

ILAC Policy on Metrological Traceability of Measurement Results

ILAC-P10:07/2020

About ILAC

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of Accreditation Bodies (ABs) and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among ABs. The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of "accredited once, accepted everywhere".

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.

Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

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PREAMBLE

To ensure confidence in the results of accredited bodies in the ILAC framework, Accreditation Bodies (ABs) implement ILAC policies and use guidance documents to assist in the uniform and harmonised approach of accreditation criteria. Metrological traceability of measurement results is a key topic for which a harmonised policy is needed if the market is to have confidence in any accredited service provided by an organization covered by the ILAC Arrangement.

Metrological traceability requires an unbroken chain of calibrations to stated references, all having stated uncertainties – refer VIM [1]. The persistent misconception that metrological traceability may be linked to a particular organization (e.g., "traceable to a specific National Metrology Institute") fosters continued confusion with regard to its nature. Metrological traceability pertains to reference quantity values of measurement standards and measurement results, not the organization providing them.

Factors that influence the establishment of a harmonised ILAC policy on metrological traceability of measurement results include the following:

(a) The awareness of the relevance of metrological traceability of measurement results is continuously growing and supporting more areas;

(b) Not all economies have easy access to a complete range of national measurement standards or calibration and measurement capabilities needed to support the calibration and testing needs of all applicants for accreditation in their economy;

(c) The role of reliable and traceable certified reference materials (CRMs) in providing metrological traceability of measurement results has not yet been fully established internationally.

(d) The availability of metrological traceability chains alternative to SI units when it is not possible to trace measurement results to those units.

In this document, the following verbal forms are used:

- "shall": indicates a requirement;
- "should": indicates a recommendation;
- "may": indicates a permission;
- "can": indicates a possibility or capability.

Further details can be found in the ISO/IEC Directives, Part 2[2].

PURPOSE

This document describes the ILAC policy with regard to the metrological traceability requirements in testing and calibration. This policy also applies to other conformity assessment activities where measurement is involved – i.e. medical laboratories; inspection bodies; biobanks; reference material producers and proficiency testing providers. For calibrations performed by an Accredited Organization in order to establish metrological traceability for its own activities, and which are not a part of the organization's scope of accreditation, the ILAC policy in section 2 is applicable. These internal calibrations are also known as "in-house" calibrations.

The date of implementation is one year from the date of publication.

AUTHORSHIP

This version was reviewed by the ILAC Accreditation Committee (AIC) and endorsed for publication by the ILAC General Assembly in 2020.

1. TERMS AND DEFINITIONS

The following definitions apply throughout this document:

Accredited Organization
Throughout this document, the term "Accredited Organization", which includes CABs, is used to refer to organizations covered by the ILAC Arrangement. Whenever the term "Accredited Organization" is used in the text, it applies to both the applicant and the Accredited Organization, unless otherwise specified.

BIPM
Bureau International des Poids et Mesures
BIPM is the intergovernmental organization through which Member States act together on matters related to measurement science and measurement standards.

CAB
Conformity Assessment Body
Body that performs conformity assessment activities and that can be the object of accreditation.

CIPM MRA
International Committee for Weight and Measures Mutual Recognition Arrangement
The CIPM MRA – is an arrangement between National Metrology Institutes which provides the technical framework to assure the mutual recognition of national measurement standards and for recognition of the validity of calibration and measurement certificates issued by National Metrology Institutes.

CRM
Certified Reference Material
Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO 17034:2016[3]).

JCTLM
Joint Committee for Traceability in Laboratory Medicine
JCTLM formed by the BIPM, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and ILAC, provides a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

KCDB
Key Comparison Database
The KCDB is a publicly available, free web resource related to the CIPM MRA. It contains information on participants of the CIPM MRA, results of key and supplementary comparisons and peer reviewed Calibration and Measurement Capabilities (CMCs) (https://www.bipm.org/kcdb).

Metrological traceability (VIM 3 clause 2.41)
Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.
Note 1: For this definition a 'reference' can be a "definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard".

ISO/IEC 17025:2017[4] and ISO 15189:2012[5] refer to the VIM´s term of "metrological traceability".

