



The Role of ILAC in the Acceptance of Tests and Measurements Worldwide

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16 June 2011

What is ILAC ?

International Laboratory Accreditation Cooperation



- Started in 1977 as a conference to promote communication among laboratory accreditation bodies of the world and set standards
- 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 by those members who had successfully completed a peer evaluation
- ILAC was incorporated in the Netherlands on 20 January 2003
- As of the 31 March 2011, there are 71 Signatories (Full Members) to the Arrangement, representing 58 economies

ILAC Vision



“Accredited once, accepted everywhere”

to support

Tested once, accepted everywhere

The Global Role of ILAC



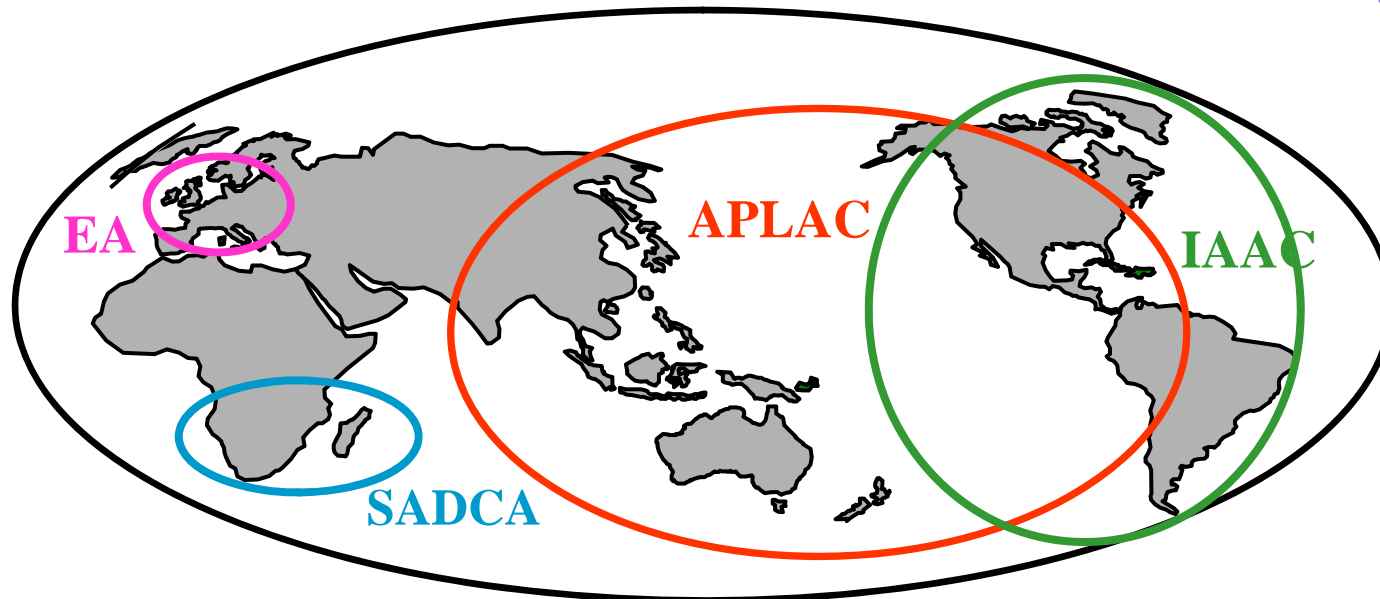
The international forum for:

- Recognition of competent test and calibration labs world-wide through its Mutual Recognition Arrangement (Arrangement or MRA)
- Development of harmonization of laboratory accreditation practice
- Promotion of laboratory accreditation as a trade facilitation tool
- Assisting the development of laboratory accreditation systems

The International Picture



ILAC



- EA** European Cooperation for Accreditation
- APLAC** Asia Pacific Laboratory Accreditation Cooperation
- ILAC** International Laboratory Accreditation Cooperation
- IAAC** Inter-American Accreditation Cooperation
- SADCA** Southern African Development Community Accreditation

Unaffiliated Bodies Peer evaluated ABs who are not geographically located in one of the established regions

How is ILAC Structured?



