# Training Workshop on Water Monitoring Network and Early Warning System

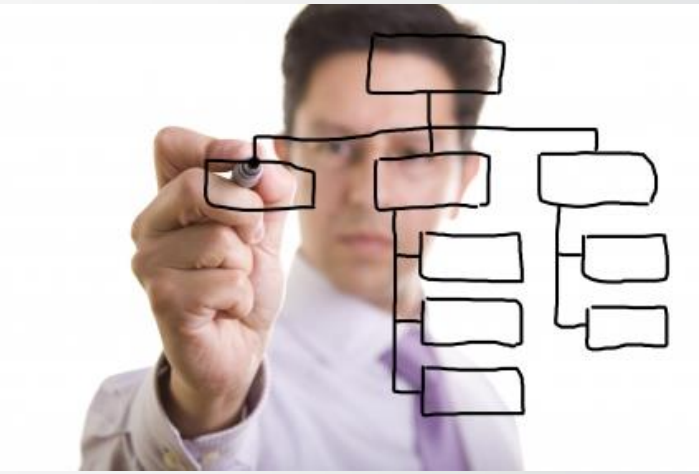
## 16-19 August 2021

## Virtual-SESRIC, Ankara - Turkey

The Importance of Water labs Accreditation by International Accreditation Commission

**Lebanese University, Tripoli, Lebanon**

# Learning Objectives



- Define and explain accreditation.
- Explain the accreditation process as it relates to laboratories.
- Describe the purpose and key benefits of accreditation.
- Describe the role proficiency testing plays in obtaining and maintaining accreditation.

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# Laboratory Accreditation

Defined as a procedure by which an authoritative body* gives formal recognition that a *Conformity Assessment Body* fulfills specified requirements and is ***competent*** to carry out specific tasks.

**Usually using ISO/IEC 17025**

ILAC is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC 17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO 17034).

# AROUND THE WORLD

**TESTING LABORATORIES USING ISO / IEC 17025**
99 signatories to the ILAC MRA
60,014 accredited CABs

**CALIBRATION LABORATORIES USING ISO / IEC 17025**
86 signatories to the ILAC MRA
11,376 accredited CABs

**MEDICAL TESTING USING ISO 15189**
70 signatories to the ILAC MRA
8,405 accredited CABs

**INSPECTION BODIES USING ISO / IEC 17020**
77 signatories to the ILAC MRA
11,310 accredited CABs

**PROFICIENCY TESTING PROVIDERS USING ISO / IEC 17043****
34 signatories to the ILAC MRA
461 accredited CABs

**REFERENCE MATERIAL PRODUCERS USING ISO 17034****

**The ILAC MRA was extended in May 2019 to include accreditation of Proficiency Testing Providers to ISO/IEC 17043 and Reference Material Producers to ISO 17034 in April 2020

**5** regional cooperation bodies recognised under the ILAC MRA

**102** signatories to the ILAC MRA from 104 economies.

# What is ILAC ?

## International Laboratory Accreditation Cooperation

- Established in 1977 to promote communication among laboratory accreditation bodies around the world
- Formalized as a cooperation in 1996 with 44 bodies signing a Memorandum of Understanding (MOU)
- On 2 November 2000, a mutual recognition arrangement was signed, among the 36 accreditation body members from 28 economies, which had successfully completed a peer evaluation
- ILAC was incorporated in the Netherlands on 20 January 2003.
- Approx. 33,000 laboratories & over 6,000 inspection bodies have now been accredited by the 67 ILAC Full Members.

