

NVLAP Assessor Training

NVLAP: An Introduction

What is NVLAP?

NVLAP is:

- A system for accrediting laboratories found competent to perform specific tests or calibrations or types of tests or calibrations

NVLAP is not:

- A certifier of test data
- A certifier of products
- An operator of a certification program

NVLAP by the Numbers

- Established in 1976
- Accreditation offered in 18 fields of testing; 8 fields of calibration, covering > 90 parameters.
- Labs are located in North America, Asia Pacific, Europe, and South America
- Nearly 800 testing and calibration laboratories

NVLAP Facts

- NVLAP is a fee-supported program
- Procedures set out in the U.S. Code of Federal Regulations (15 CFR Part 285)
- Linked to NIST measurement research
- Operates in accordance with ISO/IEC standards
 - ISO/IEC 17011 (for Accrediting Bodies)
 - ISO/IEC 17025 (for Laboratories)
- Accreditation available to any qualifying laboratory

Partial Listing of Laboratory Accreditation Programs (LAPs)

- Calibration >100 labs
- Electromagnetic Compatibility ~130 labs
- Cryptographic & Security Testing ~ 20 labs
- Ionizing Radiation Dosimetry ~ 30 labs
- Asbestos Fiber Testing > 200 labs

NVLAP Support of Federal Agency Programs

- U.S. Department of Energy (DOE) & Environmental Protection Agency's (EPA) Energy Star Program
- DOE's Nuclear Weapons Program; the Nuclear Regulatory Commission (NRC) programs for commercial grade calibration services and testing of personnel dosimetry performance
- National Information Assurance Partnership (NIAP), a partnership between NIST and the National Security Agency (NSA), for testing encryption/ decryption products that ensure information security

NVLAP Support of Federal Agency Programs

- Federal Communications Commission's (FCC) implementation of Part 15 requirements and its designation responsibilities in support of various Mutual Recognition Arrangements covering telecommunications and electromagnetic compatibility testing
- Department of the Navy (DoN) for electromagnetic compatibility testing
- Department of Housing and Urban Development (HUD) for testing of wood based products & carpet and carpet cushions

NVLAP Support of Federal Agency Programs

- National Institute of Justice (NIJ) for personal body armor
- Department of Homeland Security (DHS) for radiation detection instruments and biometrics
- Department of Health and Human Services (National Coordinator for Health Information Technology) for healthcare information technology

NVLAP Conducts Three Programs Mandated by Congress

- Asbestos Hazard Emergency Response Act (AHERA) for testing for asbestos in public schools
- Help America Vote Act (HAVA) for the testing of voting machines
- Fastener Quality Act (FQA): Public Law 101-592- which requires that certain fasteners sold in commerce conform to the specifications to which they are represented to be manufactured.

What is Laboratory Accreditation?

- Independent, third party assessment of laboratory technical competence
- Assessment is based on international standard (ISO/IEC 17025)
- Assessment of specific scope of accreditation
- Assessment by peer technical experts
- Results in formal recognition by an authoritative body

Developing a Laboratory Accreditation Program (LAP)

- NVLAP receives request for new program
- NVLAP may conduct a public workshop
- NVLAP announces the establishment a new program in the Federal Register
- Balanced expert advice sought at all phases of development and implementation

Developing a LAP

- Define scope (e.g., test methods, areas of accreditation to be offered)
- Create NIST Program-Specific Handbook 150-XX for the new program giving detailed, specific management and technical requirements/guidelines for accreditation
- Create NVLAP program-specific checklists(s)

Developing a LAP

- Set criteria for, seek, and select peer technical expert assessors
- Train assessors to use ISO/IEC 17025 and NIST Handbook 150 in conjunction with the relevant technical standards

NVLAP Accreditation Process

- Application
 - Includes payment of appropriate fees
 - Submission of management system documentation
- Document/Desk Review
 - Does the lab appear to meet the requirements?

NVLAP Accreditation Process

- On-site Assessment
 - **Verify** implementation of the Management System
 - Observe processes
 - Check records
 - Evaluate technical competence

NVLAP Accreditation Process

- Reporting out
 - Done at the close of the on-site
 - No surprises
- Nonconformity resolution - 30 days
- Accreditation decision- based on review of information
- Surveillance and reassessment

Basis for Accreditation: What the Assessor Reviews

- Documented Management System
- Policies (Management and Technical)
- Quality Manual
- Quality Procedures
- Instructions (Test methods, calibration procedures)
- Records (Equipment maintenance, personnel training, complaints, etc.)

