Presentation Outline

- Describe accreditation process in general terms
- Define some critical terms
- Clarify some ISO/IEC 17025 technical requirements
- Describe the interrelationships among the provisions and elements of ISO/IEC 17025
- Help you 'love' it rather than 'hate' it !!!

Scope of ISO/IEC 17025:2005(E) . . . *Page 1 of 2*

"General requirements for the competence of testing and calibration laboratories" (Second Edition; 15-May-2005)

ISO = International Organization for Standardization
IEC = International Electrotechnical Commission

- Contains requirements for testing and calibration laboratories for demonstrating that they:
  - Operate a management system compliant with ISO 9001 for quality, administrative and technical operations
  - Are technically competent
  - Are able to generate technically valid results

Scope of ISO/IEC 17025:2005(E) . . . *Page 2 of 2*

- Covers testing, calibration, and sampling performed using standard methods, non-standard methods, and laboratory-developed methods
- Applies to first-, second- and third-party labs, and labs where testing and/or calibration forms part of inspection and product certification
- Does not cover compliance with regulatory and safety requirements on the operations of the laboratories

Laboratory Accreditation

What is "Accreditation"?

- Procedure by which an authoritative body (organization) gives formal recognition that a body or person is competent to carry out specific tasks (ISO/IEC Guide 2)
  - *Need to identify which agency is this for your lab (national, regional, or international recognition)*
- Procedure used to provide formal notice that a body or person is competent to carry out specific tasks
- **Users of ISO 17025 Accreditation**: Laboratory customers, regulatory authorities and associated bodies may in confirming or recognizing the competence of laboratories.

What is "Laboratory Accreditation"?. . . *Page 1 of 2*

- Formal recognition that a testing or calibration laboratory is competent to carry out specific tests or calibrations
- Key Words;
  - *"competent"*
  - *specific tests or calibrations*
- Accreditation is having a **Management System and demonstrating competency**
- Laboratories are accredited for specific tests or calibrations and particular products and test or calibration specifications

What is "Laboratory Accreditation"?. . . *Page 2 of 2*

- Granted by an identified and qualified accreditation body to prescribed criteria:
  - *For specific test methods*
  - *After an onsite assessment:*
    - of the lab's management and technical expertise
    - by qualified (peer-expert) assessors, and
  - *Surveillance of ongoing performance:*
    - by re-assessment at periodic intervals
    - by proficiency testing

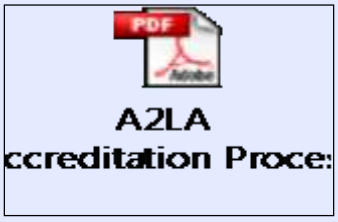
Rationale for Accreditation

- Establish minimum competency standards
- Identifies laboratory's specific competencies
- Documents nonconformities
- Enables continuous improvement
- Assists user selection
- Meets regulatory/procurement requirements
- Assures acceptance of laboratory data
- Breaks down barriers to international collaboration and trade

Generic Accreditation Process

- Application
- On-site assessment
- Deficiencies
- Proficiency testing
- Accreditation decisions
- Annual review
- Re-assessment/Renewal of accreditation

Example Accreditation Process – *A2LA Procedures*



Application for Accreditation

- Provide specific information on your laboratory
- Select appropriate Field(s) of Testing
- Complete ISO/IEC 17025:2005 Checklist
- Submit quality manual and send in accreditation fee
- Attach a technical staff matrix
- Application date:
  - Attests to when lab is ready for assessment
  - Earliest date deficiencies should be written
- Agree to set of conditions
  - Cooperate with accrediting body
  - Comply with requirements for accreditation and policies
  - Inform accrediting body with changes in lab status and key staff

On-Site Assessment

- Agreement on assessor
- Assessor conducts document review
  - *Quality manual*
  - *System and technical procedures*
- Schedules assessment
- Evaluates pre-assessment considerations
- Conducts on-site assessment
  - *Assessor report*
  - *Deficiency report*

Assessment Criteria

- ISO/IEC 17025:2005 and policies of accrediting body
- Specific field/program criteria
- Laboratory's management system
- Technical requirements of methods
- Customer specifications

What is a "Deficiency"?

- Definition: Any nonconformity to accreditation requirements
- Deficiency includes:
  - *Inability to perform a test or calibration*
  - *Policies or procedures do not conform to ISO 17025 provisions*
  - *Lab has not completely documented or implemented required policies and procedures*
  - *Lab does not conform to additional accrediting body's policies and procedures*
- Laboratory is expected to:
  - *Correct deficiencies*
  - *Submit report to accrediting body – usually 6 months maximum for new laboratories and within 30 days for renewals*

Proficiency Testing (PT)

- Laboratories are required to participate in "relevant and available" PT programs
- Typical PT program includes:
  - *Proficiency testing activities twice a year every year*
  - *Based on the number of sub-disciplines*
  - *Cover all sub-disciplines & matrices in 4 years*
  - *Results to be within acceptance criteria*
  - *Cannot miss two (2) PT analyte results in a row*
- Example PT Programs:
  - *U.S. Department of Energy's MAPEP*
  - *IAEA's Network of Analytical Laboratory (NWAL)*
  - *U.S. Environmental Protection Agency's Mixed Fission Products*

