ISO, ILAC and the International Approach to Accreditation

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Acronyms

- ISO – International Organization for Standardization
- IEC – International Electro-technical Commission
- CASCO – ISO Committee on Conformity Assessment
- REMCO – Reference Material Committee of ISO
- ANSI – American National Standards Institute
- ICAC – ANSI International Conformity Assessment Committee
- ILAC – International Laboratory Accreditation Cooperation
- MRA – Mutual Recognition Arrangement
- CAB – Conformity assessment body
- CITAC – Co-operation on International Traceability in Analytical Chemistry

Relevant International Standards

- ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17011:2004 – Conformity assessment: General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17043:2010 – Conformity assessment: General requirements for proficiency testing
- Numerous other 17000-series standards developed by CASCO
- ISO Guide 34– General requirements for the competence of reference materials producers by REMCO

Annex B of ISO/IEC 17025: Guidelines for establishing applications for specific fields

- Explanations might be needed; applications of general requirements
- Applications for technical requirements:
  - Broadly covering a field
  - A technology for a group of tests; or
  - Narrowly for a specific test

ISO/IEC 17025 Section 4

4.1 Organization
4.2 Management
4.3 Document Control
4.4 Review of requests, tender and contracts
4.5 Subcontracting
4.6 Purchasing services & supplies
4.7 Service to the customer
4.8 Complaints
4.9 Control of nonconforming testing work

ISO/IEC 17025 Section 4 (cont.)

4.10 Improvement
4.11 Corrective action
4.12 Preventive action
4.13 ***Control of records***
4.14 ***Internal audits***
4.15 Management reviews

ISO/IEC 17025 Section 5

5.1 General
5.2 Personnel
5.3 Accommodation and environmental conditions
5.4 ***Test methods and method validation***
5.5 Equipment
5.6 ***Measurement traceability***
5.7 Sampling
5.8 Handling of test items
5.9 Assuring the quality of results
5.10 Reporting the results
Specific tests and supplemental requirements

Top Ten NCs for Environmental Labs
1371 NCs from 106 assessments

1.	Specific Tests & Supplements:	36.0%
2.	5.4 Methods & Validation:	10.5%
3.	4.3 Document Control:	7.3%
4.	5.9 Quality Control & PT:	5.6%
5.	5.5 Equipment:	5.5%
6.	4.13 Records:	5.0%
7.	4.14 Internal Audits:	2.9%
8.	4.11 Corrective Action:	2.8%
9.	4.6 Purchasing service/supply:	2.3%
10.	4.2 Management system:	2.3%

NCs for Environmental Labs

- The top ten NCs represent 80% of all types of nonconformities
- Over 58% are technical in nature
- The rest are related to the lab's management system or A2LA policies

ISO/IEC 17011 Major Sections

4. Accreditation body

5. Management

6. Human resources

7. Accreditation process

8. Responsibilities of the accreditation body and the CAB

4. Accreditation body

4.1 Legal responsibility

4.2 Structure

4.3 ***Impartiality***

4.4 Confidentiality

4.5 Liability and financing

4.6 Accreditation activity

5. Management

5.2 Management system

5.3 Document control

5.4 Records

5.5 Nonconformities and corrective actions

5.6 Preventive actions

5.7 Internal audits

5.8 Management reviews

5.9 ***Complaints***

6. Human resources

6.1 Personnel associated with the accreditation body

6.2 Personnel involved in the accreditation process

6.3 ***Monitoring***

6.4 Personnel records

Assessor Competence

- Assessor Selection and Initial Qualification
- Assessor Training and Personal Development
- ***Evaluation of Performance***
- Technical Advisory Groups
- Assessor Integrity

Assessor Selection and Qualification

- Education: ABs should require at least post-secondary qualification in a scientific/technological discipline.

- Work experience: At least 4 years of experience in the relevant technical field with at least 2 years in quality management/quality assurance

- Completing training course and passing exam: A2LA 5-day training plus exam to determine knowledge of ISO/IEC 17025 and related requirements

- Personal development: progress through a series of steps including observation of veterans, oversight of initial assessments and reaching the ‘lone ranger’ stage

- Conflict of interest and confidentiality: assessors sign agreements

Evaluation of Assessor Performance

- Initial Evaluation: ABs monitor and evaluate on-site the initial assessment(s) of new assessors with experienced staff, lead or technical assessors.

