The National Voluntary Laboratory Accreditation Program (NVLAP)

An Introduction

NIST
National Institute of Standards and Technology
U.S. Department of Commerce

NVLAP®

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 ~200 labs
- Cryptographic & Security Testing ~ 12 labs
- Ionizing Radiation Dosimetry ~ 25 labs
- Environmental 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
- National Institute of Justice (NIJ) for personal body armor
- Department of Homeland Security (DHS) for radiation detection instruments

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 a 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

- 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 ISO/IEC 17025:2005
- Referencing NVLAP Accreditation
- Cross-Frontier Policy

NIST Handbook 150-XX

- Calibration LAP
  - 8 Program-Specific handbooks covering 8 Fields/93 parameters
  - Guidance Documents
- Testing LAPs
  - 19 Program Specific Handbooks
  - Requirements Documents

Metrological Traceability

- Requires a calibration hierarchy
  - Each step of the process
  - Time each reference used in the hierarchy – HISTORY of the references
- All input quantity values (each component or reference) must be metrologically traceable
  - Commensurate with contribution to the measurement result

ISO/IEC Guide 99:2007
VIM 3:2007

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

Elements Confirming Traceability (to the Source)

- An unbroken metrological traceability chain to an International or National Measurement Standard
- A documented measurement uncertainty
- A documented measurement procedure
- Accredited technical competence
- Metrological traceability to the SI where possible
- Appropriate Calibration Intervals (ILAC-P10:2002)

International Recognition

- International Laboratory Accreditation Cooperation (ILAC)
- Global Mutual Recognition Arrangement (MRA) among accreditation bodies
- Based on evaluation of competence
- 70 signatories from 58 economies

International Recognition

- Asia Pacific Laboratory Accreditation Cooperation (APLAC)
  - 32 signatories from 23 economies
  - 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
  - NVLAP is a signatory to the IAAC MLA (September 2009)

What this means to an assessor…

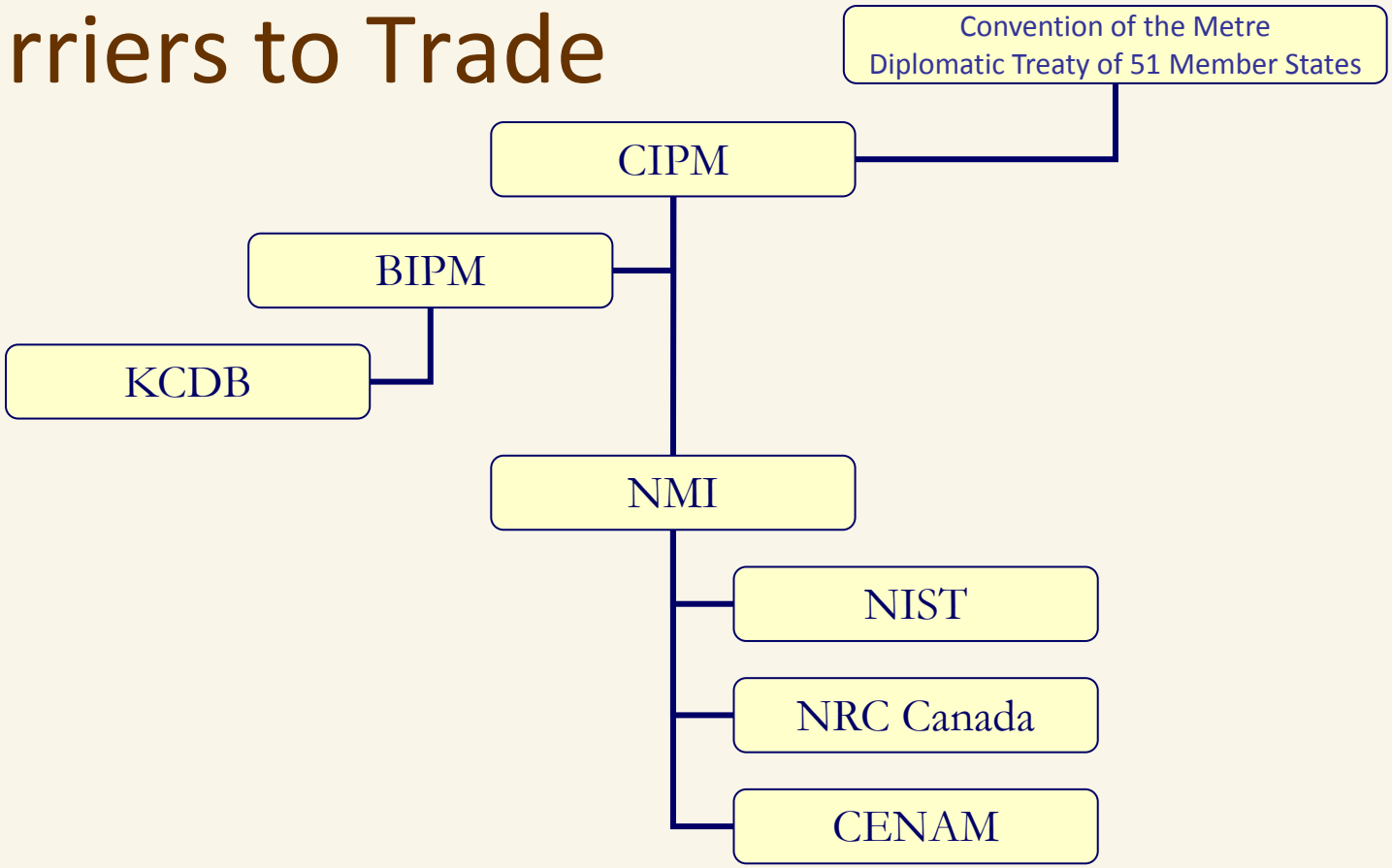
- Primary issue is acceptance of calibration certificates for demonstration of traceability
- Calibration certificates from labs accredited by signatory partner ABs acceptable **if:**
  - Report/data are technically valid and appropriate for intended purpose
  - Calibrations and uncertainties are within 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