TÜRKAK

DAC
مركز اعتماد تقييم المطابقة
DUBAI ACCREDITATION CENTER

JAS
Jordanian Accreditation System
نظام الاعتماد الأردني
Accreditation Unit

المجلس الوطني للاعتماد
EGAC

cofrac

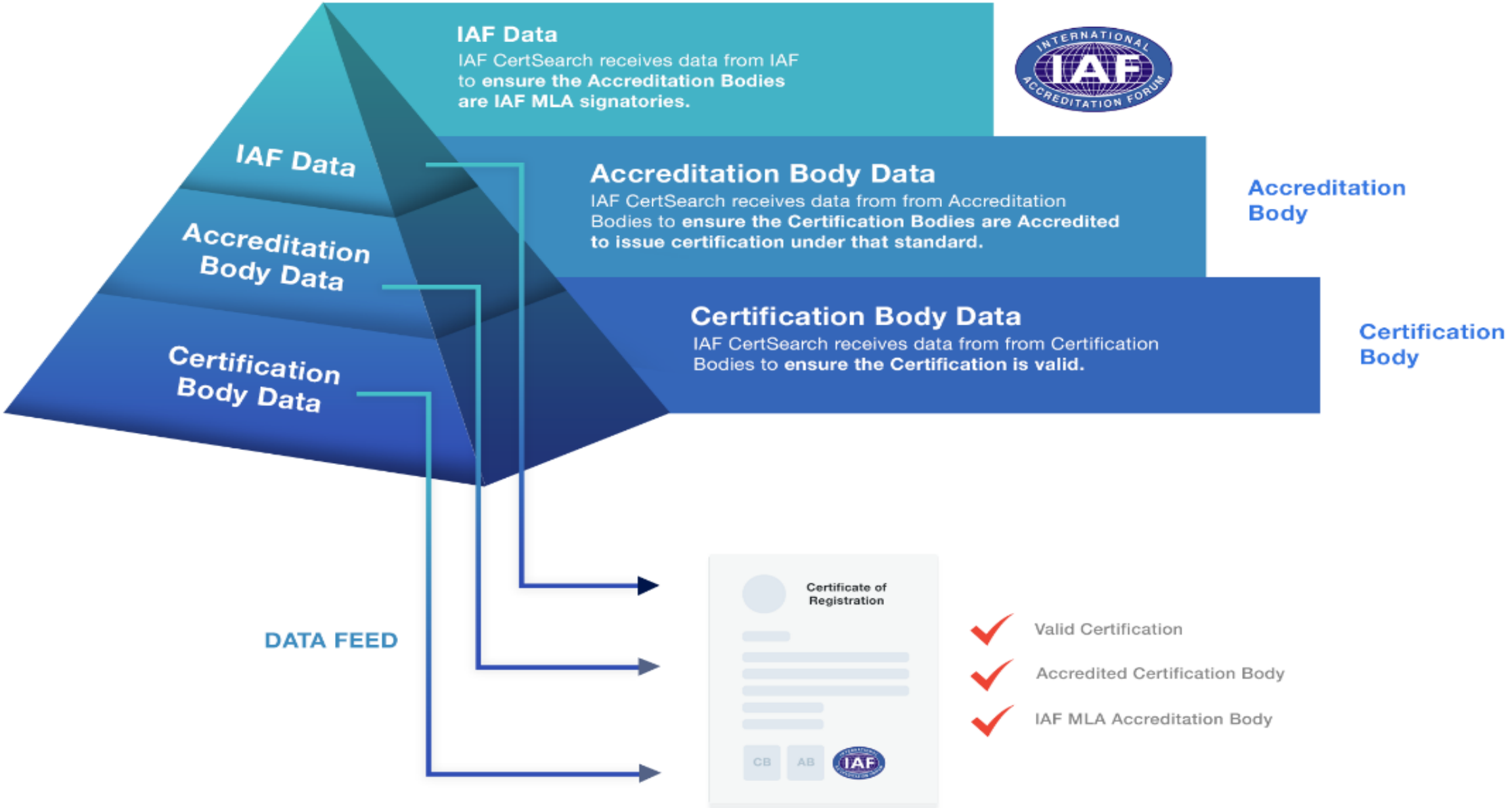
DAkkS

FINAS
Finnish Accreditation Service

CYPRUS ORGANISATION FOR STANDARDISATION

ANAB
ANSI National Accreditation Board

UKAS
UNITED KINGDOM ACCREDITATION SERVICE


IAF Data
IAF CertSearch receives data from IAF to ensure the Accreditation Bodies are IAF MLA signatories.
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IAF MLA Accreditation Body

# Hierarchy of Accredited Certification

**International Accreditation Forum (IAF)**

Provides oversight & governance of Multilateral Recognition Agreement (MLA)

**Accreditation Body (AB)**

- Recognized by IAF and Signatory of MLA
- Accredits CBs

**Certification Body (CB)**

Accredited by AB to certify organizations

**Organization**

Achieves accredited certification to Management System Standard(s)

ilac

cofrac

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# Accreditation Ten Second Tutorial

