

POLICY ON THE TRACEABILITY OF MEASUREMENT RESULTS

1. Scope :

This document covers SLAB’s policy on metrological traceability concerning testing and/or calibration, inspection and certification activities.

2. Reference :

ILAC- P10: 01/2013 – ILAC Policy on the Traceability of Measurement Results

3. Responsibility :

All applicant and accredited Conformity Assessment Bodies (CABs)

Authorized Officer

Technical Manager

Lead Assessors/ Team Leaders/ Technical Assessors/ Assessors

4. Definitions:

4.1 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 15189:2012 the term “traceability” is equivalent to the VIM’s “Metrological traceability” and the term “traceability” is used throughout this document.

4.2 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.

4.3 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.

4.4 BIPM (International Bureau of Weights and Measures):

The BIPM is an intergovernmental organisation established by the Metre Convention, through which Member States act together on matters related to measurement science and measurement standards.

The key task of the Bureau is to ensure world-wide uniformity of measurements and their traceability to the International System of Units (SI).

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4.5 CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement):

Signatories to the MRA include BIPM Member States, Associates of the BIPM General Conference on Weights and Measures, and other international organisations. The MRA provides a means of comparability of national metrology services including national measurement standards and calibration / measurement certificates issued by NMIs.

4.6 JCTLM:

The CIPM, IFCC (International Federation of Clinical Chemistry) and ILAC Joint Committee for Traceability in Laboratory Medicine

4.7 KCDB (BIPM Key Comparison Database):

The KCDB is a public website containing all information relating to the CIPM MRA, an arrangement establishing the equivalence of measurements made by, and certificates issued by, all the participating signatories.

The KCDB comprises two main sections, one containing information about the internationally recognised Calibration and Measurement Capabilities (CMCs) of the participating signatories and the other containing information about the comparisons supporting these CMCs.

4.8 National Metrology Institute (NMI) - Derived from Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability: 11/09/2011):

A national laboratory that is tasked with the realization, maintenance, improvement and dissemination of the SI units via traceable calibration and measurement services based on their Calibration and Measurement Capabilities (CMCs) for the metrology activities (ex. fundamental metrology, applied, technical or industrial metrology and legal metrology) within a particular country. This includes designated institutes that are empowered by an NMI for specified functions. 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.

4.9 Designated Institute:

Where another institute is responsible for certain national measurement standards and associated services disseminating traceability not covered by the activities of the “traditional” NMI.

Note 1: Designate Institutes in the CIPM MRA, version 2, March 2014.

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4.10 Calibration (VIM3 clause 2.39):

Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

VIM NOTE 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

VIM NOTE 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

VIM NOTE 3: Often, the first step alone in the above definition is perceived as being calibration.

4.11 Calibration and Measurement Capability (CMC):

A CMC per the CIPM MRA-D-04, *Calibration and Measurement Capabilities in the context of the CIPM MRA* is a calibration and measurement capability available to customers under normal conditions:

- a) as described in the laboratory’s scope of accreditation granted by a signatory to the ILAC Arrangement; or
- b) as published in the BIPM key comparison database (KCDB) of the CIPM MRA.

4.12 Mutually Recognized Accreditation Body:

An accreditation body that is a signatory to the ILAC MRA.

4.13 Reference Material (ISO Guide 34:2009):

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.

4.14 Reference Standard (ISO Guide 30:1992):

Standard, generally having the highest metrological quality available at a given location or in a given organization, from which subsequent measurements are derived.

4.15 ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement):

SLAB is a member of the ILAC MRA for Testing and Calibration to ISO/IEC 17025.

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5. Policy for traceability when performing calibration

5.1 For equipment and reference standards that have an effect on the reported result and associated uncertainty of measurement shall be calibrated by one of the following:

- a) A NMI whose service is suitable for 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 of each listed service.

Notes: 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.

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.

- b) An accredited calibration laboratory whose service is suitable for the intended need (i.e. the scope of accreditation specifically identifies the appropriate calibration) and the accrediting body is covered by the ILAC MRA for calibration.

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 MRA e.g. Asia Pacific Laboratory Accreditation Cooperation (APLAC), may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

5.2 The following two options should only be applicable when options a) and b) above are not possible for a particular calibration.

- c) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA.
- d) A non-accredited calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

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It is unlikely that a decision to choose option c) and d) will be made purely on economic grounds and is more likely to be a last resort if other routes are unavailable. The CAB must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available and the evidence will be reviewed by SLAB during assessments.

Appropriate evidence for the competence of the calibration laboratory and claimed metrological traceability is likely to include but not be limited to the following (the numbers in brackets refer to the clause numbers of ISO/IEC 17025:2005):

- Records of calibration method validation (5.4.5)
- Procedures for estimation of uncertainty (5.4.6)
- Reference instruments used for calibration (5.5)
- 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)

In practical terms, the CABs would need to have evidence of a practical assessment of the calibration laboratory used, similar to that which would be conducted by an accreditation body against the standard ISO/IEC 17025.

5.3. When calibration cannot be strictly made to SI units

ISO/IEC 17025, clause 5.6.2.1.2 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 characterisation 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.

Clause 5.6.2.1.2 can only apply when the laboratory has demonstrated that options a) to d) cannot reasonably be met. It is the responsibility of the laboratory to choose a way to satisfy the clause and to provide the appropriate evidence which shall be reviewed by SLAB at assessments of the laboratory.

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6. Policy for traceability when performing tests

- e) If the results of calibration of equipment used contributes significantly to the overall uncertainty, the same policy for traceability applies (as detailed above).
- f) If the result of a calibration is not a dominant factor in the test or measurement result, the laboratory shall have quantitative evidence to demonstrate that the associated contribution of the calibration contributes little (insignificantly) to the test or measurement result and associated measurement uncertainty and therefore traceability does not need to be demonstrated.
- g) If inspections are performed with testing/measurements, above requirements shall apply.

6.1 When traceability to SI units is not possible

ISO/IEC 17025:2005, clause 5.6.2.2.2 states:

Where traceability of measurements to SI units is not possible and/or 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).

ISO 15189:2012, clause 5.3.1.4 states:

Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.

Note: *Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.*

Where this is not possible or relevant, other means for providing confidence in the results shall be applied including but not limited to the following:

use of certified reference materials

examination or calibration by another procedure

mutual consent standards or methods which are clearly established, specified, characterised and mutually agreed upon by all parties concerned

Accordingly, where traceability to SI units cannot be achieved, the same criteria as covered in 5.3 shall apply.

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7 Policy for Traceability provided through Reference Materials (RMs) and Certified Reference Materials

ISO/IEC 17025:2005, clause 5.6.3.2 states:

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

| For ISO 15189:2012, clause 5.3.1.4 and 5.3.2 as noted above applies.

Values associated with RMs may not be metrologically traceable. Values associated with CRMs are, by definition, metrologically traceable.

Traceability is considered to have been established where:

h) The values assigned to CRMs are produced by NMIs and included in the BIPM KCDB or produced by an accredited Reference Material Producer (RMP) under its accredited scope of accreditation to ISO Guide 34:2009.

Note: RMPs accredited by a signatory to a regional body e.g. Asia Pacific Laboratory Cooperation (APLAC), are considered to have established valid traceability.

i) The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

j) 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 clause 4.6 in ISO 15189:2012.

k) If inspections are performed with testing/measurements, above requirements shall apply.

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