

ACCREDITATION

How the international system works

Second International Workshop on Mutual Recognition Agreements for Conformity Assessment of EMC and Telecommunications Regulations

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NIST
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Accreditation – what and why

Accreditation is a third party process to assess a laboratory or conformity assessment body for competence, impartiality, technical and management requirements

Accreditation is used to attain needed confidence

- ✂ in the results obtained by a testing facility and in its operation**
- ✂ in the certification system and the certificates**
- ✂ in the results of any other CAB**

International and regional organizations

ILAC – International Laboratory Accreditation Cooperation

IAF – International Accreditation Forum

IAAC – Inter American Accreditation Cooperation

APLAC – Asia Pacific Laboratory Accreditation Cooperation

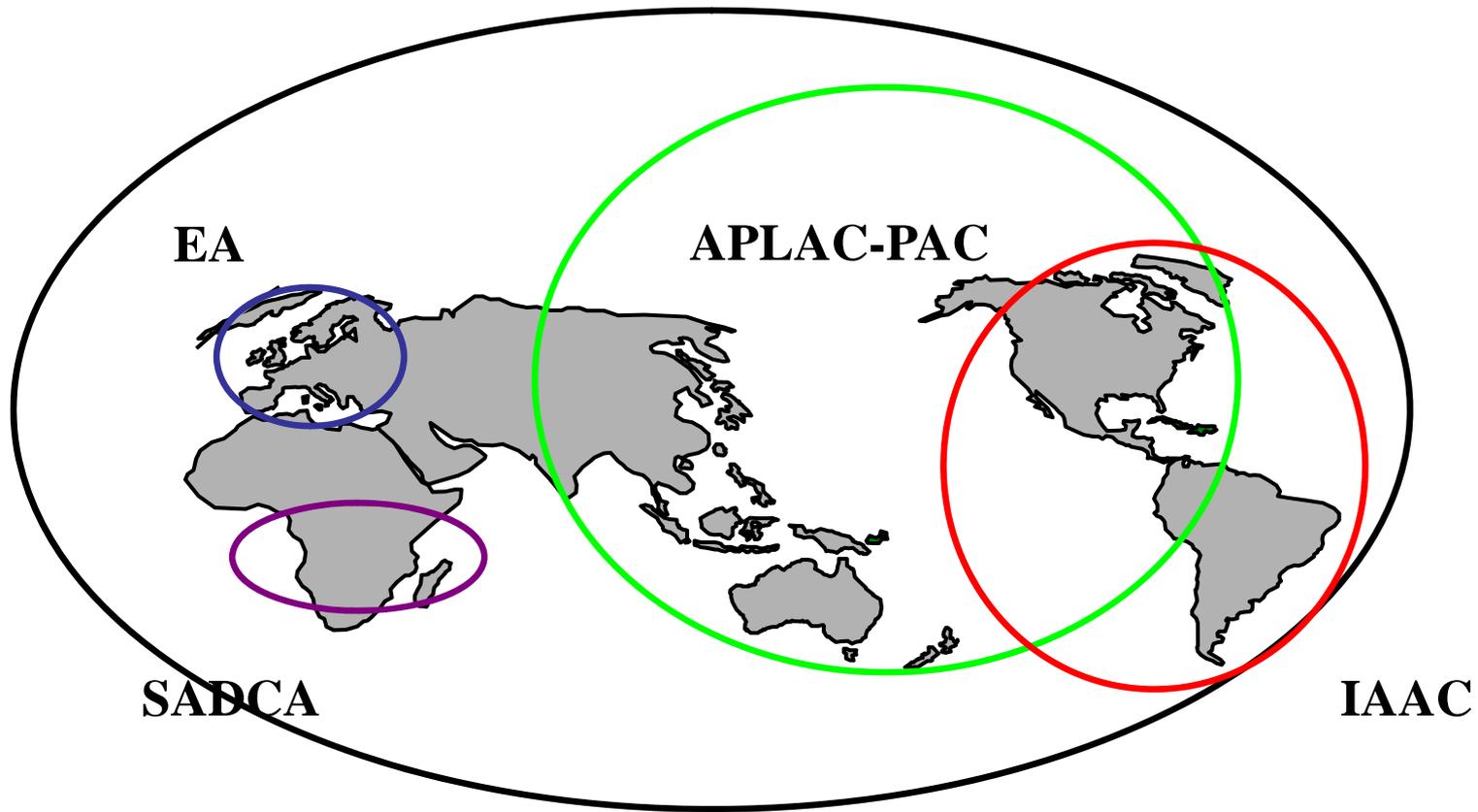
PAC – Pacific Accreditation Cooperation

EA – European Cooperation for Accreditation

SADCA – Southern Africa Accreditation Cooperation



ILAC - IAF



Accreditation arrangements

Arrangements among ABs provide stakeholders with confidence in the results reported by labs and conformity assessment bodies located in other countries and accredited by other signatories

Signatories promote the acceptance of the results of other accredited entities

International accreditation arrangements operate at two levels: the competence of an AB to accredit and the competence of a region to manage an MRA

Why arrangements and not agreements?