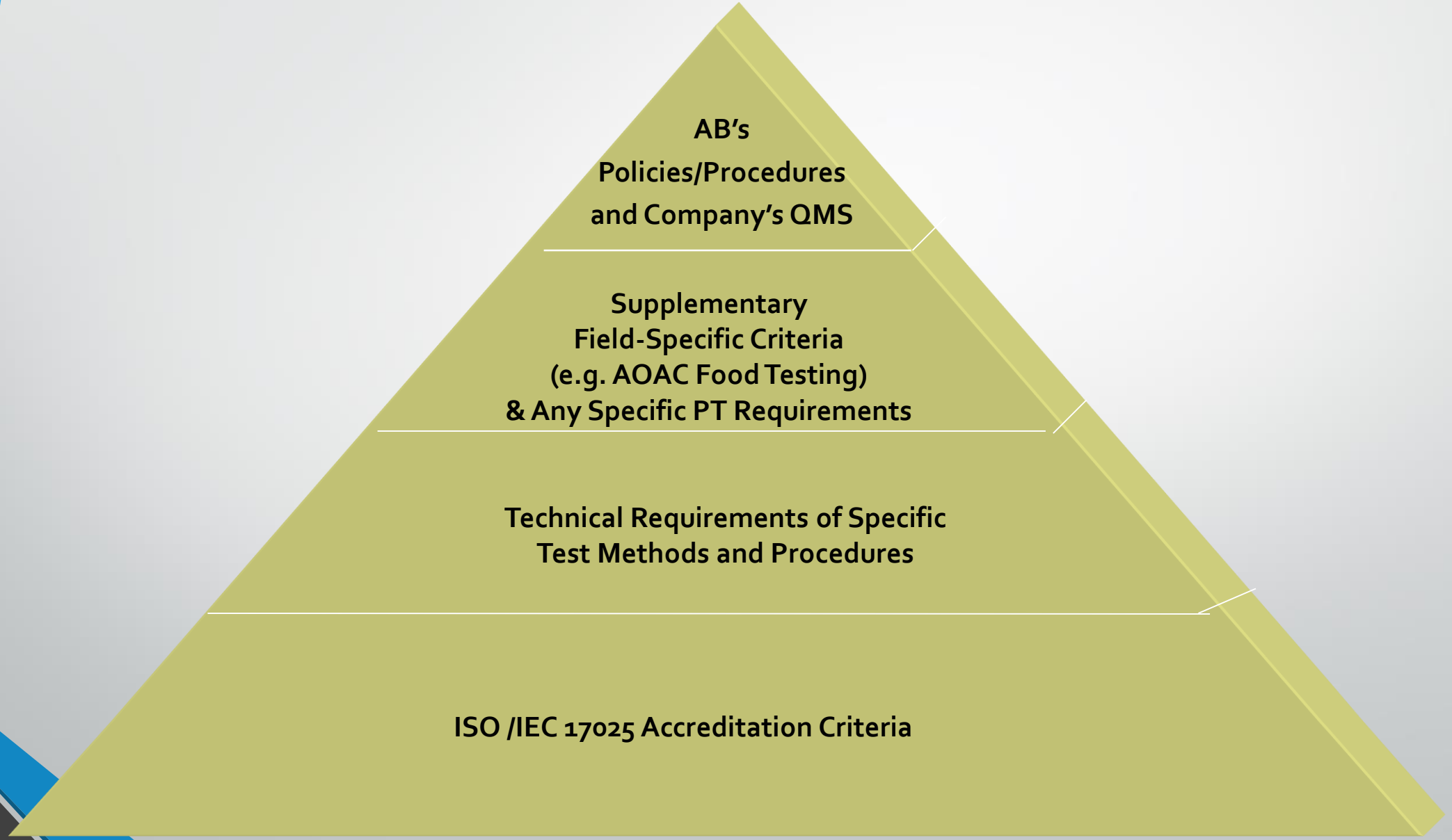
***Do what you say you are doing***

***and be able to prove it!***

# Three Critical Thoughts

- Does the laboratory "say" what they do?
  - **Are there written <u>documents</u> (policies, procedures, arrangements) that meet the requirements of ISO 17025?**
- Does the laboratory "do" what they say?
  - **Are they in <u>compliance</u> with their own quality system, test methods and ISO 17025?**
- Can they "prove" it with their records?
  - **Including everything from training <u>records</u> to standards preparation records to work books to client reports to audit reports and everything in between?**

# Accreditation Requirements



# One Test, Accepted Everywhere

## Mutual Recognitions…

# Mutual Recognition Between Accreditation Bodies

**The Fundamental Purpose:**

A conformity assessment body (testing lab) accredited by one partner has equivalent competence to carry out the same conformity assessment tasks as a conformity assessment body (testing lab) accredited by the other partner(s).

