A COMPARISON OF TNI's ACCREDITATION STANDARD TO ISO/IEC 17025

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).

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

# TNI's NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)

FUNDAMENTAL CONCEPTS

- TNI develops consensus requirements (i.e., standards) that are voluntarily adopted by states agencies approved as accreditation bodies (ABs).

- TNI's NELAP Accreditation Council oversees accreditation bodies to assure uniformity.

- State grants accreditation, which is unconditionally recognized, by other participating ABs.

NELAP Accreditation Bodies

NELAP Accreditation Body
Working on Application
Accept NELAP
Incorporate NELAP elements
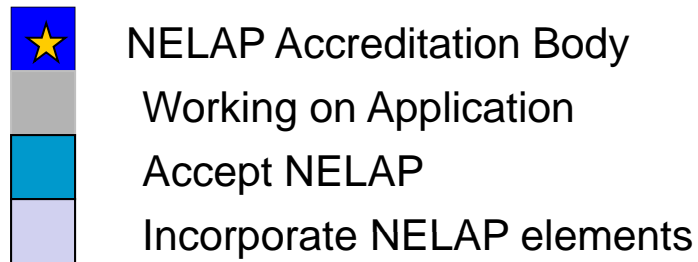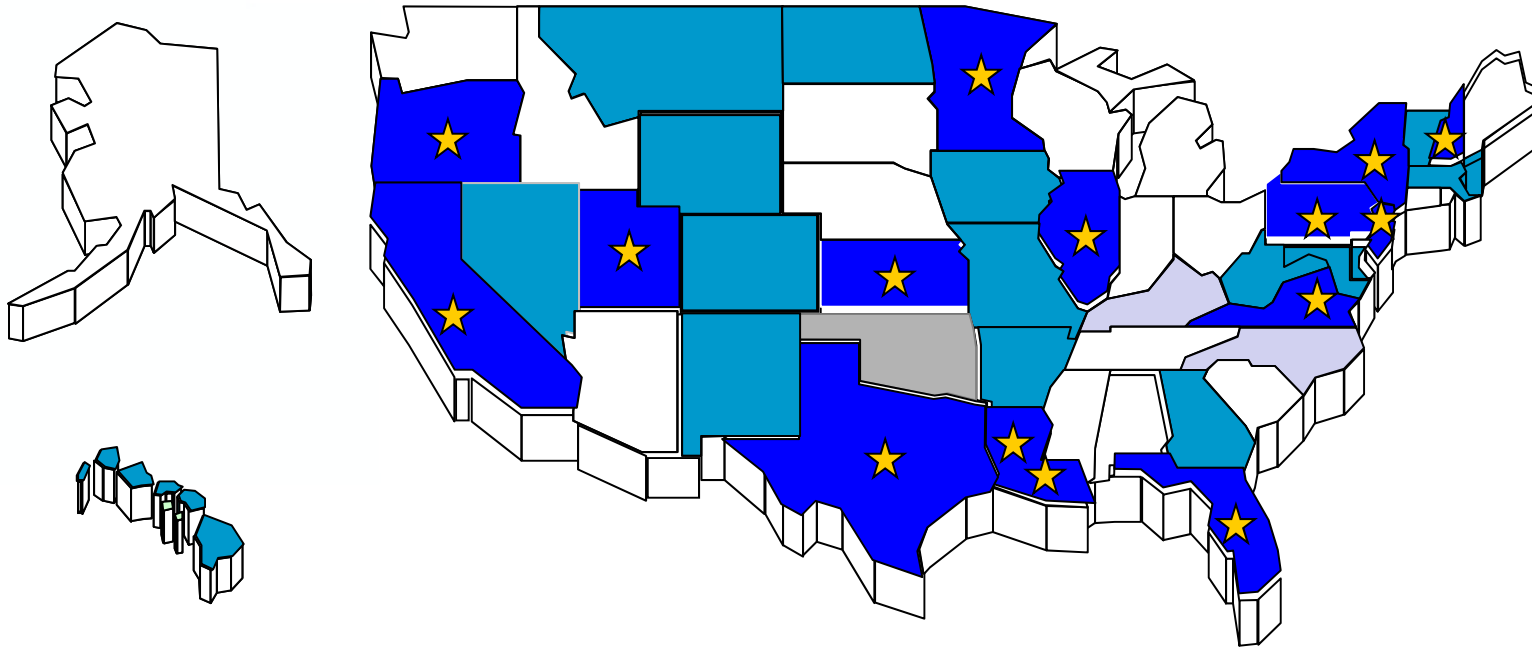
NELAP STANDARDS

- Developed using a consensus process that included the perspectives of multiple stakeholders.

