



***Seminar on Reference Material
Producer and Proficiency Testing
Provider Accreditation
Rio de Janeiro, Brazil
June 5th – June 6th 2008***



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OVERVIEW OF PRESENTATION

- ***General Introduction***
- ***Importance of good measurements***
- ***Role of laboratory accreditation and ILAC (and ISO/IEC 17025)***
- ***Accreditation of Reference Material Producers***
- ***Accreditation of Proficiency Testing Providers***
- ***Summary and Conclusions***
- ***References***

IMPORTANCE OF GOOD MEASUREMENTS

(1)

Measurement results must be fit for their intended use in order to achieve:

- ***Sustainable development and economic growth***
- ***Environmental integrity of the planet***
- ***Societal equity***

IMPORTANCE OF GOOD MEASUREMENTS

(2)

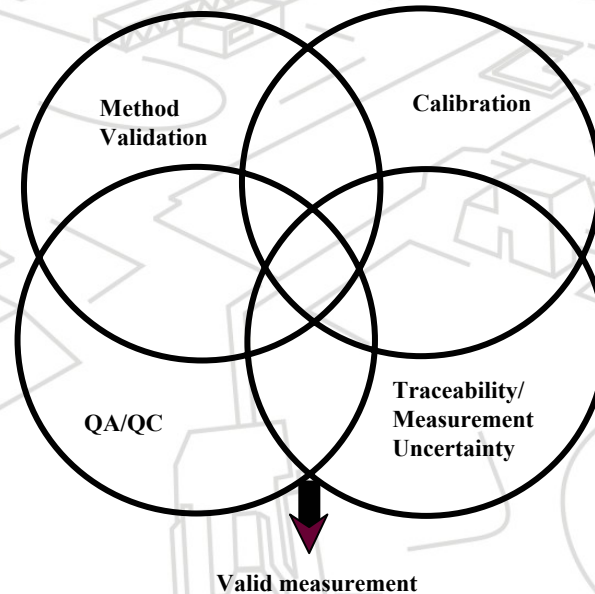
Confidence in measurement results can result in:

- ***Minimizing Technical Barriers to Trade (TBT)***
- ***Sensible decisions based on, for example, food, health and environmental analyses***
- ***Cost effective spending on measurement infrastructure by governments***

All measurements must be underpinned by sound metrological practices – method validation, calibration, QA/QC and Traceability/Measurement Uncertainty

IMPORTANCE OF GOOD MEASUREMENTS

(3)



ROLE OF LABORATORY ACCREDITATION AND ILAC

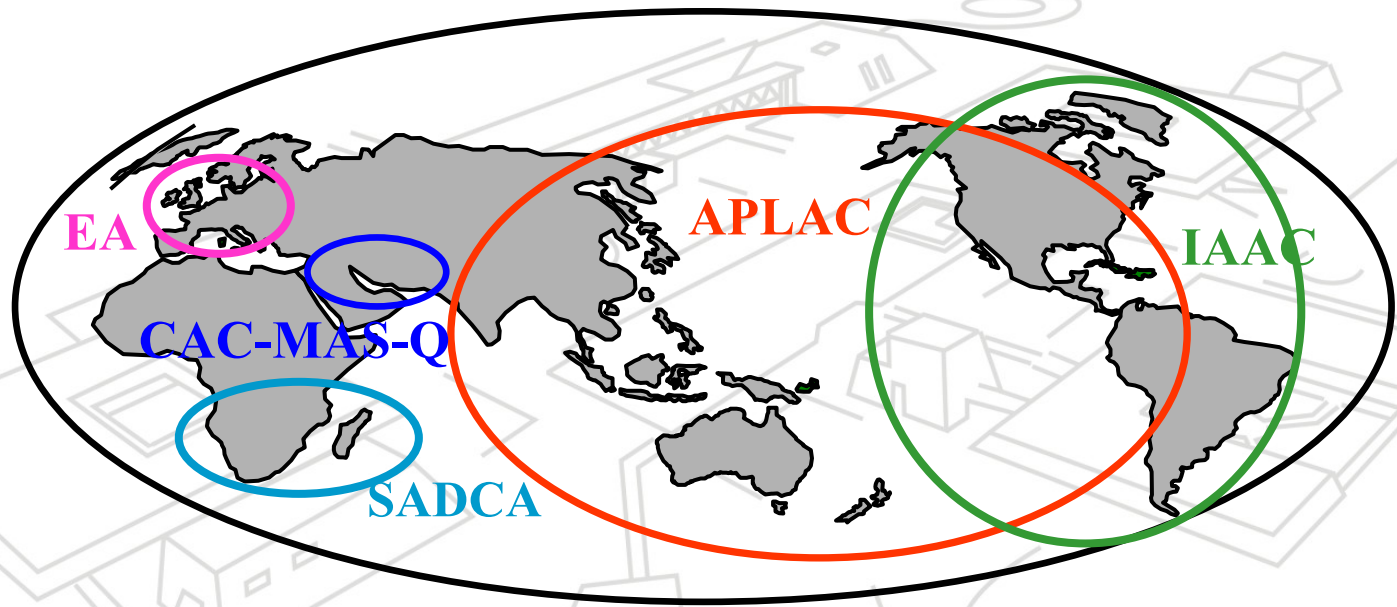
- ***Laboratory Accreditation is the formal recognition of technical competence for specific tasks***
- ***This (cost-effective) recognition is undertaken by an independent, authoritative 3rd party bodies***
- ***On-site Laboratory assessments, based on ISO “General Requirements” documents, give confidence in measurement results and thus facilitate access to world markets and provide domestic and international socio-economic benefits.
(particularly in relation to the ever increasing need to monitor our global environment and address public health and safety issues)***