# Primary Objective of Mutual Recognition

- Eliminate conformity assessment as a **Technical Barrier to Trade** *through*
- Recognition of **Competence** *between*
- **Accreditation Bodies.**

# Recognized Accreditation Bodies

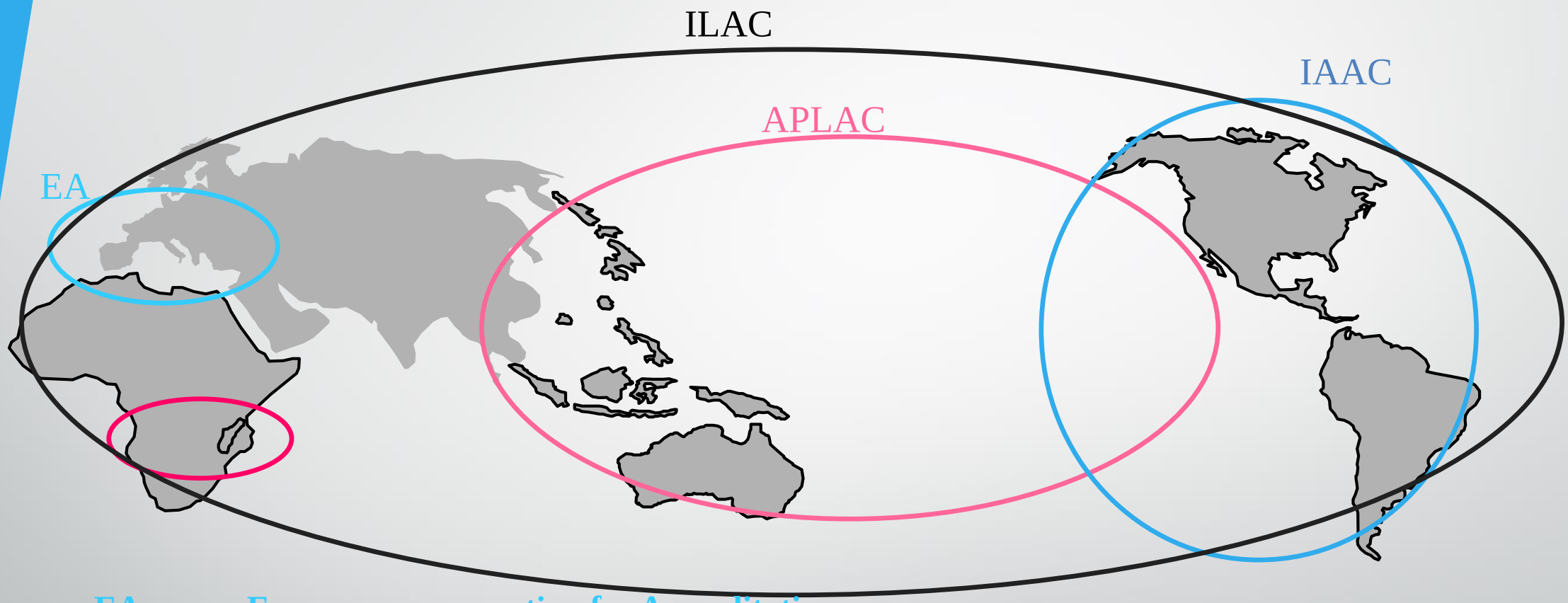
- - Operate to ISO/IEC 17011:2004 by:

  - Using ISO/IEC 17025 as minimum criteria for labs.

  - Undergoing periodic peer evaluations.

- - Are signatories to regional and international mutual recognition arrangements.