- General Assembly: highest decision making body consisting of one representative from each membership category.
- General Assembly: meets once each year and these meetings are now held in conjunction with the annual meetings of the International Accreditation Forum (IAF).
- All classes of membership (including stakeholder members) and other interested parties (liaison organizations such as the BIPM, OIML, ISO/CASCO, IEC, UNIDO, WTO, WADA, etc) are invited to contribute to ILAC's work.

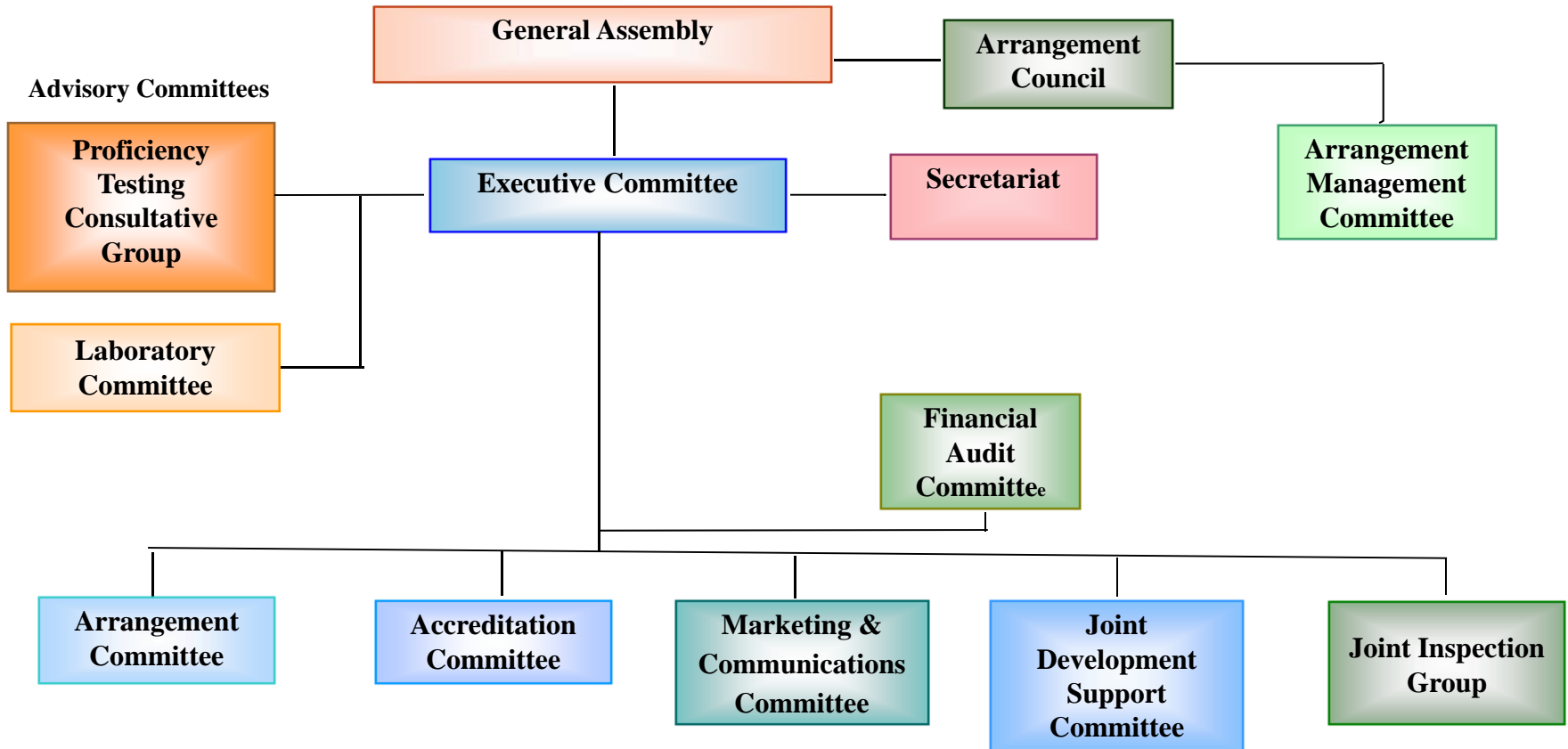


How is ILAC Structured (cont'd)?