ILAC – an overview

- Established in 1977 to promote communication among laboratory accreditation bodies of the world***
- 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***
- As of the 2 April 2008, there were 60 Signatories (Full Members) to the Arrangement, representing 47 economies.***
- ILAC was incorporated in the Netherlands on 20 January 2003.***
- Approx. 30,000 laboratories & 5,000 inspection bodies have been accredited by the 60 ILAC Full Members***

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*
- CAC-MAS-Q** *Central Asia Cooperation*
- Unaffiliated Bodies** *Peer evaluated ABs who are not geographically located in one of the*

ILAC-MRA Mark



ISO/IEC 17025 (2005) GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES (1)

- ***“Reference Materials” (RMs and CRMs) and “Proficiency Testing” (PT) are both mentioned frequently***
- ***Fundamentally important for laboratories to have ready access to good quality CRMs and PT***

ISO/IEC 17025 (2005)

CLAUSES RELATING TO REFERENCE MATERIALS AND PROFICIENCY TESTING

(2)

5.9 Assuring the quality of test and calibration results

5.9.1 *The laboratory shall have quality control procedures for monitoring the validity of tests and calibration undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. The monitoring shall be planned and reviewed and may include, but not limited, the following:*

- (a) regular use of certified reference materials and/or internal quality control using secondary reference materials;*
- (b) participation in interlaboratory comparison or proficiency-testing programmes;*
- (c) replicate tests or calibrations using the same or different methods;*
- (d) retesting or recalibration of retained items;*
- (e) correlation of results for different characteristics of an item;*

NOTE: The selected methods should be appropriate for the type and volume of the work undertaken.

5.9.1 *Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.*

ISO/IEC 17025 (2005)

CLAUSES RELATING TO REFERENCE MATERIALS

(3)

4.6 Purchasing services and supplies

- 4.6.2** *The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of test and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of action taken to check compliance shall be maintained.*
- 4.6.4** *The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.*

ACCREDITATION OF REFERENCE MATERIAL PRODUCERS (RMPs) (1)

After many years of discussion and debate, this service is now being offered by some Accreditation Bodies.

- *About 50 RMPs are currently accredited (mainly in APLAC region) for a wide range of materials*
- *APLAC has established a MRA for this service (4 signatories – NATA, Australia; CNAS, China; IAJapan, Japan; A2LA, USA)*

Users can have confidence that these RMs and CRMs are fit for their intended use either in CALIBRATION, METHOD VALIDATION or QUALITY CONTROL (all essential for metrological underpinning of measurement results).

ACCREDITATION OF REFERENCE MATERIAL PRODUCERS (RMPs) (2)

The core requirements documents are:

- ***ISO Guide 34 (2000) Requirements for the Competence of Reference Material Producers (with Nov 03 Technical Compendium). This document is currently under revision by ISO REMCO.***
- ***ISO/IEC 17025 (2005)***

Other related documents include:-

- ***REMCO – ISO Guides 30, 31, 32, 33, 35 and 80 (in preparation)***
- ***APLAC – TC 008-2007 Guidelines on the Approach to the Assessment of Reference Material Producers and the Resulting Scope of Accreditation***
- ***ILAC - G9 (2005) The Selection and Use of Reference Material
- G12 (2000) Guidelines for the Requirements for the
Competence of Reference Material Producers***

ACCREDITATION OF REFERENCE MATERIAL PRODUCERS (RMPs) (3)

Cape Town, South Africa Oct 04

ILAC Resolution GA 8.11

The General Assembly acknowledges that assessing the technical competence of bodies producing reference materials with assigned values is accreditation of a conformity assessment activity

ILAC Resolution GA 8.12

The General Assembly resolves that accreditation of technically competent bodies producing reference materials with assigned values will be conducted against harmonized criteria based on ISO Guide 34 and ISO/IEC 17025 in combination.

