Environmental Measurement Symposium

Improving the Reliability of Laboratory Testing

Paul Junio – The NELAC Institute

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TNI Mission

MISSION - to foster the generation of environmental data of known and documented quality through an open, inclusive and transparent process that is responsive to the needs of the community.

Reliable Data

- Much more than the analytical result
- TNI Standard is built on the shoulders of ISO/IEC 17025
- We've added specificity to the ISO/IEC requirements
- TNI Standard contains requirements for a Quality Management System

TNI Quality Management System

TNI's Quality Management System has been developed over a 25-year period by a consensus body and is periodically updated as potential improvements are identified. All TNI Expert Committees have balanced representation from affected stakeholders: Accreditation Bodies, Accredited Organizations, and "Others".

ISO/IEC 17025:2017

- ISO/IEC 17025 was updated in 2017
- It looks like they may have liked some of what we did, as there's some similar language
- Now it's time for TNI to update its Standard to make use of ISO/IEC 17025 – and improve on it

Standards Development Process

- A Notice of Intent is published on the TNI website
- Expert Committees develop Standards during in-person and virtual meetings
- Any TNI member or member of the public may provide comment
- Draft Standard goes through as many revisions as are necessary to achieve acceptance by the Expert Committee and no additional persuasive comments

Development of Draft Language

- 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
- When two-thirds of the Committee vote in favor of the Standard, it is posted for public comment

Consideration of Comments

- The Expert Committee rules 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 and their outcome are 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.
- Standard then provided to other TNI groups for adoption.
  - NELAP Accreditation Council
  - Laboratory Accreditation System Executive Committee
  - Proficiency Testing Executive Committee
  - NEFAP Executive Committee

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Environmental Laboratory Standard Volume 1

Management and Technical Requirements for Laboratories Performing Environmental Analysis

Module 1: Proficiency Testing
Module 2: Quality Systems General Requirements
Module 3: Quality Systems for Asbestos Testing
Module 4: Quality Systems for Chemical Testing
Module 5: Quality Systems for Microbiological Testing
Module 6: Quality Systems for Radiochemical Testing
Module 7: Quality Systems for Whole Effluent Toxicity Testing

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Environmental Laboratory Standard Volume 2
General Requirements for Accreditation Bodies Accrediting Environmental Laboratories

Module 1: General Requirements & On-Site Assessment
Module 2: Proficiency Testing

Field Activities Standard

Volume 1: General Requirements for Field Sampling and Measurement Organizations
Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations

Proficiency Testing Standards

Volume 1 Module 1: Proficiency Testing (Laboratories)
Volume 2 Module 2: Proficiency Testing (Accrediting Bodies)
Volume 3: General Requirements for Environmental Proficiency Test Providers (PT Providers)
Volume 4: General Requirements for an Accreditor of Environmental Proficiency Test Providers (PT Provider Accreditors)

Status of PT Standards

- Early stage of modification.
- All Volumes/Modules (V1M1, V2M2, V3, V4) will be revised.
- Volumes 1 and 2 have no substantive changes required but are temporarily tabled.
- Volumes 3 and 4 require the most 'urgent' revision due to ANSI requirements.
- Drafts of Volumes 3 and 4 were taken back to committee following comments made at the Forum on Environmental Accreditation in Columbus, OH in January.

Status of Module 2 – Quality Systems

- ISO 17025:2005 → ISO 17025:2017
- Definitions
- Technical Manager → Technical Specialist
- What are:
  - Procedures
  - Policies
  - Documents

ISO 17025:2005 → ISO 17025:2017

- Crosswalk created via Workgroup
  - 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

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

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

Unique or Traceable?

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

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

BECOMES

- All containers of prepared standards, reference materials, and reagents shall be traceable to the preparation records and expiration date

Revisions to Dates

- Date of last use vs. Date of last entry
  - Last use is problematic to demonstrate and for records retention
  - Last entry is easier to demonstrate, but may leave gaps in the record, especially as it relates to IDOCs
  - Last entry is the proposed direction, but there may be specific recordkeeping requirements for IDOCs

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

Technical Specialist (formerly Technical Manager)

- 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 records must be maintained

Technology

- Used in Accreditation (Matrix, Technology, Analyte)
- Used in Proficiency Testing (Matrix, Technology/Method, Analyte)
- Used in Assessor qualifications (combination of method and technology that the assessor will assess)
- Used in Technical Specialist (years of experience in representative technologies)
- Revision to Internal Audit requirements used the term

LAMS has 116 of them!

Technology

- Too intertwined with Accreditation and PTs
- What do we mean when we say ‘Technology’?
- Do Technical Specialists and Assessors need the same understanding of Analytical Disciplines?
- How about the differentiation between what is needed for Internal Audits and a Technical Specialist?

Analytical Discipline

- Possible way to characterize a person's abilities, based on knowledge in certain areas
- "Simple" breakdown – Preparation, Inorganic Nonmetals, Inorganic Metals, Organic Analysis, Microbiology, Toxicity, Radiochemistry
- "Complex" breakdown – Inorganic Nonmetals becomes UV/VIS, Titrimetric, Gravimetric, Ion Chromatography, ISE, Autoanalyzer Techniques, Turbidimetry, Electrometric determinations, Dissolved Oxygen Depletion, Combustion, Luminescence Sensors

Technology

- This is an ongoing effort, involving many people from many different perspectives
- This is in no way final
- We need to consider how all of this relates to Emerging Technology so that we can't deal with the 'unknown'

Modules 3-7

- Technical Modules are formatted similarly
- Numbering
  1 Introduction
  2 Scope
  3 Terms and Definitions
  4 Technical Specialist
  5 Method Selection
  6 Method Validation
  7 Demonstration of Capability
  8 Technical Requirements

What's our Result?

- Flexible – allow freedom to use experience and expertise in performing work to allow for new and novel approaches by specifying the 'What' and avoiding the 'How To'
- Auditable – include sufficient detail so that the assessors can evaluate laboratories consistently
- Practical and Essential – contain only necessary policies and procedures that should not place an unreasonable burden upon laboratories of any size

What's our Result?

- Widely Applicable – be applicable to laboratories of all sizes and complexity
- Appropriate – ensure that data generated in compliance with the Standard will be of known quality and that the quality is adequate for the intended use. (Not all data must be of the highest quality;' as sometimes a "screening result" is adequate)

What's our Result?

Implementing a QMS provides confidence in the data.

- Reported result is a good estimate of the true concentration.
- Reported result is of known and documented quality.
- Laboratory complied with mandated method requirements.
- Laboratory implemented a strong quality management system to ensure confidence in the result.
- Laboratory met customer requirements such as measurement quality objectives including precision, accuracy, representativeness, completeness, and comparability.

What's our Result?

Implementing a QMS improves laboratory performance.

- Results can be reconstructed due to sufficient documentation of calibration, QC results, and SOP in use.
- Reference materials, reference standards, and reagents are all traceable.
- Training records, PT results, and DOC results all demonstrate competency of analyst.
- Samples are handled correctly and are traceable.
- Quality control results document data quality.
- Results are reported correctly by meeting requirements relating to quantitation limits and data flagging.

What's our Result?

Implementing a QMS ensure the laboratory met Daubert standards for data admissibility (e.g., "legal defensibility").

- The technique has been tested,
- There is a known rate of error, and
- There are professional standards controlling the technique's operation

What's our Result?

- No other Standard for the generation of environmental laboratory data provides this confidence
- The TNI Standard is the State of the Art in generating data of known and documented quality in the laboratory and in the field
- The TNI Standard should be the choice of an Accreditation Body

Questions?

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