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Why Laboratory Accreditation?

• So you don’t have to worry.

• Confidence - it has been done right
• Competence - get the right answer
• Equivalence - get the same answer
• Independence - nothing else is going on
• Appropriateness - fit for purpose
• Repeatability - get the same answer twice
• Reproducibility - others get same answer
World Trade Organization (WTO)

- Final Act - Agreement Establishing the World Trade Organization
- Annex 1 - Multilateral Agreements on Trade in Goods
- Agreement on Technical Barriers to Trade
  - Article 5 - Procedures for Assessment of Conformity by Central Government Bodies
  - Article 6 - Recognition of Conformity Assessment by Central Government Bodies

Mutual Recognition Arrangement (MRA)
For Laboratory Accreditation

Test Anywhere - Sell Anywhere

SALES IN USA
SALES IN ECONOMY X

USA Regulations
USA Regulatory Bodies

Economy X Regulations
Economy X Regulatory Bodies

Mutual Recognition Arrangement

USA Laboratory Accreditation Bodies
Economy X Laboratory Accreditation Bodies

USA Accredited Testing Laboratories
Economy X Accredited Testing Laboratories

USA Manufacturers
Economy X Manufacturers

Laws of Importing Economy
Rules of Importing Economy
Regulations of Importing Economy
Test Methods of Importing Economy
Specifications of Importing Economy

Permission
Law
Recognition
Signatory
Accreditation
Testing
Contract

Test Anywhere - Sell Anywhere

Laws, Rules, Regulations, Test Methods, Specifications of the IMPORTING Economy always apply

National Institute of Standards and Technology • Technology Administration • U.S. Department of Commerce
DOMESTIC AND INTERNATIONAL TRADE
ISO 9000 and ISO/IEC 17025

ISO 9000 is a stripe across the top of an organization

<table>
<thead>
<tr>
<th>ISO 9000</th>
<th>Laboratory</th>
<th>Quality System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Manufacturing</td>
<td>ISO/IEC 17025</td>
<td>Engineering Sales etc</td>
</tr>
</tbody>
</table>

ISO/IEC 17025 is a stripe from top to bottom covering the entire laboratory
## Conformity Assessment - ISO Guides and Standards

<table>
<thead>
<tr>
<th>Testing and Calibration Laboratories</th>
<th>Product Certification Bodies</th>
<th>Management Systems Registrars - Quality and Environment</th>
<th>Inspection Bodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recognition Body (ILAC P1, APLAC MR001, EA-2/02)</td>
<td>Recognition Body (No ISO Guides or Standards)</td>
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</tr>
<tr>
<td>Samples (Test methods and sampling methods)</td>
<td>Products and services (Appropriate product or service standards)</td>
<td>Companies or organizations (ISO 9000, ISO 14000, or equivalent)</td>
<td>Products (Appropriate product standards)</td>
</tr>
</tbody>
</table>
Document it ....

Document it - write it down
Do it
Record it
Audit it
Fix it
CONFIDENCE
IN
INDEPENDENCE and COMPETENCE
International Mutual Recognition Arrangements (MRA)

World MRAs:

• International Laboratory Accreditation Cooperation (ILAC) for testing and calibration laboratories
  <http://www.ilac.org/>

• International Accreditation Forum (IAF) for QMS, EMS, and product certification
  <http://www.iaf.nu>
International Mutual Recognition Arrangements (MRA)

Regional MRAs:
- Asia Pacific Laboratory Accreditation Cooperation (APLAC)  
  <http://www.ianz.govt.nz/aplac/>
- European co-operation for Accreditation (EA)  
  <http://www.european-accreditation.org/>  
- InterAmerican Accreditation Cooperation (IAAC) - MRA in the near future  
  <http://www.ibpinetsp.com.br/iaac>
NVLAP Develops a Program

- Start with NIST Handbook 150
- NVLAP seeks input from all sectors of the community including laboratories, developers, vendors, standards writers, regulators, customers, certifiers, the public
- NVLAP publishes the request for a new program in the Federal Register
- Expert advice is sought
- Input is needed both now and later
Program Specific Requirements

- NIST Handbook 150
- NIST Handbook 150-17
  *Cryptographic Module Testing* extends and defines Handbook 150 specifically for this program
- Proficiency Testing is designed specifically for this program
Accreditation to ISO/IEC 17025:1999

- On-site assessment by a team of peer technical experts (who have had ISO 17025 training)
- Participation in proficiency testing
- Evaluation of the above by NVLAP team
- Feedback to the laboratory
- Corrective action by the laboratory
ISO 17025 - Management Requirements (Section 4 of NIST Handbook 150)

• Organization
• Quality system
• Document control
• Review of requests, tenders and contracts
• Subcontracting of tests and calibrations
• Purchasing services and supplies
• Service to the client
• Complaints
ISO 17025 - Management Requirements cont’d

- Control of nonconforming testing and/or calibration work
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews
ISO/IEC 17025-Technical Requirements
(Section 5 of NIST Handbook 150)

• General - factor contributing to correctness and reliability
• Personnel
• Accommodation and environmental conditions
• Test and calibration methods and method validation
• Equipment
ISO/IEC 17025-Technical Requirements cont’d

- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and calibration results
- Reporting the results
Additional NVLAP requirements

- Referencing NVLAP accreditation (use of logo and “NVLAP”)
- Implementation of traceability policy
- Approved Signatory
- Authorized Representative(s)
New Applicants for Accreditation

- Send application to NVLAP including:
  - General Application
  - Program Specific Application
  - Fees
  - Quality Manual
- Quality documentation review by assessors
- On-site Assessment with proficiency testing
- NVLAP review and grant of accreditation
NVLAP Fees for domestic laboratories (subject to change)

- First Year - $8400
  - Admin/Tech, One-time, On-site, PT
- Second Year - $3300
  - Admin/Tech
- Third Year - $7900
  - Admin/Tech, On-site, PT
- Fourth Year - $3300
  - Admin/Tech
Typical On-site Visit - conducted every other year

- Team of two assessors for 1 1/2 days
- Entry meeting with lab management
- Review quality system documentation including, records, personnel folders, technical documentation
- Examine facilities, hardware, software,..
- Staff interviews on all aspects of standards and testing with appropriate demonstrations
- Proficiency testing
Typical On-site Visit - conducted every other year - cont’d

- Exit meeting
  - On-Site Assessment Report given to lab
  - Required written responses to NVLAP are discussed
Quality System documentation includes

- Quality manual
- Policies, objectives, commitments
- Procedures - management and technical
- Instructions - management and technical
- Records - management and technical
- Roles and responsibilities
Proficiency Testing

- An integral part of the accreditation process - customized for field

- A means of periodically checking laboratory performance and ability

- Required for initial and/or continuing accreditation
Proficiency Testing

- Before the on-site visit
  - A written examination is sent to the laboratory
  - The laboratory chooses who works on exam
  - Results returned to NVLAP and reviewed by assessors before on-site visit
  - If the laboratory does not perform satisfactorily, the on-site visit will be delayed
Proficiency Testing

- During the on-site visit
  - Assessors review exam and exam results with staff
  - An artifact is given to the laboratory for testing after the on-site visit. Instructions are discussed. CMVP person will act as a vendor. Artifact is tested by lab while interacting with “vendor” and validation authority.
- After the on-site visit
  - The artifact test is reviewed
Granting Accreditation

• Application
• Review of quality system documentation
• On-site visit with PT
• NVLAP panel to review all information
• All non-compliances must be resolved
• NVLAP grants accreditation for one year

• Renewal each year with on-site every-other year