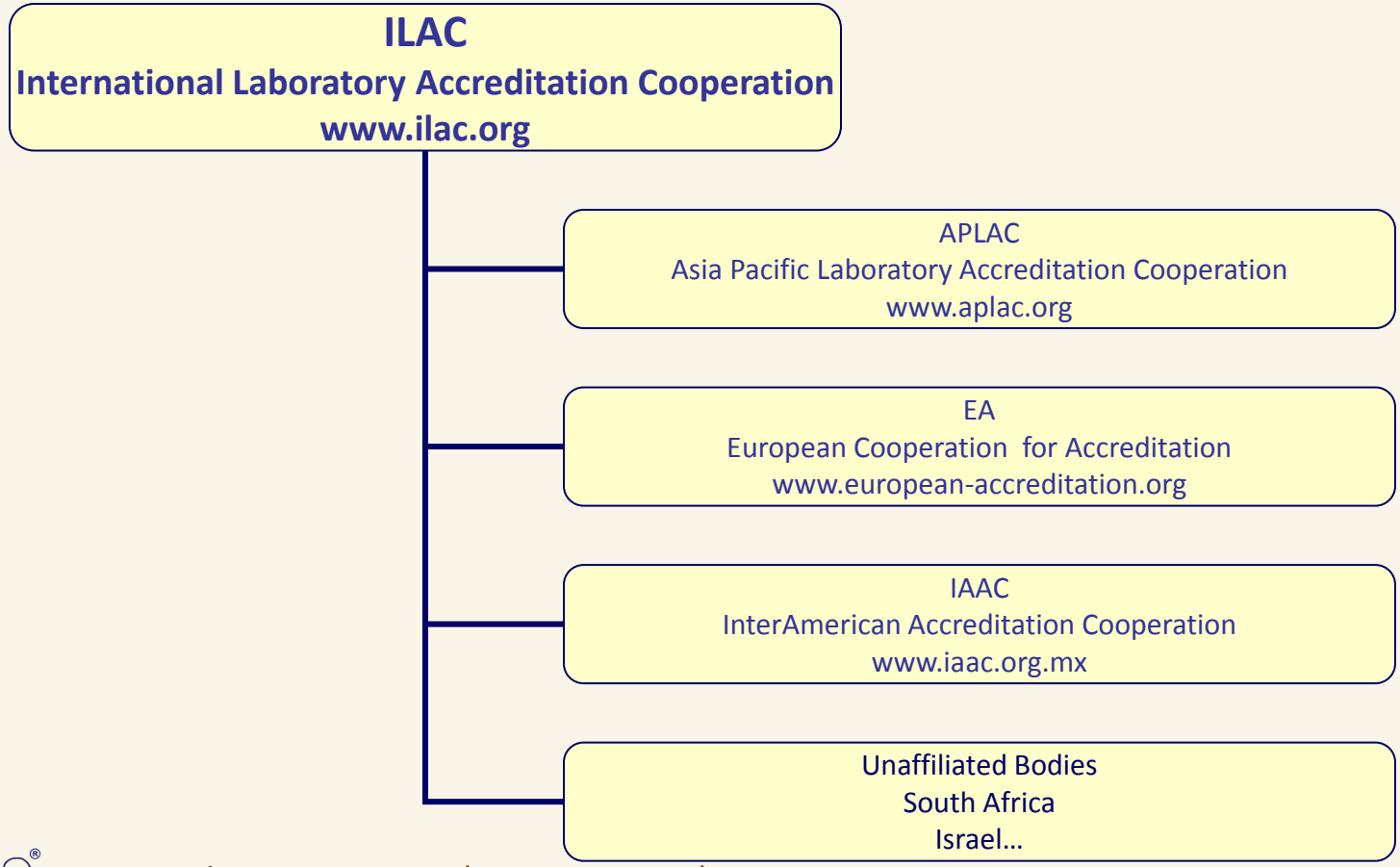
- Global Coordination
- National Metrology Institutes (NMIs) establish degrees of equivalence
  - Calibration Measurement Capabilities (CMC)
  - Uncertainty
- Key Comparisons for base units of the SI
  - KCDB: **K**ey **C**omparison **D**ata **B**ase

CIPM MRA: To Reduce Technical Barriers to Trade



Accreditation Entities

Mutual Recognition Arrangements (MRAs)



ILAC MRA Signatory Accrediting Bodies in United States

- 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)
- 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