The Benefits of Accreditation Using Developed Standards

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NEMC: Government Public Health and Private Environmental Laboratory Partnerships with Environmental Health Programs

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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

A Better World Through Accreditation

Benefits to Specifiers

- 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 Specifiers

- 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

The Top Ten Deficiencies

A Better World Through Accreditation

Tenth Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 4.6: Purchasing services and supplies**
  - Details in purchase orders lacking
  - Supplies/consumables not verified before use or records of action are lacking
  - Suppliers not evaluated or list incomplete

Ninth Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 5.10: *Reporting the Results***

  - Reported results inadequately reviewed before release.
  - Unaccredited subcontracted analysis not clearly identified
  - Amended report not properly documented as such.

Eighth Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 5.6: *Measurement Traceability* .**
  - Using non-accredited calibration laboratories.
  - Lack of accreditation body endorsement on calibration certificates.
  - Improper reference standards for in-house calibrations.
  - Lack of procedures for the safe handling, transport, storage and use of reference standards/materials.

Seventh Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 5.9: *Assuring the Quality of Test and Calibration Results.***
  - Failure to participate in available and relevant commercial PT programs or not meeting minimum PT frequency participation requirements.
  - Lack of corrective action response to outliers.
  - PT Plan not complete or current and/or PT Schedule not being followed.
  - PT Data records incomplete.
  - Lack of quality control procedures /Failure to perform qc checks on accredited tests.

Sixth Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 4.14: *Internal Audits.***
  - Inadequate procedure.
  - Lack records of findings (both good and adverse).
  - No corrective actions for IA findings.
  - Not verifying continued compliance with all elements of their activities.
  - Lacking evidence of internal auditor training and qualified to perform the audit.
  - The area of activity audited was not recorded.
  - Failure to meet the lab-established audit schedule.

Fifth Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 4.3: *Document Control*.**
  - Lacking defined control procedure.
  - Documents not undergoing Periodic Review.
  - Use of obsolete/uncontrolled instructions.
  - Failure to control externally-generated documents.
  - Master list of documents not current or complete.
  - Lacking record trail for archived documents.
  - Documents not uniquely identified and/or did not include all the required identification.

Fourth Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 5.4: *Test (and Calibration) Methods and Method Validation*.**
  - Modification to method not validated.
  - Method not confirmed prior to use.
  - Did not follow method procedure as written.
  - Measurement uncertainty: Improper or incomplete estimate. Lacking a procedure for estimation for in-house calibrations.
  - Failure to validate in-house software.

Third Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 5.5: *Equipment*.**
  - Equipment not uniquely ID'ed/labeled with calibration status/calibrated before placed into service.
  - Lacking records of calibrations & maintenance.
  - Defective/suspect equipment not sequestered.
  - Intermediate checks not performed after calibration, maintenance or repair.
  - Calibration cycles have been extended and not properly documented.

Second Most Cited Deficiency

- Laboratories were cited for deficiencies against ISO/IEC 17025, **section 4.13: *Control of Records*.**
  - Failure to record original observations.
  - Failure to retain adequate records to establish an audit trail of the test performed.
  - Procedures lacking all of the required record traceability requirements.
  - Inadequate protection of electronic records.
  - Records with information made illegible or scratched out and/or alterations to the records were not signed or initialed.

#1 Most Cited Deficiency

- Laboratories were cited for deficiencies against ***Specific Program Requirements***, such as TNI requirements.
- Not following the labs own written policies/procedures.

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