- Ongoing Evaluation:

    - Formal observation every three years

    - Review of assessor reports

    - Feedback from laboratories, accreditation staff, and peers.

Technical Advisory Groups

- ABs organize special meetings for assessors and technical experts in specific fields to discuss specific problem areas

- Assessor meetings used to:

  – establish consensus on specific policies related to the fields of testing, and

  – promote consistency in assessments among assessors.

Integrity of Assessors

- Integrity: ABs need to ensure that assessors are free from undue pressure
- Impartiality: Assessors and technical experts need to act objectively
- Consultancy: Assessors not allowed to consult for a lab during the time that they are responsible for the most recent assessment

7. Accreditation Process

7.1 Accreditation criteria and information

7.2 Application process, resource review and subcontracting

7.3 Resource review

7.4 Subcontracting the assessment

7.5 Preparation for assessment

7.6 Document and record review

7.7 ***On-site assessment***

7.8 Analysis of findings and assessment report

7. Accreditation Process (cont.)

7.9. Decision-making and granting accreditation

7.10 Appeals

7.11 Reassessment and surveillance

7.12 Extending accreditation

7.13 Suspending, withdrawing or reducing accreditation

7.14 Records of CABs

7.15 Proficiency testing and other comparisons for laboratories

8. Responsibilities of the accreditation body and the CAB

8.1 Obligations of the CAB

8.2 Obligations of the accreditation body

8.3 Reference to accreditation and use of symbols by CABs

What is ILAC ?

- Established in 1977 to promote communication among laboratory accreditation bodies of the world and to facilitate trade
- 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, among those members which had successfully completed a peer evaluation
- ILAC was incorporated in the Netherlands on 20 January 2003.
- Approx. 40,000 laboratories & about 7,000 inspection bodies have been accredited by the 90 ILAC Full Members & Associates.

ILAC's Global Role

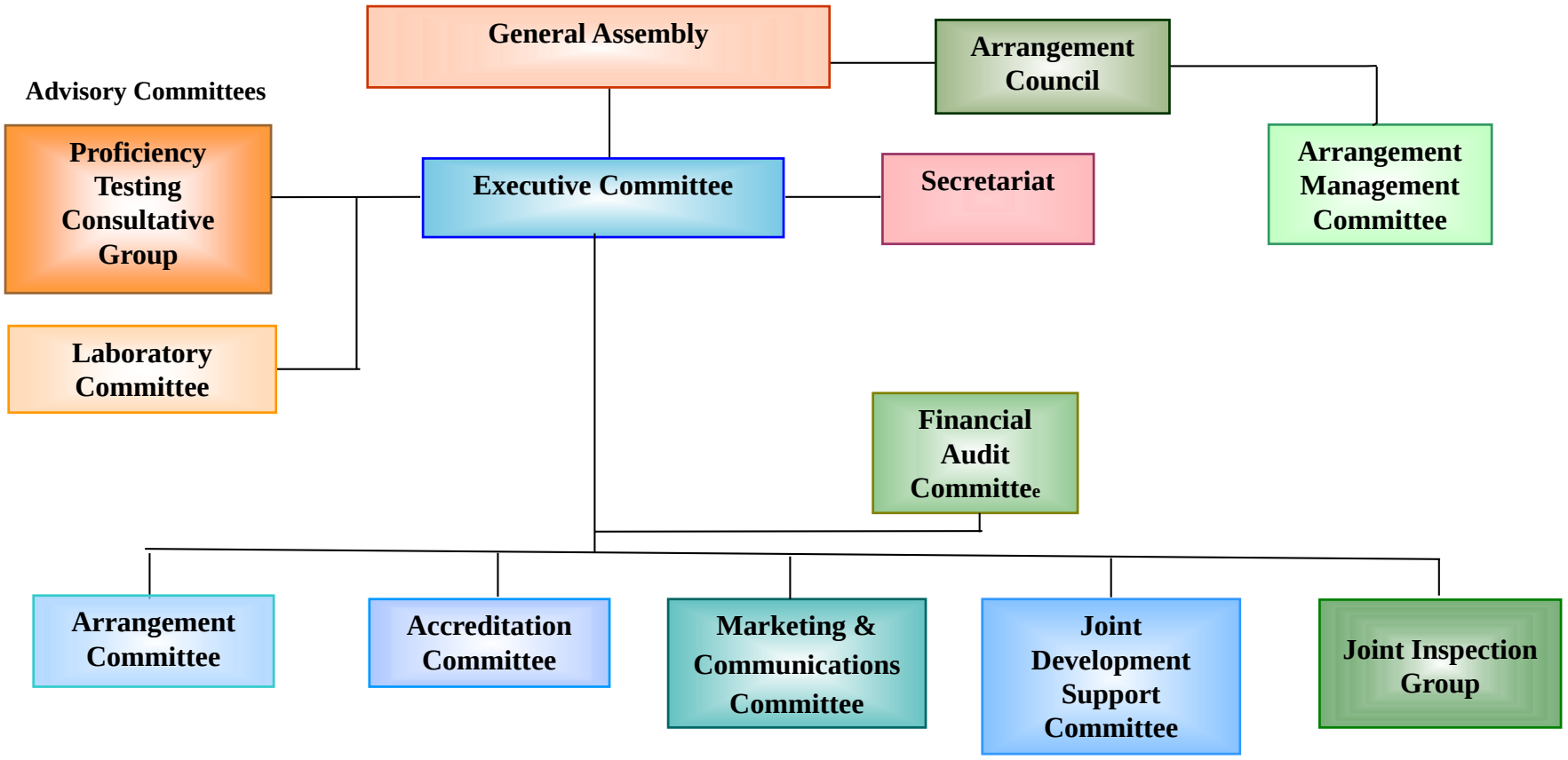
International forum for:

