ILAC Policy on the Traceability of Measurement Results

ILAC P10:01/2013

ILAC – International Laboratory Accreditation Cooperation

ILAC is the international authority on laboratory and inspection body accreditation, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

ILAC provides the infrastructure that supports the world-wide demonstration of competence and equivalence of testing (including medical) and calibration laboratories, inspection bodies and other types of bodies serving or supporting laboratories and inspection bodies through accreditation. Accreditation of laboratories and inspection bodies supports activities within and between economies including trade, protection of health, safety and the environment for the public benefit. Its fundamental purpose is to provide confidence in the competence of bodies supporting these activities.

The ILAC Arrangement is an international, multilateral mutual recognition arrangement for accreditation bodies. Participating accreditation bodies agree to promote acceptance of the equivalence of calibration, test and inspection reports produced by accredited facilities. Each accreditation body undergoes peer evaluation according to ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

ILAC values the critical complementary and supportive activities of its Regional Cooperation Body members in the realisation of its vision, mission, goals and associated strategies. The Regional Cooperation Body members through the implementation of their multilateral mutual recognition arrangements provide all of the peer evaluation resources and much of the technical inputs to ILAC documents.

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TABLE OF CONTENTS

PREAMBLE

To ensure confidence in the results of accredited laboratories, accreditation bodies 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 calibrations, testing and inspections performed by accredited laboratories and inspection bodies 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 results, not the organization providing the results.

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

(a) The concept of metrological traceability of measurement results in fields such as the chemical, medical, and biological sciences is still under development;

(b) Not all economies have the 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 in providing metrological traceability of measurement results has not yet been fully established internationally.

PURPOSE

This document describes the ILAC policy with regard to the metrological traceability requirements from ISO/IEC 17025:2005 [2] and ISO 15189:2007 [3]. This policy may also be applied to other conformity assessment activities where testing and/or calibration is involved (e.g., inspection and product certification). For calibrations performed by a laboratory in order to establish metrological traceability for its own activities, and which are not a part of the laboratory's scope of accreditation, the ILAC policy in section 2 is applicable. Internal calibrations are also known as "In-house" calibrations.

The date of implementation is January 2014.

AUTHORSHIP

This version was reviewed by the ILAC Accreditation Committee (AIC) and endorsed for publication by the ILAC General Assembly in 2013.

1. TERMS AND DEFINITIONS

The following definitions apply throughout this document:

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 clause 2.41 states that 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."

In ISO/IEC 17025:2005 and ISO 15189:2007 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this document.

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
Note1: The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

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

JCTLM
The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine

2. ILAC POLICY FOR TRACEABILITY COVERED BY THE ILAC ARRANGEMENT IN CALIBRATION

The general requirement for traceability in ISO/IEC 17025:2005 is:

> *5.6.1 All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.*

It is an obligation of the laboratory to justify the need for calibration. In ISO/IEC 17025:2005, the further traceability requirement for calibration laboratories is:

> *5.6.2.1.1 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités).*

For reference standards the traceability requirements of ISO/IEC 17025:2005 are:

> *5.6.3.1 The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.*

In order to maintain traceability in calibration programmes, guidance can be found in *ILAC G24:2007* [4] "*Guidelines for the determination of calibration intervals of measuring instruments*.

Clause 5.6.2.1.1 in ISO/IEC 17025:2005 further states that "*When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability*". For equipment and reference standards that must be calibrated, the ILAC policy is that they shall be calibrated by:

1) An NMI whose service is suitable for the intended need and is covered by the CIPM MRA. Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty 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 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 need (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.
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   Note: Some calibration laboratories indicate that their service is covered by the ILAC Arrangement by including the ILAC Laboratory Combined MRA mark on the calibration certificate. Alternatively, the accreditation symbol of the accreditation body that is a signatory to the ILAC Arrangement and/or a recognised regional MLA may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

   or

3a) An NMI whose service is suitable for the intended need 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 17025:2005.

   or

3b) A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC. In these cases the accreditation body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025:2005.

Laboratories that have demonstrated traceability of their measurements 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. The laboratory must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available and the accreditation body shall assess this evidence. Further guidance is found in Annex A.

Clause 5.6.2.1.2 of ISO/IEC 17025:2005, states:

There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- *the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;*
- *the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.*

Participation in a suitable programme of inter laboratory comparisons is required where possible.