Basis for Accreditation: What the Assessor Reviews

- Test methods/calibration procedures
- Environmental conditions
- Test and measurement equipment
- Trained personnel
- Uncertainty budgets

Basis for Accreditation: What the Assessor Reviews

- *Metrological Traceability*
- Reports/Certificates
- Proficiency Test results
- International Laboratory Comparisons (ILCs) conducted with accredited labs in other countries

Accreditation Decision

- Based on results obtained during each step of the process
 - Documentation review
 - On-site assessment
 - Proficiency testing/ILCs
- Reviewed by independent subject matter experts and/or NVLAP Program Managers
- Granted by NVLAP Chief

NIST Handbook 150

- NVLAP Procedures and General Requirements
 - General information
 - Accreditation process
 - Conditions and Criteria for Accreditation
 - Sections 4 & 5 contain the managerial and technical requirements of 17025:2005
- Referencing NVLAP Accreditation
- Cross-Frontier Policy

NIST Handbook 150-XX

- Calibration LAP
 - 8 Program-Specific handbooks covering 8 Fields/90+ parameters
 - Guidance documents
- Testing LAPs
 - 20 Program-Specific Handbooks
 - Requirements documents

International Recognition

- International Laboratory Accreditation Cooperation (ILAC)
- Global Mutual Recognition Arrangement (MRA) among accreditation bodies
- Based on evaluation of competence
- > 80 signatories from multiple economies
- <http://www.ilac.org>

International Recognition

- Asia Pacific Laboratory Accreditation Cooperation (APLAC)
 - http://www.aplac.org/aplac_mra.html
 - Membership roughly parallel to APEC
 - Designated as Specialist Regional Body by APEC

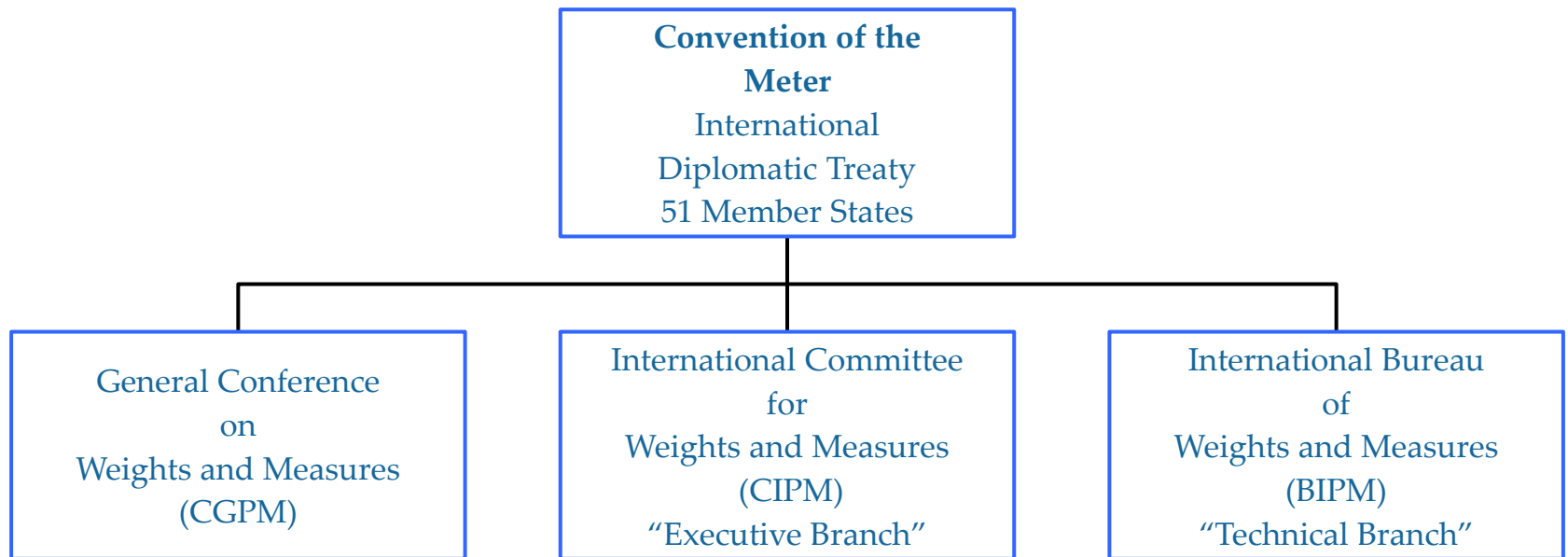
International Recognition

- InterAmerican Accreditation Cooperation (IAAC)
 - Regional body for the Americas
 - All types of accreditation (laboratories, certification, inspection)
 - November 2006 recognition as a region under ILAC
 - <http://www.iaac.org.mx/English/Mla.php>

What this means to an assessor...