- Recognition of competent labs using its MRA process
- Harmonization of accreditation practice
- Promotion of accreditation as a trade facilitation tool
- Assisting development of accreditation systems world-wide

How is ILAC Structured?

- General Assembly: decisions by consensus
- General Assembly: meets once each year
- All interested parties can contribute

ILAC Organization Chart



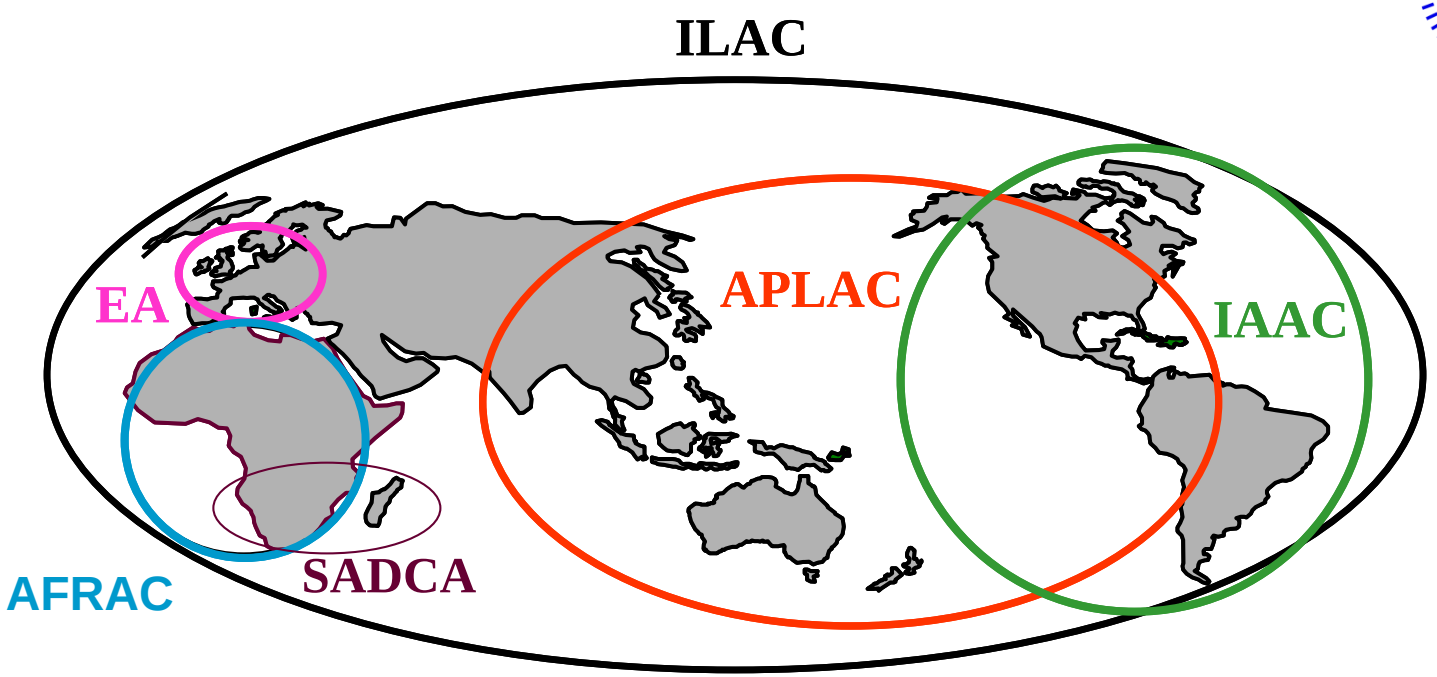
How is ILAC Structured (cont'd)?

