

American Association for Laboratory Accreditation



Excellence in Accreditation, Commitment to Service

The Role of Accreditation in Risk Management, Global Trade and Quality of Services - The Case of Calibration

**American Association for Laboratory Accreditation
(A2LA)**

**MEXICO: NORTH AMERICAN CONFERENCE ON GOOD
REGULATORY PRACTICE**

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Objectives

- Role of Accreditation in Risk Management
- Role of Accreditation in Global Trade
- Role of Accreditation in Quality Services
- The Case for Calibration
- Benefits of Accreditation



About A2LA

- Accreditation Body with national and international recognitions
 - Non-profit
 - Non-governmental
 - Public Service
 - Membership Organization



A2LA Recognition



International
Laboratory
Accreditation
Cooperation (ILAC)



Asia Pacific
Laboratory
Accreditation
Cooperation
(APLAC)



Inter-American
Accreditation
Cooperation
(IAAC)

A2LA is a signatory
to both the ILAC &
APLAC MRA and the
IAAC MLA



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A2LA Specific Fields of Testing/Calibration/Inspection

- **Acoustics & Vibration**
- **Calibration**
- **Construction Materials**
- **Environmental**
- **Geo-technical**
- **Mechanical**
- **Non-destructive**
- **Thermal**
- **Biological** (Food, Pharmaceutical Testing Laboratory Accreditation Program; Veterinary Laboratory Accreditation Program)
- **Chemical**
- **Electrical**
- **Forensics**
- **Information Technology**
- **Medical Testing**
- **Sustainable Energy**



Accreditation Defined

■ Accreditation

“Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks”

■ Conformity Assessment Body (CAB)

“Body that performs conformity assessment services and that can be the object of accreditation”

Source: ISO/IEC 17011 **Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies, 2004.**



A2LA Accreditation Process

- Organization is evaluated against a consensus standard (ISO, National, Local) for compliance
- Standard includes both quality management system requirements and technical requirements
- Organization is evaluated for technical competence
- Publish a Scope of Accreditation





SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005
& ANSI/NCSL Z540-1-1994

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CALIBRATION

Valid To: September 30, 2016

Certificate Number: 1823.01

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following calibrations¹:

I. Chemical

Parameter/Equipment	Range	CMC ² (±)	Comments
pH Meters ³ –	(4, 7, 10) pH units	0.020 pH units	Standard buffer solutions
Temperature	(-10 to 110) °C	0.17 °C	Fluke 743B
Conductivity Meters ³ –	(1 to 10) µS/cm (10 to 100) µS/cm (100 to 1000) µS/cm (1000 to 10 000) µS/cm (10 000 to 200 000) µS/cm	0.44 µS/cm 1.1 µS/cm 3.9 µS/cm 50 µS/cm 300 µS/cm	Standard conductivity solutions
Temperature	(-10 to 110) °C	0.17 °C	Fluke 743B



Standards & Regulations

- Laboratory accreditation (ISO/IEC 17025 & ISO 15189)
- Inspection body accreditation (ISO/IEC 17020)
- Proficiency testing providers (ISO/IEC 17043)
- Reference materials producers (ISO Guide 34)
- Product certification body accreditation (ISO/IEC 17065)
- American National Standard for Calibration (ANSI/NCSL Z540.3)
- Environmental (TNI NELAP)
- Putting Green (USGA)
- Underground Storage Tank Testing (State of KY)



Role of Accreditation in Risk Management



Accreditation as a Risk Management Tool

- Accreditation process enables organizations to identify opportunities for improvement and specific methods to achieve improvement.
 - Helps organizations to manage their own risks.
 - Helps organizations to manage the associated risks to clients.
- The process looks at both quality management system and **technical competence**



Role of Accreditation in Global Trade



Framework - WTO Principles

- Transparency
- Openness
- Impartiality
- Effectiveness and relevance
- Consensus
- Performance based
- Coherence
- Due process
- Technical assistance



Accreditation Ensures Global Consistency

- Tested, inspected or certified once, accepted everywhere.



