remote assessments by removing the term on-site



# Field Activities Standards

- Volume 1: General Requirements for Field Sampling and Measurement Organizations
  - Significant changes to increase value, comparable to the laboratory standard.
- Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations
- Formatting/clean up being performed now for the presentation of the Draft Standard



# When???

- There is no driving factor for when this will be done
- ABs are limited in their ability to get new regulations written into their respective state codes
  - Incorporate by reference
  - Re-write with new language
- Anticipate all Modules to be completed so that all can be approved at one time
- Once that happens, there's still the lag of when every AB can use the revised Standards





# Questions?

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