# Accreditation Co-Operations




**EA** **European co-operation for Accreditation**

**SADCA** **Southern African Accreditation Cooperation**

**IAAC** **Inter-American Accreditation Cooperation**

**APLAC** **Asia Pacific Laboratory Accreditation Cooperation**

**ILAC** **International Laboratory Accreditation Cooperation (www.ilac.org)**

- - Define and explain accreditation.
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- - Describe the purpose and key benefits of accreditation.
- - Describe the role proficiency testing plays in obtaining and maintaining accreditation.

- Develop, implement, and review all policies, procedures and the quality manual with staff assistance.

- Proficiency Testing data needed for:

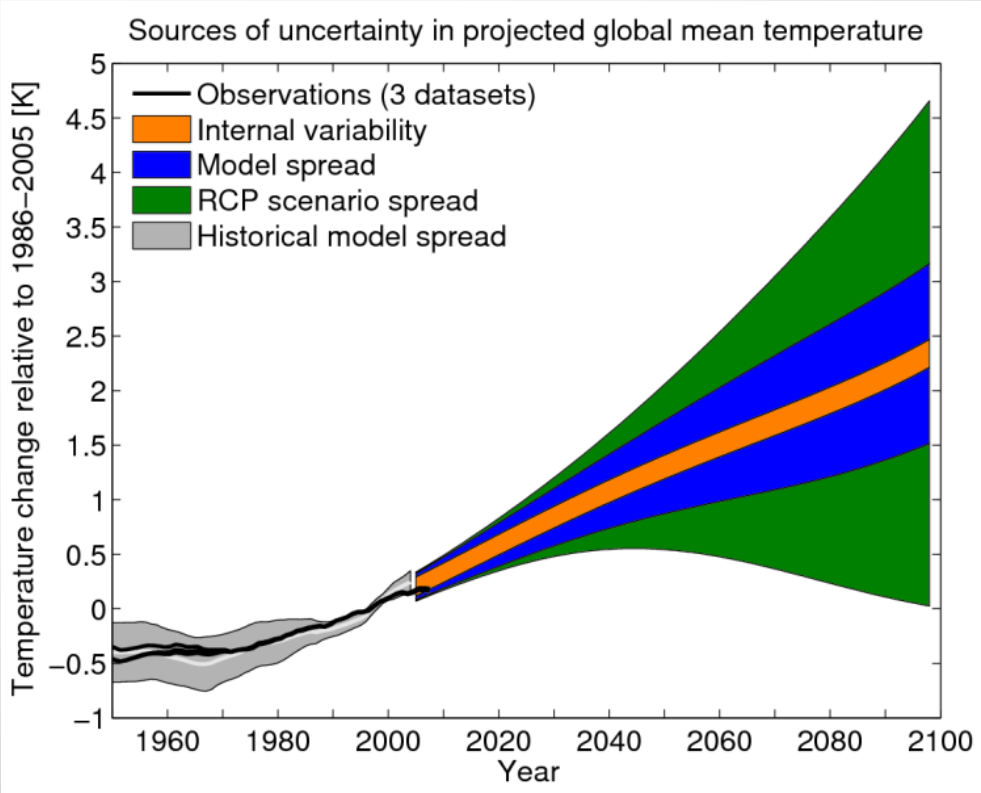
  - Each major testing sub-discipline.

  - As many analyses/methods as possible.

- Estimates of Measurement Uncertainty:

  Develop procedures and identify contributing factors.

  Train personnel to perform calculations.




- Traceability of Calibrations:

  -Through an unbroken chain of comparisons, each step having stated uncertainties.

  -Demonstrable competence performing calibration.

- - Application;
- - Quality Manual;
- - Quality and Technical SOPs & WIs;
- - Completed ISO 17025 Assessor Checklist;
- - Equipment List & Technical Staff Matrix;
- - Scope: Test names w/corresponding method IDs;
- - PT (General): Enrollment & Successful PT

- Commercially available and relevant PT data for all tests and/or methods (if available) for which accreditation is sought (such as ASTM PT programs).

# On-site Assessment Actions

- - Review of quality manual and lab procedures (including test methods):

- Do they contain required polices and procedures?

- - Review of past PT results:

- Do they cover the Scope?

- Are there outliers or evidence of “concern”?

- - Report on potential areas of noncompliance:

- Allows lab to make *minor* fixes in advance.

- Serves as warning if *major* problems exist.