Accreditation Decisions

- Usually, there are three (3) parts to becoming accredited:
  - *Fact finding by assessor*
  - *Review of laboratory's corrective actions by the accrediting body*
  - *Final decision by the Accreditation Council*
    - *Comprised of "peer experts"*
    - *Use of majority positive votes and no "negative" votes*

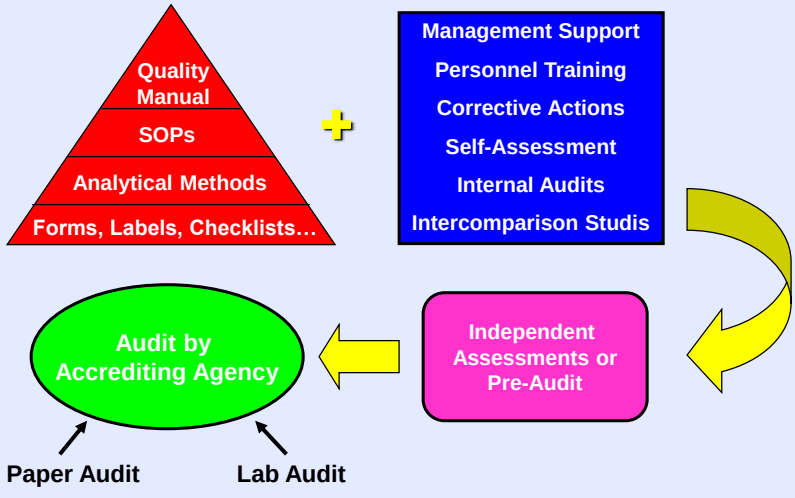
Annual Review

- Accreditation is typically granted for two (2) years
- After 1st year of accreditation, each new laboratory must:
  - *Pay annual fees*
  - *Undergo a one-day surveillance visit to:*
    - *Confirm laboratory is still in compliance*
    - *Demonstrate that the management system is still in place*
- Normal annual review:
  - *Pay annual fees*
  - *Submit internal audits and management review*

Re-Assessment & Renewal

- Typically full on-site assessment every 2 years
- Submittal of completed checklists, staff matrix, fees, etc.
- On-site assessment
- Response to deficiencies
- Corrective actions
- Accreditation Council or staff visits and decisions

Review: The Road to Accreditation



In Conclusion . . .

- Accreditation is an absolute necessity
- Accreditation facilitates world collaboration and trade
- Accreditation leads to:
  - *More reliable results*
  - *More credibility for our laboratories*

Critical Thoughts on Best Practices

- Does the laboratory "say" what they do?
  - *Do written documents (policies, procedures, arrangements) 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 the lab "prove" it with its records?
  - *Training records, standards preparation, work books, customer reports, audit reports, etc.*

Compliance does not always require best practices, but it's a very good idea.

How to maintain ISO 17025 accreditation?

- ***Document… Document… Document…***
  Develop "living" document (with flexibility and modularity): administrative and technical SOPs
- ***Control… Control… Control…***
  Access to facilities/laboratories/instruments; materials (e.g. SRMs, samples, reagents); records; data/results,
- ***Improve… Improve… Improve…***
  Methods/procedures; training/qualifications; corrective actions; lessons learned; management; assessments & audits; intercomparison studies

The

ISO/IEC 17025(E)

Standard

Organization of ISO/IEC 17025

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

Scope of ISO/IEC 17025

- Specifies general requirements a laboratory shall meet to be considered competent
- Applicable to all types of laboratories
- Notes are for guidance, not requirements
- Stakeholders: used by laboratories, customers, regulators, and accreditation bodies

Normative References, Terms, and Definitions

- ISO/IEC 17000: *Conformity Assessment – Vocabulary and general principles*
- VIM: *International vocabulary of basic and general terms in metrology*
- For the purpose of ISO/IEC 17025, the relevant terms and definitions given in ISO/IEC 17000 and the VIM apply

#1 Rule of Auditing

If you cannot express the non-conformity in the words of the management system standard, the appropriate technical specification or test method, or the company's own policies and procedures,

THEN YOU DO NOT HAVE A NON-CONFORMITY!

ISO/IEC 17025 – Management Requirements *(page 1 of 2)*

4.1 Organization

4.2 Management System

4.3 Document Control

4.4 Review of Requests, Tenders, Contracts

4.5 Sub-Contracting of Tests

4.6 Purchasing Services and Supplies

4.7 Service to Customer

ISO/IEC 17025 – Management Requirements *(page 2 of 2)*

4.8 Complaints

4.9 Control of Non-conforming Work

4.10 Improvement

4.11 Corrective Action

4.12 Preventive Action

4.13 Control of Records

4.14 Internal Audits

4.15 Management Reviews

ISO/IEC 17025 – Technical Requirements

5.1 General
5.2 Personnel
5.3 Accommodation/Environmental Conditions
5.4 Test Methods and Method Validation
5.5 Test and Measurement Equipment
5.6 Measurement Traceability
5.7 Sampling
5.8 Handling of Test Items (Samples)
5.9 Assuring the Quality of Test Results
5.10 Reporting the Results

QUESTIONS