- Used recognized international standard for the competency of laboratories (ISO 17025) as the basis.

- Added additional specificity to address specific issues associated with environmental testing.

- Focus is on generation of authentic data (*i.e., data of known and documented quality generated according to accepted professional practices of the industry).*
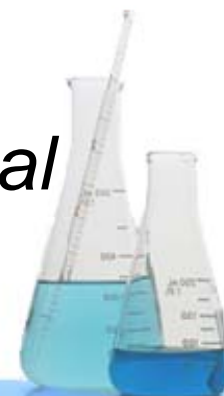
THE 2009 STANDARDS

➤ 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.

THE TNI NELAP STANDARDS

- Four Small Volumes = Four Standards
  - Volume 1: Requirements for Laboratories
    - 7 Modules (155 pages)
  - Volume 2: Requirements for Accreditation Bodies
    - 3 Modules
  - Volume 3: Requirements for PT Providers
  - Volume 4: Requirements for a PT Provider Accreditor

ISO Quality Standards

9000

Industry

14000

Environment

17025

Testing or Calibration Laboratory
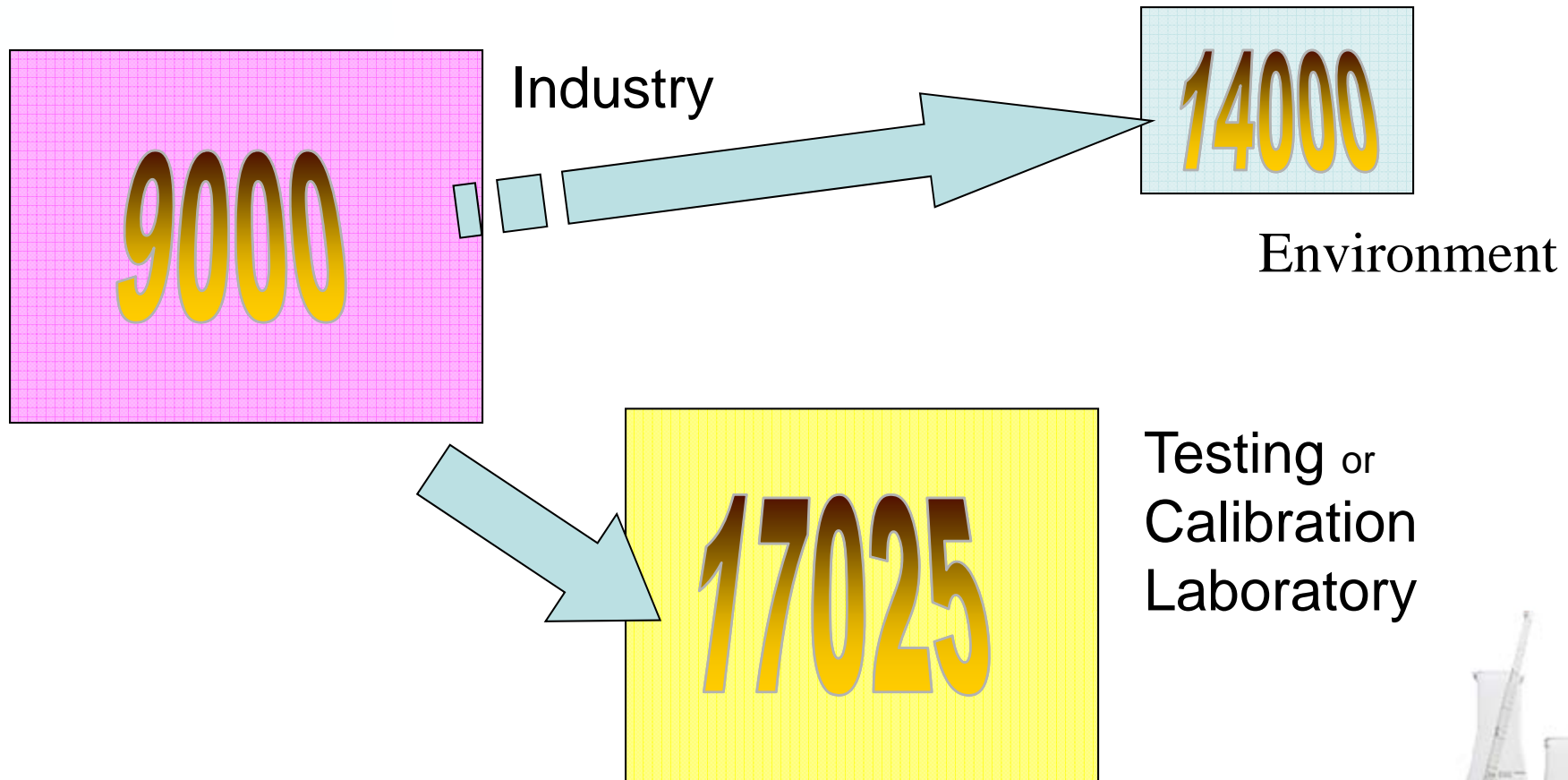
ISO 17025