- **Management System:**

- Management /administrative activities, such as -

  - purchasing of consumable materials;
  - management of calibration system;
  - contracts / client interactions;
  - document control and revision;
  - training records.

- Strict adherence to documented procedures.

- Audit can be conducted by non-technical personnel.

- **Technical:**
- - Scientific judgment
    - performance of test;
    - sampling activities;
    - preparation of reagents and/or samples;
    - Results / data analysis.

- Strict adherence as well as technical correctness.

- Audit must be conducted by those familiar with test/technology.

- - Confirm that technicians are following procedure;
- - Judge technical skill;
- - Gain information about training and supervision;
- - Observe status of equipment;
- - Confirm answers.

- Assessor leaves a deficiency report detailing any areas of non-conformance.

- Initial corrective action response required within 30 days of the exit briefing.

- A new applicant must resolve all deficiencies within 6 months of the date of the exit briefing.

- Corrective action is reviewed by A2LA staff; additional information is requested, if needed.

- The Accreditation Council is balloted.

- Accreditation is granted when <u>all</u> issues are resolved.

- - Root cause is reviewed / evaluated for relevance.
- - Responses require full *objective* evidence -

- Staff review – non technical responses.

- Assessor review – technical responses.

- Accreditation Council review – full assessment package, once complete.

- - Do Not:

- Provide draft documents.

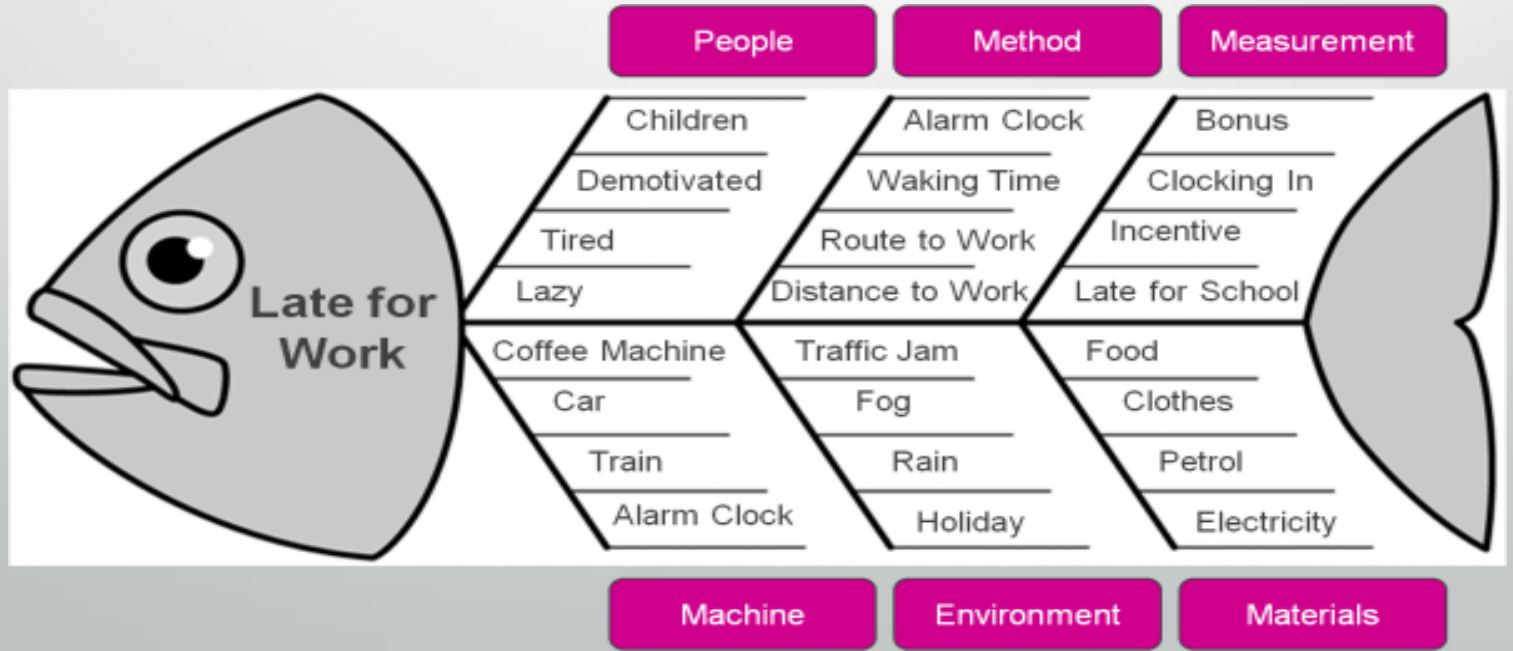
- Supply inappropriate / irrelevant sections of larger documents.