Auckland, NZ Sept 05

ILAC Resolution GA 9.28

Following 2004 ILAC GA resolutions 8.11 and 8.12 relating to accreditation of Reference Materials Producers, the General Assembly resolves that the accreditation to ISO Guide 34 in combination with ISO/IEC 17025 be included under the current ILAC arrangement when appropriate procedures for this activity are developed and agreed by ILAC.

Pretoria, South Africa, June 04

REMCO Resolution 15/2004 - Application of ISO Guide 34

Remco members confirm the 2003 resolution (3/2003) "that producers of reference materials apply ISO Guide 34 when developing quality management systems and demonstrating technical competence, noting that ISO Guide 34 makes

ACCREDITATION OF REFERENCE MATERIAL PRODUCERS (RMPs) (4)

Stages and tasks of (Certified) Reference Material ((C)RM) Production	ISO Requirements Document(s)	✓ = Tasks actually performed by each organisation Org 1-5 etc = Examples only					
		Org 1	Org 2	Org 3	Org 4	Org 5	etc
Material preparation	ISO Guide 34	✓	EC	EC	✓	EC	EC
Homogeneity & Stability assessment	ISO Guide 34	✓	✓	EC	✓	EC	EC
Characterization of Property values	ISO Guide 34 +ISO/IEC 17025	✓	✓	EC	EC	EC	✓
* Authorisation and Assignment of values on (C)RM and issue of certificates	ISO Guide 34 +ISO/IEC 17025	✓	✓	✓	✓	✓	✓
Supply & distribution	ISO Guide 34	✓	EC	✓	EC	EC	EC

The RMP accreditation process needs to assess the competence for each task (ie on-site assessment of RMP and also external collaborator(s) (EC), if appropriate)

Note: The Reference Material Producer (ie The body which is subject to formal accreditation) is the organisation that takes responsibility and authorises the values on the (C)RM certificate - not the actual material/product itself. The RMP itself may perform one or several tasks, as shown above, but must have a quality system that covers all of the tasks involved and the necessary expertise to competently evaluate all the inputs.

ACCREDITATION OF REFERENCE MATERIAL PRODUCERS (RMPs) (5)

What is ILAC Doing?

ILAC Committees, members and stakeholders are:

- ***Contributing to the revision of ISO Guide 34***
- ***Developing “Harmonised Criteria” (AIC (07)004-Dec 06) including the identification of key criteria (based on ISO Guide 34)***
- ***Developing a guidance document for ABs who assess RMPs against “Harmonised Criteria”: (refer APLAC TC 008)***
- ***Working to include this activity under the current ILAC Arrangement (MRA)***
- ***Working with other organisations eg REMCO, BIPM (JCTLM, JCRB, JCGM, CCQM), CITAC, EURACHEM, EUROLAB, UNIDO, WADA and Commercial Providers - to find solutions to outstanding issues/problems***

SUMMARY

- 1. It is essential that (accredited) labs have access to good quality RMs (which are fit for their intended use).***
- 2. There is still a need to finalise the harmonisation of the requirements used by ABs (based on ISO Guide 34 and ISO/IEC 17025).***
- 3. ILAC and other bodies are working hard together in an attempt to do this and resolve a few outstanding issues - there is still some work to do.***
- 4. The laboratory community and accreditation bodies have a important role in finalising this work.***

USEFUL WEB-SITES (REFERENCE MATERIALS)

- *APLAC* <http://www.aplac.org>
- *ILAC* <http://www.ilac.org>
- *BIPM* <http://www.bipm.fr>
- *CITAC* <http://www.citac.cc>
- *COMAR* <http://www.comar.bam.de>
- *EA* <http://www.european-accreditation.org>
- *Eurachem* <http://www.eurachem.org>
- *Eurolab* <http://www.eurolab.org>
- *Euromet* <http://www.euromet.org>
- *REMCO* <http://www.iso.org/remco>
- *Springer (ACQUAL)* <http://link.springer.de>
- *Various NAB sites*

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (1)

As with Reference Materials, it is essential that laboratories have access to good quality PT services

- It provides objective evidence that the laboratory's measurement results are reliable and fit for their intended use*
- It confirms that both laboratories and ABs have appropriate QA/QC and Assessment procedures in place*
- It can be considered to be an effective 'Market Surveillance Tool' for laboratory customers, including regulators*

Both ISO/IEC 17025 and ILAC P9 (ILAC Policy for Participation in National and International Proficiency Testing Activities – 2005 (under revision) - require accredited laboratory participation in appropriate PT schemes

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (2)

Core Documents

ISO Guide 43 (1997): Proficiency Testing by Interlaboratory Comparisons

- ***Part 1: Development and Operation of PT Schemes***
- ***Part 2: Selection and Use of PT Schemes by Laboratory Accreditation Bodies***

This document is currently under revision by ISO CASCO and will be replaced by ISO/IEC 17043 “Conformity Assessment - General Requirements for Proficiency Testing”.