Global Harmonization

- **Technical: standardization of practices**
- **Economic: Strengthen Economic Ties, Expand Trade and Investment Relationship (trade frameworks/regional agreements: i.e WTO agreements.)**



GLOBAL ACCREDITATION NETWORKS

■ International Laboratory Accreditation Cooperation (ILAC)



■ International Accreditation Forum (IAF)



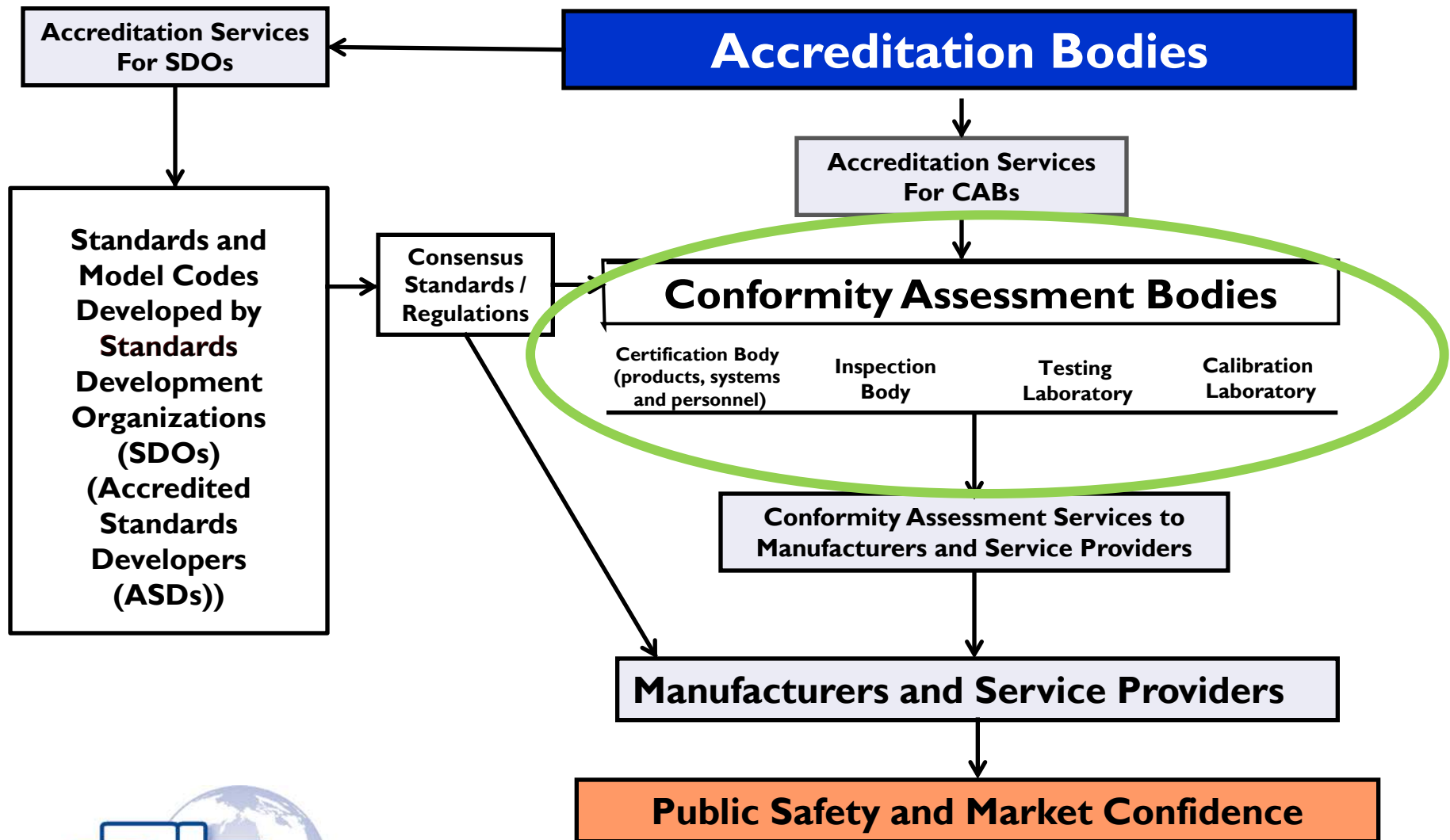
ILAC and IAF

GLOBAL networks of conformity assessment accreditation bodies.

- Recognition of competent conformity assessment activities through global multi-lateral mutual recognition arrangements(MRA)
- **Harmonization** of conformity assessment practices.
- Promotion of accredited conformity assessment as an effective mechanism for providing **confidence** in goods and services.