- Primary issue is acceptance of calibration certificates for demonstration of traceability
- Calibration certificates from labs accredited by signatory partner ABs acceptable **if**:
 - Report/data are technically valid and appropriate for intended purpose
 - Calibrations and uncertainties are within laboratory's Scope of Accreditation
 - Certificate is properly endorsed as being covered by accreditation (e.g. AB logo or statement on report)
 - Calibration areas are within the AB's defined Scope of Recognition

Metrology Authoritative Bodies

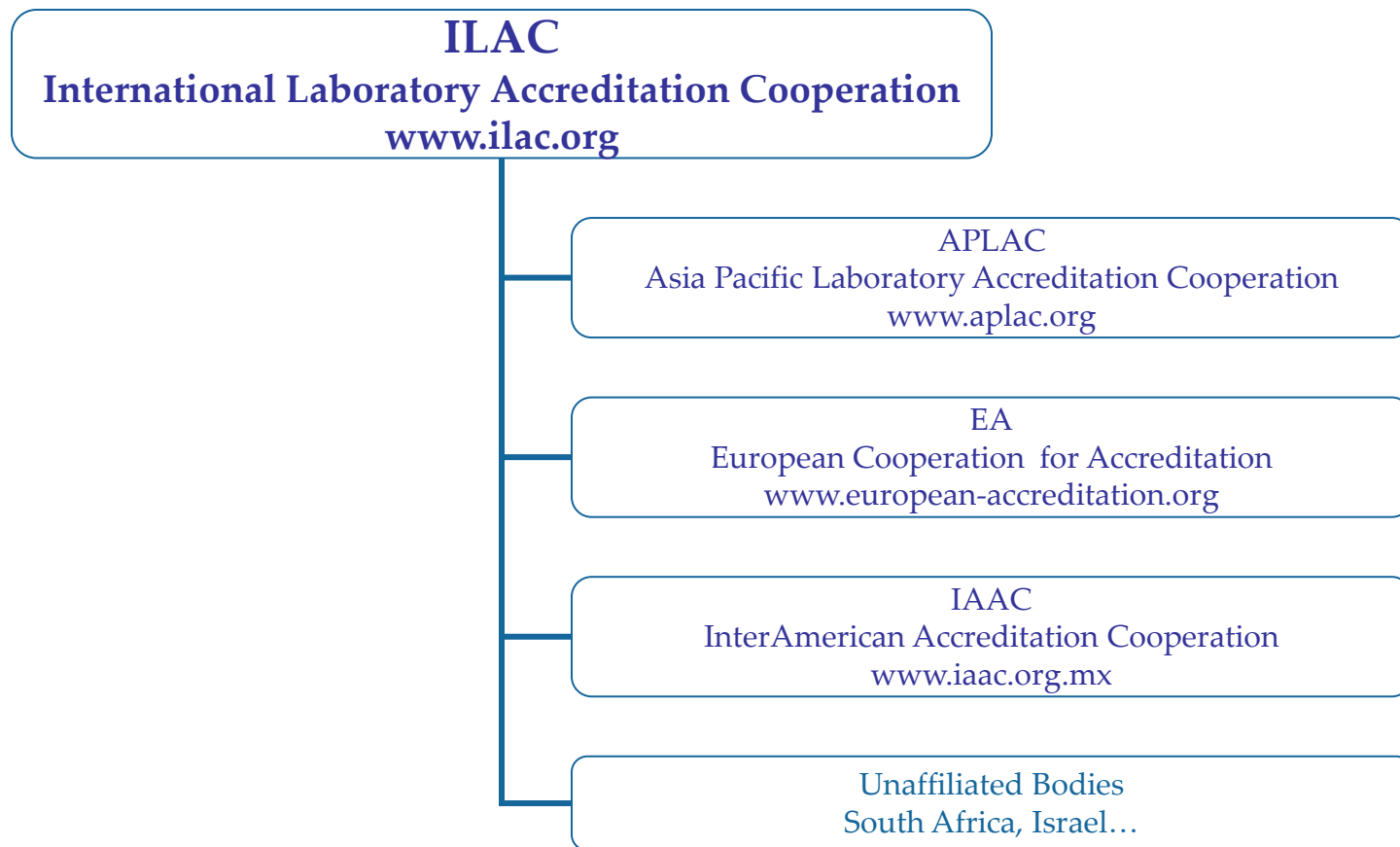


CIPM MRA

- Global Coordination
- National Metrology Institutes (NMIs) establish degrees of equivalence
 - Calibration Measurement Capabilities (CMC)
 - Uncertainty
- Key Comparisons for base units of the SI
 - KCDB: Key Comparison Data Base

Accreditation Entities

Mutual Recognition Arrangements (MRAs)



ILAC MRA Signatory Accrediting Bodies in the U.S.

- A2LA (American Association for Laboratory Accreditation)
- ACLASS (ANSI-ASQ National Accreditation Board)
- IAS (International Accreditation Service)
- L-A-B (Laboratory Accreditation Bureau)
- NVLAP (National Voluntary Laboratory Accreditation Program)
- AIHA-LAP (AIHA Laboratory Accreditation Programs)
- PJLA (Perry Johnson Laboratory Accreditation, Inc.)
- ASCLAD/LAB (American Society of Crime Lab Directors/Laboratory Accreditation Board)

Closing Thoughts

- Accreditation lends
 - Confidence
 - In technical competence and capability
 - In metrological traceability
 - Acceptance of measurement results
 - Reduces redundant audits
 - Minimizes technical barriers to trade

Closing Thoughts

- Assessors review
 - Evidence of technical competence and capability
 - Evidence of metrological traceability
 - Evidence of efficacy of management system covering both management and technical requirements based on ISO/IEC 17025