*Keep in mind that the reviewers have not been there, so the "story" must be complete, but succinct.*

- - A system of problem-solving methods aimed at identifying the root causes of problems or incidents.

- - Predicated on the belief that problems are best solved by attempting to correct or eliminate root causes, as opposed to merely addressing the immediately obvious symptoms.

- - By directing corrective measures at root causes, it is hoped that the likelihood of problem recurrence will be minimized.



- - Initial accreditation effort takes 4-6 months on average.
- - Two year accreditation term.
- - On-site surveillance after 1st year of accreditation.
- - On-site renewal every two years.
- - On-going proficiency testing participation.
- - Annual submission of Internal Audits and Management Reviews to A2LA.

- - Define and explain accreditation.
- - Explain the accreditation process as it relates to laboratories.
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A laboratory accredited by a reputable accreditation body:

- Has achieved a prescribed level of technical competence to perform specific activities.
- Is capable of producing data that are accurate, traceable and reproducible.

Using an accredited laboratory:

- Increases confidence in data.
- Reduces uncertainties associated with decisions.
- Increases public confidence because accreditation is a recognizable mark of approval.
- Eliminates redundant reviews and improves efficiency of the assessment process (may reduce costs).

- - Contract review:

- Requests and project proposals are reviewed for sufficient resources and the lab’s ability to perform the work.

- Discrepancies are discussed with the customer and all information is added to the record.

- Emphasis is placed on meeting customer requirements.

- Misunderstandings that could lead to rework and delayed completion are prevented.

# Benefits: Continuous Improvement Requirements

- - Corrective actions are issued for:

- Problem data uncovered in the recheck process.
- Processes not followed as written.
- Sample traceability issues.
- QC or PT problems.
- Customer complaints.
- Audit non-conformances.

- Preventive actions are issued when a potential problem is noted. They are usually more complex and a longer term fix is needed.

- Both CA and PA are tracked. A timeline is assigned requiring completion and verification of effectiveness.

- CA and PA tracking allows for trending of issues and "encouragement" to complete on time.

# Benefits: Continuous Improvement Requirements

- - Management Review is a periodic meeting of members of management and supervisory staff. It allows for a broad review of the quality system including:

- Trending of corrective actions and non-conforming testing.

- Customer complaints.

- QC and proficiency results.

- Supplier performance.

- Supervisory reports on resources and work flow.

# Benefits: Technical Requirements

- - Personnel / Training:

- Training plans are required for all new personnel, changes in position or changes in responsibilities and are assessed regularly.

- Training records include analytical data when appropriate.

  Example: Training summary spreadsheets showing current training status and total number trained per method allows for resource planning.

# Benefits: Technical Requirements

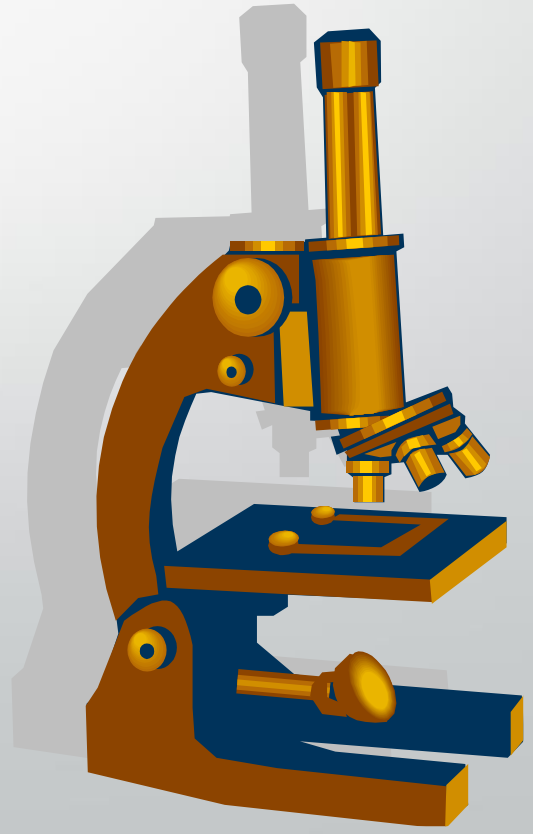
- - Equipment:

- A defined system helps ensure that all equipment is maintained and calibrated as required.