Accreditation to Support Confidence in the Market



"Standardization Roadmap: Energy Efficiency in the Built Environment, Version 1.0. ANSI"

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Regional Cooperation Bodies

- The IAF MLA recognizes EA, PAC, IAAC
- The ILAC MRA recognizes EA, APLAC, IAAC



European
Cooperation
for
Accreditation
(EA)



Pacific
Accreditation
Cooperation (PAC)



Inter-American
Accreditation
Cooperation
(IAAC)



Asia Pacific
Laboratory
Accreditation
Cooperation
(APLAC)



Southern African
Development
Community
Accreditation
(SADCA)



African
Accreditation
Cooperation
(AFRAC)



Arab
Accreditation
Cooperation
(ARAC)



USA Specifiers of the Arrangements

- **Consumer Product Safety Commission (CPSC)**
- **Federal Highway Administration (FHWA)**
- **General Services Administration (GSA)**
- **Department of Defense (DOD)**
- **Nuclear Regulatory Commission (NRC)**
- **Food and Drug Administration (FDA)**
- **Environmental Protection Agency (EPA)**



Accreditation and Trade Facilitation

- Benchmark
- Supports R&D efforts
- Meets specifier requirements



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Role of Accreditation in Quality of Services



Quality Infrastructure



Combination of standardization and quality assurance
(i.e., accreditation)

- A fully functional Quality Infrastructure is essential for **the free movement of goods** within the region as well as **for trade with international partners** (OECD/WTO - **Establishing a Regional Quality Infrastructure in the East African Community, 2011.**)



Quality Assurance: Accreditation Bodies (ABs)

- Established accreditation body – the “authoritative body that performs accreditation” ISO/IEC 17011
- Proper recognitions global and local



The Case for Calibration



Role of Calibration

- Calibration underpins all other measurements & brings confidence to marketplace

➤ How?

- Metrological Traceability
- Measurement Uncertainty



So What is a National Metrology Institute?

A National Metrology Institute (NMI) is a national laboratory that is tasked with the realization, maintenance, improvement and dissemination of the SI units via traceable calibration and measurement services for the metrology activities within a particular country.

The NMI in the United States is the National Institute of Standards and Technology (NIST).

The NMI for Mexico is **CENAM**

The NMI for Canada is **NRC-INMS**



■ International System of Units (SI): specifies a set of seven base units from which all other SI units of measurement are derived. These include:

- Kelvin (temperature)
- Second (time)
- Meter (length)
- Kilogram (mass)
- Candela (luminous intensity)
- Mole (amount of substance)
- Ampere (electric current)



SI Units

- The SI are maintained by the International Bureau of Weights and Measures (BIPM) in Paris, France
- The BIPM mission and role is to ensure and promote the global comparability of measurements including providing the SI units for
 - Scientific discovery and innovation
 - Industrial manufacturing and trade
 - Sustain quality of life and global environment

and as the basis for world-wide traceability of measurement results



Metrological Traceability per VIM

- **Metrological Traceability** is the property of a measurement result whereby the result can be related to a reference through documented unbroken chain of calibrations, **each contributing to the measurement uncertainty**



What is a Traceable Measurement and Why Does It Matter?