(The 4th meeting of ISO WG 28 will take place in September 08 and will review all comments on the CD17043 sent out March 08).

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (3)

Other related documents include

- *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*
- *ILAC P9 (2005) ILAC Policy for Participation in National and International Proficiency Testing Activities*
- *ILAC G13 (2007) Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes*
- *ILAC G22 (2004) Use of PT as a Tool for Accreditation in Testing*

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (4)

ILAC Resolutions

Auckland, NZ Sept 05

ILAC Resolution GA 9.12

Taking into account the current wide use of ILAC G13, and the need for a future Standard to be a suitable common base for accreditation of PT providers in all sectors by ILAC Members, the General Assembly endorses ILAC requesting an urgent revision of ISO/IEC Guide 43 Part 1 & 2 by ISO/CASCO and its conversion into a Standard.

ILAC Resolution GA 9.13

While awaiting the availability of a replacement Standard for ISO/IEC Guide 43, and noting the global use of many PT programs, the General Assembly recognises the need for its Members to use harmonised requirements for the accreditation of PT Providers and endorses the use of ILAC G13 and ISO/IEC Guide 43 as the base criteria for such accreditations.

ILAC Resolution GA 9.14

The General Assembly endorses a review of the text of ILAC G13, while ISO/IEC Guide 43 is being revised/replaced.

ILAC Resolution GA 9.29

The General Assembly notes the approval of ILAC P9, ILAC Policy for Participation in National and International Proficiency Testing Activities and reaffirms that it become effective from January 1, 2006.

Cancun, Mexico Oct 06

ILAC Resolution GA 10.26

Noting Resolution GA 9.13 for harmonized criteria for accreditation of PT Providers, the General Assembly resolves that accreditation of proficiency testing providers will be considered for inclusion under the ILAC Arrangement, when appropriate procedures for this activity are developed and agreed by ILAC.

Sydney, Australia Oct 07

ILAC Resolution GA 11.21

The ILAC General Assembly, taking into account the PTCG analysis of compliance with steps a) to e) of ILAC-S6, agrees to proceed with an

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (5)

Current Status

- *Over 100 PT providers have now been accredited worldwide (mainly combinations of G43/G13)*
- *This process involves about 70% of ILAC Full Member Accreditation Bodies*
- *The ILAC Proficiency Testing Consultative Group (PTCG) is very representative and active (6th meeting held recently in South Africa) and addresses a wide range of issues related to PT, including this one*

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (6) REQUIREMENTS FOR THE COMPETENCE OF PROVIDERS OF PT SCHEMES

Covers

All areas of conduct of proficiency testing schemes, including:

- *planning of PT schemes*
- *selection and preparation of materials*
- *assessment of homogeneity and stability*
- *identification, labelling, packaging and distribution of materials*
- *statistical and technical evaluation of participants' performance*
- *content of PT scheme reports*

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (7)

What is ILAC doing?

ILAC, through the PTCG and other Committees, is working on extending the current ILAC Arrangement to include this activity (refer GA Resolution 11.21).

Further work has been undertaken on harmonising the requirements (recent revision of G13). It is expected that the new ISO/IEC 17043 will either replace or reinforce G13.

ACCREDITATION OF PROFICIENCY TESTING PROVIDERS (8)

The Future - General

- *Increasing interest in establishing additional confidence in quality of PT schemes - both by PT providers and laboratories in developed and developing regions.*
- *Increasing awareness by PT providers of added value of external recognition of competence*
- *Increasing use of accredited PT providers by laboratories and laboratory accreditation bodies (to complement on-site assessments)*
- *Increasing use of PT databases (eg EPTIS)*
- *Development of MRA for accredited PT providers - worldwide recognition.*

USEFUL WEB-SITES (PROFICIENCY TESTING)

- ***APLAC:*** *<http://www.aplac.org>*
- ***CITAC:*** *<http://www.citac.cc>*
- ***EA:*** *<http://www.european-accreditation.org>*
- ***EPTIS:*** *<http://www.eptis.bam.de>*
- ***Eurachem:*** *<http://www.eurachem.org>*
- ***ILAC:*** *<http://www.ilac.org>*
- ***IFCC*** *<http://www.ifcc.org> (EQAP)*
- ***Springer:*** *<http://link.springer.de>*

FINAL CONCLUSIONS

- *The accreditation of RMPs and PTPs is gaining further momentum*
- *It is hoped that both activities will be included under the ILAC Arrangement in the near future*
- *These activities will provide further confidence in laboratory outputs (ie measurement results) and thus provide socio-economic benefits to the community at large.*
- *FINALLY this will help us achieve our primary objective (vision) of “TESTED ONCE, RECOGNISED AND ACCEPTED EVERYWHERE”*

Thankyou!