Agreements are usually those entered by governments with other governments, whether they are used voluntarily or not

Scopes of agreements vary; may cover recognition only of results of conformity assessment

The accreditation community choose the term arrangement in an attempt to avoid confusion between its own MRAs and g-2-g agreements.

MRAs in the accreditation community are about recognition of the competence of AB's to accredit and thus of its accredited entities to provide reliable results

Scopes of arrangements today

ILAC

testing
calibration

IAF

certification of QMS
certification of EMS
product certification

EA

testing
calibration
inspection
certification of QMS
certification of EMS
product certification
certification of persons

IAAC

testing
calibration
certification of QMS
certification of EMS
product certification

PAC

certification of QMS
certification of EMS
product certification

APLAC

testing
calibration
inspection
medical testing
RMP

Requirements in standards

Same set of standards are used worldwide

For the operation of the AB – ISO/IEC 17011

For the operation of labs – ISO/IEC 17025

For the operation of medical labs – ISO 15189

For the operation of certification bodies

for QMS and EMS – ISO/IEC 17021

for products – ISO/IEC Guide 65

for personnel – ISO/IEC 17024

For the operation of inspection bodies – ISO/IEC 17020

For RMP – ISO Guide 34 and ISO/IEC 17025

Additional criteria for arrangements (1)

In addition to the standards, there are a number of documents issued by ILAC that accreditation bodies [and the labs] must comply with.

For example,

ILAC P9:2005 on proficiency testing

ILAC P10:2002 on measurement traceability

ILAC G9:2005 on use of reference materials

Additional criteria for arrangements (2)

In addition to the standards, there are a number of documents issued by IAF that accreditation bodies [and CAB's] must comply with.

For example,

IAF MD1:2007 on multiple sites

IAF MD4:2008 on computer-assisted auditing techniques

IAF MD5:2009 on the duration of audits

How does an AB become an MRA signatory?

Accreditation bodies undergo peer evaluations to verify compliance with requirements

ILAC and IAF publications describe how evaluations are to be conducted

ILAC and IAF rely on regional organizations to organize, carry out and manage the peer evaluations

In the rare cases where the applicant AB does not belong to a region, ILAC/IAF will do it

Peer evaluations

AB's apply for recognition [to sign an MRA] to their regional group

Regional group assembles a team of assessors to conduct the peer evaluation

Teams are composed of volunteers from ABs, with the right mix of technical and management skills, and geographically diverse

Based on ILAC/IAF guidance, each region determines who is qualified and maintains a list to draw from

Peer evaluation process (1)

The team

Reviews the documentation submitted

Visits the AB and verifies the information

Witnesses the AB's evaluation of labs or CAB's

Prepares a report with a narrative and findings that include non conformities, concerns and comments

Report is provided to the AB

Peer evaluation process (2)

AB addresses the findings

When the evaluation team is satisfied that the AB has addressed the findings, it sends its report with a recommendation to the relevant regional MRA decision-making committee

The MRA committee makes a decision at a meeting where all other signatories are present

Decisions may have conditions such as shortened re-evaluation periods, request for more ILC, etc

The AB is welcomed as a signatory and usually there is some celebratory event

Maintenance of signatory status

There may be shortened on-site visits

Full re-evaluations are scheduled at different intervals, depending on a number of factors

AB's must notify its region when there are significant changes in personnel, programs or any other relevant issues. The region then decides if such changes merit a documentary review, an on-site visit or a re-evaluation

Role of regional cooperations

Regional organizations have their own MRAs, some that pre-date the international ones

For regional MRAs to be “valid” internationally, ILAC and IAF must have confidence that the region operates and manages its MRA according to international rules

So ILAC and IAF evaluate the regions in similar ways as AB's are evaluated

Recognition of a region is granted after a peer evaluation and is specific to each MRA

Scopes of arrangements today

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testing
calibration

IAF

certification of QMS
certification of EMS
product certification

EA

testing
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testing
calibration
inspection
medical testing
RMP

Trends in international accreditation (1)

ILAC cooperation with WADA, the World Anti-Doping Association

Medical labs and clinical labs

Reference materials producers and/or supplier

Proficiency testing providers

Forensic laboratories

Food safety testing and product certification

GHG

Trends in international accreditation (2)

Scopes under consideration for new international MRAs

for inspection bodies

for bodies that certify persons

for medical / clinical laboratories [or may be part of testing labs]

for proficiency testing providers

for reference material producers (or providers)

Trends in international accreditation (3)

Increased involvement of stakeholders

Increased responsiveness to the market

**Protection of the credibility and reputation of
“accredited” certificates**

**Managing market expectations of what a certificate
(especially for QMS certification) issued by an
accredited entity provides**

Inter American Accreditation Cooperation (1)

All countries in the Americas are eligible

40 members (AB + stakeholders) from 23 countries

28 AB's

MRAs for testing/calibration and QMS certification bodies are recognized by ILAC and IAF

MRAs for EMS and product certification bodies have been signed and IAF recognition is expected

Developing MRAs for inspection bodies and for bodies that certify persons

Inter American Accreditation Cooperation (2)

Strong training program on standards, ILAC/IAF requirements, on managing an AB, etc

Strong training program for peer evaluators

Organizes proficiency testing rounds, often with APLAC participation

Have MOUs with APLAC, PAC and SADCA

THANK YOU!

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