Metrological traceability chain (VIM 3 clause 2.42)
Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

Metrological traceability to a measurement unit (VIM 3 clause 2.43)
Metrological traceability where the reference is the definition of a measurement unit through its practical realization.
Note: The expression "traceability to the SI" means 'metrological traceability to a measurement unit of the International System of Units'.

NMI
National Metrology Institute
National Metrology Institute (NMI) and Designated Institutes (DI) maintain measurement standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both a National Metrology Institute as well as a Designated Institute.

RM
Reference Material
Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034:2016).

RMP
Reference Material Producer
Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces (ISO 17034:2016).

2. ILAC POLICY ON METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

When metrological traceability is required, the ILAC policy is that the measuring equipment (1) shall be calibrated by:

1) A National Metrology Institute (NMI) whose service is suitable for the intended use and is covered by the International Committee for Weight and Measures Mutual Recognition Arrangement (CIPM MRA). Services covered by the CIPM MRA can be viewed in the Bureau International des Poids et Mesures Key Comparison Database (BIPM KCDB) which includes CMCs for each listed service.

Note 1: Some NMIs may also indicate that their service is covered by the CIPM MRA by including the CIPM MRA logo on their calibration certificates, however the fixing of the logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

Note 2: NMIs from Member States participating in the Metre Convention may take metrological traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services (including the range and uncertainty). Individual calibration certificates issued by the BIPM are also listed.

or

2) An accredited calibration laboratory whose service is suitable for the intended use (i.e., the scope of accreditation specifically covers the appropriate calibration) and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.

Note 3: Only certificates bearing the accreditation symbol or a text reference to the accreditation of the calibration laboratory can benefit fully from the recognition that the ILAC MRA and its regional counterparts bring. Calibration laboratories can indicate that their service is covered by ILAC Arrangement by including on the calibration certificate:

- The combined ILAC MRA mark, or
- The accreditation mark of the Accreditation Body (that is signatory to ILAC Arrangement) or the reference to its accreditation status.

Both of these options can be taken as evidence of metrological traceability (ILAC P8[6]).

or

3a) A NMI whose service is suitable for the intended use but not covered by the CIPM MRA. In this case the Accreditation Body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025.

or

3b) A laboratory whose calibration service is suitable for the intended use but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC. In this case, the Accreditation Body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025.

(1) The term “equipment” is mentioned as interpreted in the ISO/IEC 17025:2017 standard (i.e. also includes standards and reference materials).

Accredited Organizations that have demonstrated metrological traceability of their measurements results through the use of calibration services offered according to 1) or 2) above have made use of services that have been subject to relevant peer review or accreditation. In the situation where 3a) or 3b) applies, this is not the case, so these routes should only be applicable when 1) or 2) are not possible for a particular calibration.

Accredited Organizations must therefore ensure that appropriate evidence for claimed metrological traceability and measurement uncertainty is available and the Accreditation Body shall assess this evidence. Further guidance is found in Appendix A.

The ILAC policy in regard to metrological traceability provided by Reference Material Producers (RMPs) through Certified Reference Materials (CRMs) is that the certified values assigned to CRMs are considered to have established valid metrological traceability when:

4) CRMs are produced by NMIs using a service that is included in the BIPM KCDB.

or

5) CRMs are produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.

or

6) The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

Recognizing that the accreditation of RMPs is still developing and CRMs may not be available from accredited RMPs, where CRMs are produced by non-accredited RMPs, Accredited Organizations shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

When metrological traceability to the SI is not technically possible, it is the responsibility of the Accredited Organization to:

7a) Choose a way to satisfy metrological traceability requirements by using certified values of certified reference materials provided by a competent producer.

or

7b) Document the results of a suitable comparison to reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use. Evidence of this comparison shall be assessed by the Accreditation Body.

Note 4: When metrological traceability to solely SI units is not appropriate or applicable to the application, a clearly defined measurand should be selected. Establishing metrological traceability therefore includes both the proof of identity of the property measured and the comparison of the results to an appropriate stated reference. The comparison is established by ensuring the measurement procedures are properly validated and/or verified, that measuring equipment is appropriately calibrated and that conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result.