- Introductory Sections
- Section 4: Management Requirements
- Section 5: Technical Requirements
- Annexes
- 24 pages of requirements
- Applies to all types of laboratories

ISO 17025 Management

- Organization
- Quality System
- Document Control
- Review of Work
- Subcontracting
- Purchasing
- Complaints
- Management

- Control of Nonconforming Work
- Corrective Action
- Preventive Action
- Records Control
- Internal Audits
- Management Review

ISO 17025 Technical

- General
- Personnel
- Facilities
- Test Methods and Method Validation
- Equipment
- Traceability

- Sampling
- Handling of Samples
- Assuring the Quality of Results
- Reporting the Results

TNV V1 and 17025

Volume 1

- M1: Proficiency Testing
- M2: ISO 17025 plus supplemental language
- Technical Modules
  - M3: Asbestos
  - M4: Chemistry
  - M5: Microbiology
  - M6: Toxicity
  - M7: Radiochemistry

17025

- ISO 17025

GUIDING PRINCIPLES

- **Flexible**: Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel approaches. specify the *What* and avoid where possible the *How To*.

- **Auditable:** Sufficient detail included so that the assessors can evaluate laboratories consistently.

- **Practical and Essential:** Necessary policies and procedures that should not place an unreasonable burden upon laboratories.

- **Widely Applicable:** Applicable to laboratories regardless of size and complexity.

- **Appropriate:** Ensure that data is of known quality and that the quality is adequate for the intended use.

3: Definitions

- Added 59 definitions specific to environmental testing, e.g.:
  - Batch
  - Demonstration of Capability
  - Limit of Detection
  - Matrix Spike
  - Mobile Laboratory
  - Quality Systems Matrix

4.1 and 4.2 Organization and Management

- Added sections on
  - QA Manager
  - Laboratory Technical Manager
  - QA Manual
  - Data Integrity System
  - Laboratory SOPs

4.13 Records

- Significantly expanded section
  - Stresses reconstruction of data from records

4.14-16 Internal Audits and Management Review

- Requires internal audit and management review to be preformed annually

- New section on data integrity investigations

5.2 Personnel

- Specific qualifications for Technical Manager
- Requirement for data integrity training for all laboratory staff

5.4 Method Validation

- Expanded validation requirements specific to the type of testing to be performed

- Recognizes differences between reference and non-reference methods

- Requires use of mandated test methods in regulations

- Supports the performance approach

5.5 Calibration

- New section on calibration of support equipment
- Instrument calibration covered in Technical Modules

An Example

17025

- "Equipment and its software used for testing shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests concerned."

TNI Standard

- Extensive discussion of items such as
  - Second source standards,
  - Frequency,
  - Number of calibration points,
  - Acceptance criteria, and
  - Initial and continuing calibration.

So what's the harm?

- A technically competent assessor and a qualified lab manager could technically agree, and if so, no problem

- TNI standard provides clarity to resolve disagreements, based on best practices of the industry

5.6 Traceability

- Added focus on prepared reagents and standards

5.8 Handling Samples

- Added sections for
  - Documentation
  - Sample receipt
  - Chain of custody
  - Storage and disposal

5.9 Quality Assurance

- Added section on QC samples with reference to Technical Modules

5.10 Reporting

- Added exemption for internal reporting
- Clarify language for holding times and related items

Technical Modules

- 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

Technical Modules

- Laboratories must validate all methods and the validation study must evaluate the limit of detection, limit of quantitation and precision;

- All analysts must demonstrate their proficiency in every test method; and

- Specific quality control samples (e.g., blanks, laboratory control samples, duplicates) must be analyzed at some prescribed frequency and corrective actions performed if results are not within acceptance limits.

Summary

- The 2009 TNI Standard is a significant improvement over ISO 17025 because of the incorporation of specific elements for environmental analyses
    - PT requirements
    - Additional management and technical requirements
    - Additional clarity
    - Technical Modules

QUESTIONS

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