The ILAC Policy is:

4) Clause 5.6.2.1.2 can only be applied in the case in which the laboratory has demonstrated that the policy 1) to 3) cannot reasonably be met. It is the responsibility of the laboratory to choose a way to satisfy 5.6.2.1.2 and to provide the appropriate evidence. This evidence shall be documented and the documentation shall be assessed by the accreditation body.

3. ILAC POLICY FOR TRACEABILITY COVERED BY THE ILAC ARRANGEMENT IN TESTING

The ILAC Arrangement in testing covers both testing laboratories accredited to ISO/IEC 17025:2005 as well as medical laboratories accredited to ISO 15189:2007. In ISO/IEC 17025:2005, the requirements for traceability in testing laboratories are:

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed. NOTE: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

In ISO 15189:2007, the requirements are:

5.6.3 A programme for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference.

The ILAC policy is:

5) If the calibration of instruments used in testing contributes significantly to the overall uncertainty, the same policy for traceability applies (as detailed under 1) to 4) above).
6) If a calibration is not a dominant factor in the testing result, the laboratory shall have quantitative evidence to demonstrate that the associated contribution of a calibration contributes little (insignificantly) to the measurement result and the measurement uncertainty of the test and therefore traceability does not need to be demonstrated.

In ISO/IEC 17025:2005 the further requirement for traceability for testing laboratories is:

5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

In ISO/IEC 15189:2007 the requirement for traceability is:

5.6.3 Where none of these (referring to first sentence of 5.6.3) are possible or relevant, other means for providing confidence in the results shall be applied including but not limited to the following:
a) participation in a suitable programme of inter-laboratory comparisons;
b) use of suitable reference materials, certified to indicate the characterization of the material;
c) examination or calibration by another procedure;
d) ratio or reciprocity-type measurements;
e) mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned;
f) documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.

In this case, the ILAC Policy for traceability is identical to point 4) above.

4. ILAC POLICY FOR TRACEABILITY PROVIDED THROUGH REFERENCE MATERIALS (RMS) AND CERTIFIED REFERENCE MATERIALS (CRMS)

ISO/IEC 17025:2005 traceability requirements in relation to reference materials include:-

5.6.3.2 Reference materials
Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.

Note 1: Values associated with RMs may not be metrologically traceable. Values associated with CRMs (by definition) are metrologically traceable.

Note 2: At present, the ILAC Arrangement does not cover the accreditation of reference material producers (RMPs). At the regional level, APLAC operates an MRA for RMPs and a number of countries operate systems for the accreditation of RMPs, and the number of accredited RMPs is therefore increasing.

The ILAC policy in regard to traceability provided by RMPs is:

7) The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO Guide 34:2009 [5], are considered to have established valid traceability (see ILAC General Assembly resolution ILAC 8.12).
8) The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.
9) The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the laboratory shall demonstrate that each RM or CRM is suitable for its intended use as required by clause 4.6.2 in ISO/IEC 17025:2005 or ISO 15189:2007.

5. REFERENCES

[1] International Vocabulary of Metrology – Basic and General Concepts and Associated Terms VIM, 3rd edition, JCGM 200:2012 (JCGM 200:20008 with minor corrections) available from the BIPM homepage www.bipm.org or ISO/IEC Guide 99:2007 available from ISO.

[2] ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories.

[3] ISO 15189:2007, Medical laboratories – Particular requirements for quality and competence.

[4] ILAC-G24:2007 Guidelines for the determination of calibration intervals of measuring instruments.

[5] ISO Guide 34:2009, General requirements for the competence of reference material producers.

[6] ILAC P14:01/2013 ILAC Policy for Uncertainty in Calibration.

ANNEX A

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

When 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 traceability; secondly, for the laboratories who will then need to comply with this policy; and finally for peer evaluators who will assess the effectiveness of this policy during peer reviews of Accreditation Bodies. It is recognised that 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 laboratories which are not accredited for any service (for whatever reason).

Appropriate evidence for the technical competence of the laboratory and claimed metrological traceability is likely to include but not be restricted to the following:- (numbers refer to clauses in ISO/IEC17025:2005):

- Records of calibration method validation (5.4.5)
- Procedures for estimation of uncertainty (5.4.6)
- Documentation for traceability of measurements (5.6)
- Documentation for assuring the quality of calibration results (5.9)
- Documentation for competence of staff (5.2)
- Documentation for accommodation and environmental conditions (5.3)
- Audits of the calibration laboratory (4.6.4 and 4.14)

For non-accredited laboratories it should be noted that it may be necessary to perform a practical assessment of the laboratory used, similar to that which would be undertaken by an Accreditation Body against the standard ISO/IEC 17025, 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.