



The Benefits of Accreditation Using Developed Standards

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Who is A2LA

- Established in 1978
- Largest U.S. multi-discipline Conformity Assessment Body (CAB) Accreditation system
 - *More than 2800 accreditations granted*
- Fourth largest system in the world
- Non-profit and non-governmental
- First lab accredited was an environmental lab 35 years ago and remains with us to this day!



The Bottom Line

- Does the laboratory *“say”* what they do?
 - Do they have written documents (policies, procedures, arrangements) that meet the requirements of ISO 17025?
- Does the laboratory *“do”* what they say?
 - Are they in compliance with their own management system and ISO 17025?
- And can they *“prove”* it with their records?
 - From training records to standards preparation to work books to customer reports to audit reports and everything in between.



Accreditation Using ISO/IEC 17025:2005

- Evaluation of a conformity assessment body to determine **technical** competence
- ISO/IEC 17025:2005
- Management system requirements
 - Technical requirements - competency
 - Used by labs to manage and operate systems
 - Used by accreditation bodies domestically and internationally to evaluate labs



ISO/IEC 17025:2005 Standard

- Uses general terms enabling it to be applied broadly and forms the foundation
 - Adapts to specific program requirements (AOAC) which can be built upon the foundation
- Commercial, governmental and in-house laboratories
- Laboratories performing routine testing or R&D
- Large and small laboratories
- For accreditation purposes, tied to a Scope of testing



Organization of ISO/IEC 17025:2005

- Section 1: Scope
- Section 2: Normative References
- Section 3: Terms and Definitions
- Section 4: Management Requirements
- Section 5: Technical Requirements



Scope

- Specifies general requirements a laboratory shall meet to be considered competent
- Applicable to all types of testing and calibration laboratories
- Notes are for guidance, not requirements
- Stakeholders: used by laboratories, customers, regulators, and accreditation bodies
- Does ISO/IEC 17025:2005 meet the requirements of ISO 9001:2008?
 - “Laboratories will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001.” (Scope Section 1.6)
 - “Testing and calibration laboratories that comply with this International Standard will therefore also operate in accordance with ISO 9001.” (Introduction, Paragraph 4)
 - However, laboratories may not claim ISO 9001 registration



ISO 17025 – Sections 4 and 5

- Section 4 = Management System Requirements
 - Document Control, Purchasing, Contracting, Preventative/Corrective Actions, Non-conforming Work, Internal Audits, Management Reviews
- Section 5 = Technical Requirements
 - Personnel, Environment, Method Selection, Validation, Equipment, Traceability, Handling of Test Items, Reporting



TNI Standard

- Current version is 2009, however, many states are still using the 2003 version
- Based on the requirements of ISO/IEC 17025:2005
- ISO language is in *italics* with additional requirements added specific to environmental testing laboratories



TNI Standard

- Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis
- Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories
- Volume 3: General Requirements for Environmental Proficiency Test Providers
- Volume 4: General Requirements for an Accreditor of Environmental Proficiency Test Providers



Volume 1 Modules

1. PT
2. Quality Systems-General
3. Quality Systems-Asbestos
4. Quality Systems-Chemical
5. Quality Systems-Microbiological
6. Quality Systems-Radiochemical
7. Quality Systems-Toxicity



Why Use the TNI Standard?

- ISO/IEC 17025:2005 was written to apply to all types of testing and calibration labs
- The TNI standard builds upon these base requirements with environmental specific requirements to address issues noted in your types of testing
- Standard is heavily vetted by the environmental testing community



Can This Work for Small Labs?

- ISO/IEC 17025:2005 and the TNI Standard are both completely scalable
- A2LA accredits labs of size from 1 person to hundreds and each has to meet the same requirements



Groups that Benefit

- Laboratories
- Users of Laboratory Services
- Specifiers
- General Public



Benefits to Laboratories

- Improved data usability;
- Easier analyst training using a well-documented standard;
- Uniformity of laboratory documentation and processes;
- Improved analytical processes through established documentation and review processes;
- Easier problem identification due to more complete documentation procedures;
- Improved data defensibility and customer confidence; and
- Improved customer confidence in safeguarding the public health and the environment



Benefits to Laboratories

- Credential to qualify for testing
- Regular, objective “check-up”
- Entrée to some markets
- Increased lab productivity
- International recognition & acceptance
- Staying on “cutting edge”
- Discounts for liability insurance
- Improved performance
- Validation of traceability
- Consistent assessments
- Ability to provide feedback



Benefits to State

- Restricted budgets prevent government agencies from doing testing themselves
- Greater reliance on accredited third-party labs is needed
- Accreditation provides a fair and meaningful basis for identifying qualified labs



Benefits to State

- Accreditation Bodies have trained assessors on ISO and TNI standards
- Demonstrated competence of assessors through experience and training with an exam along with ongoing monitoring
- Resources can be redirected from assessing to focusing on issues of compliance



Why Not Develop Our Own Standard?

- Timeframe - It could take several years to develop a new standard for California
- Resources - California is already stretched thin and standard development takes a large amount of resources
- Reciprocity - Labs in California can gain reciprocity with other states by using a recognized standard



Questions?



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