- - Measurement Traceability:

- Calibrations are required to be traceable to standard reference materials, whenever possible.

- Calibrations must be performed by services with comparable quality standards, whenever possible.



# Overall Benefits of Accreditation

- - Corrective and preventive actions, method approval plans, and management review attach timelines to improvement processes ensuring completion.
- - Issues with methods, personnel, and equipment are identified and resolved more quickly.
- - System is continually maturing and improving.
- - Customer satisfaction is improved.
- - Specialized, customer quality requirements are met.
- - Business opportunities may increase.

# Learning Objectives

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# PT and Accreditation

- - To achieve initial accreditation a laboratory must be able to demonstrate successful participation in at least one PT event.
- - A laboratory must develop a plan to demonstrate how they will cover the test methods/technologies on their scope of accreditation over a 4-year period.
- - This PT plan must include commercially available and relevant PT such as PT offered by ASTM.

# PT and Accreditation

- - Proficiency testing results must be submitted to A2LA within 30 days of receipt of the final report.
- - Corrective action must be taken for any outlying results.
- - Unacceptable PT results may result in an adverse accreditation action such as suspension of that test from the scope until the lab can demonstrate acceptable performance.

# Benefits of Proficiency Testing

- - Laboratory Improvement:

- Discover sources of error.
- Systematic errors.
- Precision (inconsistency).
- Internal method comparison.
- Effectiveness of changes.
- Common understanding of method differences.
- Discovery of method sensitivities.
- Demonstration of effectiveness of changes
- To methods.
- To instructions.

- - Education:

- Interpretive information.
- New or rare analytes and matrices.
- Peer communication.

# In Conclusion

- The accreditation process requires work to prepare but it has many benefits to a laboratory.
- Accreditation increases customers' and other stakeholders' confidence in a laboratory's results.
- The accreditation process is really about demonstrating competence and continual improvement.
- Proficiency testing is a critical component of the accreditation process.

# Helping Our World Work Better

## What is ASTM?

12,000+ ASTM standards operate globally

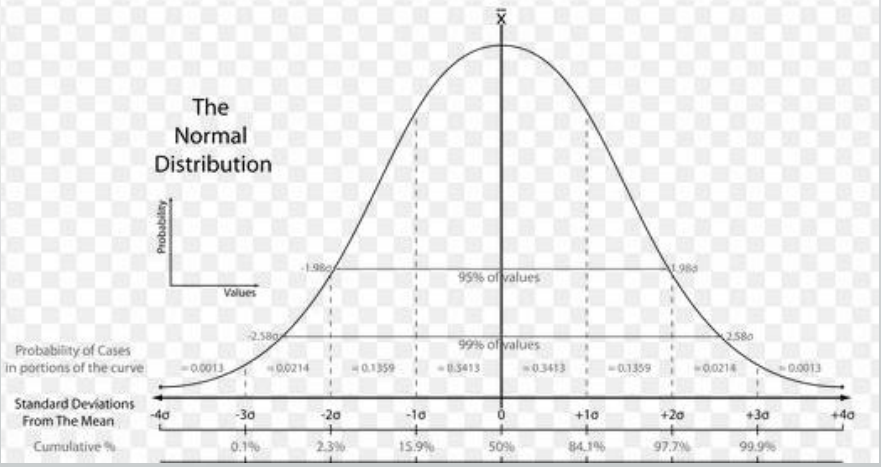
Applied to just about everything from steel to sustainability.

Standards that improve the lives of millions every day

# Why ASTM Proficiency Testing Programs?

American Society for Testing and Materials

- Participation helps satisfy lab accreditation requirements
- Lab QA Tool
  - Data for monitoring lab strengths and weaknesses
  - Residual sample material useful as internal QA sample
- Tool to evaluate other test methods for lab use
- Demonstrate testing capability to customers
- Results and associated statistics helps ASTM validate test method performance under real world conditions
- Used by ASTM committees to obtain valuable feedback on methods



# THANK YOU