- **MEMBERSHIP CATEGORIES:**
 - Full Members (Signatories);
 - Associates;
 - Affiliates;
 - Regional Cooperation Bodies
 - Stakeholders;
- **CURRENTLY:**
 - 72 Full Members from 59 economies;
 - 19 Associates from 19 economies;
 - 19 Affiliates from 18 economies;
 - 4 Regional Cooperation Bodies;
 - 26 Stakeholders.



ILAC Organization Chart



MRAs Between Accreditation Bodies



The Fundamental Purpose -

A laboratory accredited by one partner has equivalent competence to a laboratory accredited by the other partner(s) for the same tests.

MRA Requirements for Signatory Bodies



Compliance with ISO/IEC 17011 using ISO/IEC 17025,
plus ILAC mandatory documents

Demonstration of competence through rigorous
evaluation by peers

Periodic performance through proficiency testing

Regular re-evaluations; maximum interval 4 years

How does the ILAC MRA Work?



Each accreditation body signatory to the Arrangement agrees to abide by its terms and conditions and by the ILAC evaluation procedures and shall:

Maintain conformance with the current version of ISO/IEC 17011, related ILAC guidance documents, and a few, but important, supplementary requirements, and

Ensure that all accredited laboratories comply with ISO/IEC 17025 or ISO 15189 (for medical testing laboratories) and related ILAC policy and guidance documents.

ISO/IEC Standards



ISO/IEC 17011:2004 - Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories

ISO 15189:2007- Medical laboratories -- Particular requirements for quality and competence

Status of ILAC MRA



- 72 Full Members representing 59 economies are signatories to the ILAC Arrangement (MRA).
- The MRAs of the recognized regions underpin the ILAC Arrangement (MRA).
- Currently, the MRAs of 3 of the 4 Regional Cooperation Body members in ILAC are recognized by ILAC (EA, APLAC and IAAC).
- Recognition of a region is achieved after successful peer evaluation by ILAC.
- Each recognized region undergoes a re-evaluation by ILAC every 4 years.
- Signatories to the EA, APLAC and IAAC MRAs, who are also members of ILAC, are entitled to become signatories (Full Members) to the ILAC Arrangement.

Status of ILAC MRA (cont'd)



- Unaffiliated bodies are ABs who do not have a Regional Cooperation body in their geographical region.
- ILAC relies on the evaluations undertaken by the recognized regions to grant and maintain ILAC signatory status for the ILAC members in their respective regions.
- ILAC itself undertakes the evaluations of the regions, the unaffiliated bodies (those ABs who do not have a region in their geographical area) and those ABs who are part of a developing region, that has not yet obtained recognition (e.g., SADCA).
- ILAC draws its peer evaluators from the regions and unaffiliated bodies.

ILAC Peer Evaluation Process



- Objective: **establish confidence** in the endorsed reports and certificates
- Evaluation focus: **how is technical competence of the accredited lab assured**
- Review: documented policies and procedures and adherence to Arrangement policies
- On site evaluation of implementation of policies and procedures
- Witness & evaluate applicant body's ability to accredit conformity assessment bodies
 - sufficient evidence obtained of technical competence
 - use of technically competent assessors
 - participation in proficiency testing
- Evaluation team collects evidence and reports the results

ILAC Peer Evaluation Process



- Signatory ABs are required to provide evaluators for use in the process
 - Experienced assessors
 - Trained in the requirements of ISO/IEC 17011
 - Participate as trainee evaluator initially
 - Evaluate for the standard ISO/IEC 17025 (calibration and/or testing), ISO/IEC 15189, etc. in which they are experienced
 - Qualified in the regions (APLAC, IAAC, EA)
 - Qualified for ILAC

Evaluator Duties



- Team members appointed based on the scope of recognition of the AB
- Team Leaders appoint members to cover
 - Specific requirements of ISO/IEC 17011
 - Witnessing of specific laboratory accreditation assessments
 - Process and personnel involved
- Evidence submitted to team leader to compile into report
- Team leader compiles and submits
 - Summary report including list of findings to the AB at conclusion of on site
 - Draft report (specified time) to Regional Body
 - Final report to Regional Body upon resolution of findings