- **MEMBERSHIP CATEGORIES:**
  - Full Members (Signatories);
  - Associates;
  - Affiliates;
  - Stakeholders;
  - Regional Cooperation Bodies; and
  - National Coordination Bodies.

- **CURRENTLY:** (as of 1 January 2012)
  - 74 Full Members from 61 economies;
  - 20 Associates from 35 economies;
  - 18 Affiliates from 21 economies;
  - 5 Regional Cooperation Bodies;
  - 27 Stakeholders.

- Full Members & Associates have voting rights for all matters except admission of new Full Members, where voting is restricted to the Full Members only.

The International Picture



EA	European Cooperation for Accreditation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
ILAC	International Laboratory Accreditation Cooperation
IAAC	Inter-American Accreditation Cooperation
AFRAC	African Regional Accreditation Cooperation
SADCA	Southern African Development Community Accreditation
Unaffiliated Bodies	Peer evaluated ABs who are not geographically located in one of the established regions

MRAs Between Accreditation Bodies

Fundamental Purpose

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

How does the ILAC MRA Work

- Peer evaluation by senior AB staff
- Regions evaluated by ILAC
- Recognized regions evaluate their member bodies
- Unaffiliated bodies evaluated directly by ILAC

Peer Evaluation

Because the MRA requires the signatories to promote the acceptance of data from each other's accredited labs *CONFIDENCE IS NEEDED.*

The peer evaluation process involves representatives from the MRA signatories which helps to build this confidence.

Regional Cooperations

Each cooperation (ILAC, APLAC, EA and IAAC) operates in accordance with requirements, including procedures for conducting peer evaluations including:

- ISO/IEC 17011 and ISO/IEC 17025
- IAF/ILAC A1, Requirement on regions for recognition
- IAF/ILAC A2, Requirements for evaluation of an AB
- ILAC documents addressing measurement traceability, proficiency testing, use of logo, ILAC MRA mark, etc.

MRA Application Process

Applicant ABs gain respect and knowledge by working and interacting with their peers on committees that develop policies and procedures before formally applying to be evaluated

- Pre-evaluation (possible)
- Full evaluation (mandatory)
- Follow-up visit (if necessary)

Peer Evaluators

- Trained and qualified senior AB staff
  - sometimes NMI staff is included
- Team leader has added qualifications
- Team members chosen based upon their technical backgrounds to cover the scope of an AB's programs

ILAC Peer Evaluation Process

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

ILAC Peer Evaluation Process

- Signatory ABs provide evaluators for use in the process
  - Experienced senior staff and assessors
  - Trained in the requirements of ISO/IEC 17011
  - Participate as trainee evaluator initially
  - Evaluate for the standard ISO/IEC 17025 and relevant technical field for 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 AB

- Team Leaders appoint members to cover:
  - Requirements of ISO/IEC 17011 and ILAC
  - Witnessing of specific accreditation assessments
    - Process and personnel involved

- Evidence submitted to team leader to compile into report

- Team leader compiles and submits:
  - Summary report includes list of findings (NCs, concerns, comments) to the AB at conclusion of visit
  - Draft report to regional MRA committee
  - Final report to MRA decision committee upon resolution of findings

US Regulatory Use of the ILAC MRA

Consumer Product Safety Commission (CPSC)

Federal Highway Administration (FHWA)

Food and Drug Administration (FDA)

Nuclear Regulatory Commission (NRC)

Environmental Protection Agency (EPA)

Conclusions

- ISO standards recognized nationally as well as worldwide
- Rigor of ILAC MRA evaluation process has no equal
- Use by federal agencies growing

For more information

ISO Website: www.iso.org

ILAC Website: www.ilac.org

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