Note 5: Surplus test materials are often available from proficiency testing (PT) providers. It should be checked whether the PT provider can provide additional stability information to demonstrate the ongoing stability of the property value and matrix of the test material. If this cannot be provided, these test materials should not be considered as an alternative way to ensure the validity of results.

3. REFERENCES

[1] International Vocabulary of Metrology – Basic and General Concepts and Associated Terms VIM, 3rd edition, JCGM 200:2012 (JCGM 200:2008 with minor corrections) available from the BIPM homepage www.bipm.org or ISO/IEC Guide 99:2007 available from ISO.

[2] ISO/IEC Directives, Part 2, Principles to structure and draft documents intended to become International Standards, Technical Specifications or Publicly Available Specifications, Eight Edition 2018

[3] ISO 17034:2016, General requirements for the competence of reference material producers.

[4] ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.

[5] ISO 15189:2012, Medical laboratories – Particular requirements for quality and competence.

[6] ILAC P8:03/2019 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies.

[7] Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability (November 2018)

APPENDIX A

Guidelines for considerations when metrological traceability is not established through the CIPM MRA and the ILAC Arrangement (Informative)

When metrological traceability is established through either 3a) or 3b) of the policy, this necessitates action, in the first instance, from the Accreditation Body that must address this situation in its policy for metrological traceability; secondly, for the Accredited Organizations who will then need to comply with this policy; and finally for peer evaluators who will assess the effectiveness of this policy during peer evaluations of Accreditation Bodies. It is recognised that metrological traceability covered by 3a) and 3b) ranges from NMI's performing calibrations outside the CIPM MRA, through accredited laboratories performing calibrations outside their scope of accreditation, to any calibration service suppliers which are not accredited for any service (for whatever reason).

Appropriate evidence for the technical competence of the calibration service supplier and claimed metrological traceability is likely to include but not be restricted to the following: (numbers refer to clauses in ISO/IEC17025:2017):

- Records of calibration method validation (7.2.2.4)
- Procedures for evaluation of measurement uncertainty (7.6)
- Documentation and records for metrological traceability of measurement results (6.5)
- Documentation and records for ensuring the validity of results (7.7)
- Documentation and records for competence of personnel (6.2)
- Records for equipment which can influence laboratory activities (6.4)
- Documentation and records for facilities and environmental conditions (6.3)
- Audits of the calibration laboratory (6.6 and 8.8)

For non-accredited calibration service suppliers it should be noted that it may be necessary to perform a practical assessment of the calibration supplier used, similar to that which would be undertaken by an Accreditation Body against the standard ISO/IEC 17025:2017, to ensure that competent work is actually being performed.
The choice of route 3a) or 3b) is unlikely to be made on purely economic grounds, and is more likely to be a last resort if other routes are unavailable.

Further informative information on the subject of metrological traceabilty can be found in Annex A of ISO/IEC 17025:2017.

APPENDIX B

Revision Table – The table provides a summary of the key changes to this document from the previous version.

Section	Amendment
About ILAC introductory text	Replaced with new version
Copyright text	Replaced with new version
Whole document	It is now written Metrological Traceability and not just traceability everywhere in the document
Purpose	The purpose has been adjusted with other policies to ensure that the policy addresses measurements performed with other Conformity Assessment Standards.
1. Terms and Definitions	Definitions for CIPM MRA, KCDB, CAB, Accredited Organization and RMP have been added.
2. ILAC Policy	References to ISO/IEC 17025:2005 have been deleted and the policy has been made independent of the Accreditation Standard being used (e.g. ISO/IEC 17020). The policy is updated with the development leading to the revision of ISO/IEC 17025:2017 for Metrological traceability. This includes update to the fact that ILAC is about extending the MRA of RMP to ISO 17034:2016. The clause 1) – 3) of the policy remains practically unchanged.
3. References	Updated
Appendix A	Updated with references to ISO/IEC 17025:2017.
Appendix B	Revision table added