Becoming Signatory to the Arrangements



- Accrediting Body (AB) submits application to the Regional Organization
- Peer Assessment Team is assembled
- AB submits documented management system and supporting documentation
- Evaluation Team is selected from signatory member bodies
- Evaluation conducted
 - Usually one week
 - Witness accreditation activities including initial, surveillance and monitoring assessments
 - Review competence of staff and assessors (qualifications)
- Report submitted to Regional Body for review by the MRA Council (APLAC) or MLA Group (IAAC)
- Reevaluation at a maximum of 4 years to maintain status

ILAC Signatory Bodies in the U.S. Currently Endorsed by the NRC



- National Voluntary Laboratory Accreditation Program
NVLAP www.nist.gov/nvlap
- American Association for Laboratory Accreditation
A2LA www.a2la.org
- ANSI-ASQ National Accreditation Board dba ACLASS
ACLASS www.aiclasscorp.com/
- Laboratory Accreditation Bureau
L-A-B www.l-a-b.com/
- International Accreditation Service, Inc.
IAS www.iasonline.org/
- Perry Johnson Laboratory Accreditation, Inc.
PJLA www.pjlabs.com/

Other ILAC Signatory Bodies in the U.S.



- American Industrial Hygiene Association Laboratory Accreditation Programs, LLC (Environmental)
AIHA -LAP www.aihaaccreditedlabs.org/
- American Society of Crime Laboratory Directors Laboratory Accreditation Board (Forensics)
ASCLD/LAB www.ascl-d-lab.org/

NVLAP in APLAC, ILAC and IAAC



- 1976 – NVLAP established
- 1997 – NVLAP signed APLAC Mutual Recognition Arrangement (MRA)
- 2000 – NVLAP signed ILAC Mutual Recognition Arrangement
- 2009 – NVLAP signed IAAC Multi Lateral Arrangement (MLA)

NVLAP Numbers



- Accreditation currently offered in 21 fields of testing; 8 fields of calibration, covering >90 parameters.
- Labs are located in North America and Asia Pacific
- More than 900 testing and calibration accreditations
- Laboratory accreditation is renewed annually



NVLAP and NIST

- NVLAP is a part of NIST
 - A program within the National Institute of Standards and Technology (NIST), an agency of the U.S. Department of Commerce (DOC)
 - A registered legal entity on the basis of its governmental status
 - Has established policies, procedures, and a structure to ensure that other parts of NIST or the federal government cannot influence the accreditation process
- NIST Technical Divisions Provide
 - Technical Guidance
 - Proficiency Testing
 - NIST Expert Level Assessors

NVLAP Facts



- NVLAP is a fee supported program
- Procedures set out in the U.S. Code of Federal Regulations (15 USC Part 285)
- Linked to NIST measurement research
- Based on ISO/IEC standards
 - ISO/IEC 17011(NVLAP)
 - ISO/IEC 17025 (Accredited labs)
- Available to any qualifying laboratory

NVLAP Support of Federal Agency Programs



- U.S. Department of Energy (DOE) and the 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
- FCC, DoD, DHS, HHS, HUD, DoJ and others

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; and
- Department of Housing and Urban Development (HUD) for testing of wood based products and carpet and carpet cushions

NVLAP Conducts Two Programs Mandated by Congress



- Asbestos Hazard Emergency Response Act (AHERA) for testing for asbestos in public schools; and the
- Help America Vote Act (HAVA) for the testing of voting machines

Federal Agency Use of the ILAC MRA



- Three Examples of Federal agencies using the ILAC MRA:
 - Consumer Product Safety Commission (CPSC) -
 - Environmental Protection Agency (EPA)
 - Food and Drug Administration (FDA)

Consumer Product Safety Commission



- CPSC regulations issued to protect children under Consumer Product Safety Improvement Act of 2008
- Lists laboratories accredited by ILAC MRA signatories to test in accordance with CPSC-mandated test methods
- Methods must appear on scopes of accreditation

Environmental Protection Agency



- Water Sense Program requires test results from laboratories accredited by an ILAC MRA signatory
- Energy Star Program requires test results from laboratories accredited by an ILAC MRA signatory
- Formaldehyde emissions of composite wood products
- Methods must appear on scopes of accreditation

Food and Drug Administration



- Draft guidance document , *Submission of Laboratory Packages by Accredited Laboratories*
 - For biological products, drugs, devices and food
 - Be an ISO/IEC 17025 accredited laboratory
 - Also meet AOAC *International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals*
 - Be accredited by an ILAC MRA signatory

For more information



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