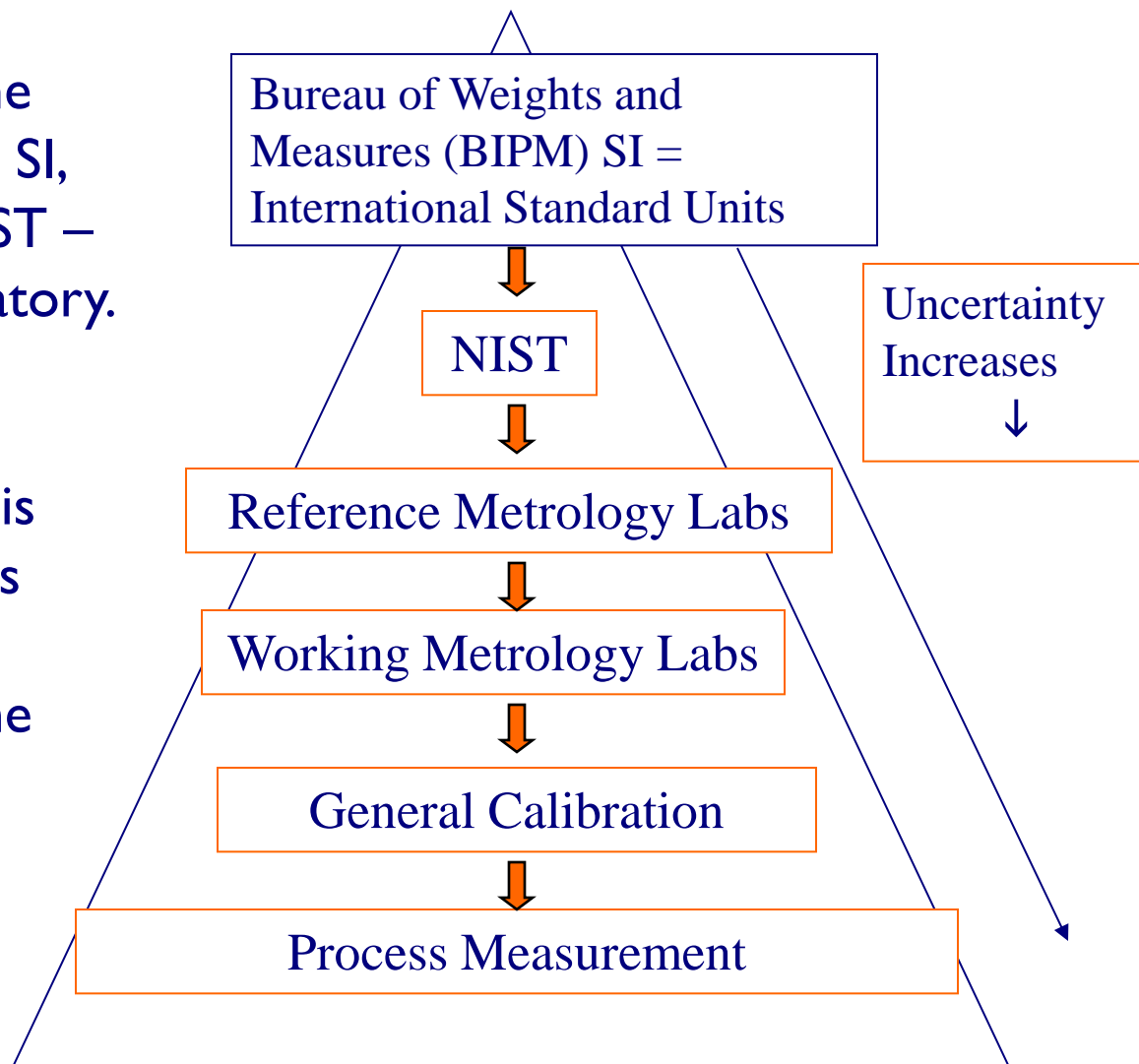
- Traceability provides assurance that the calibration results are both accurate and reliable.
- The desired outcome is to provide a linkage of measurements from your equipment to a commonly accepted reference which makes them comparable across measurement systems, location and time.
- Without traceability (and measurement uncertainty) it would be difficult for measurement results to be readily understood and properly interpreted in a uniform way throughout the world.
- Uniformity is necessary so that measurements can be easily compared both locally and globally.



Traceability Chain

Here is an example of a the traceability chain from the SI, through the US NMI – NIST – down to the testing laboratory.

You'll notice that the measurement uncertainty is additive so that it increases with each link in the chain between the SI unit and the laboratory instrument.



Benefits of Accreditation



Benefits for Government and Regulators

- Cost effective tool to support regulation
- Allows for efficient monitoring
- Enforcement/Compliance assistance



Benefits for Industry

- Greater acceptance of products and services opening up markets
- Avoiding the costs of multiple testing, inspection or certification
- Efficient management of suppliers



Benefits for Consumers

- **Public confidence in goods and services despite complex global marketplace**
- **Reduces product failures**



Path Forward: The “Four Rs”

Resources (financial, human, technology, etc.)

Research (participation in standardization initiatives, industry developments.)

Regulatory System (policies and regulations – drivers of accreditation.)

Re-engineering based on quality and technical competence.



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