



SDAC Policy on Metrological Traceability of Measurement Results



SDAC-PO-04

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HISTORY OF THE DOCUMENT

Version number	Reason(s) of revision	Scope of the revision
Ver 1.0:2/2020	- Replaces SDAC-TM-25 Traceability of Measurement - Update of layout	Full revision
Ver 2.0:10/2020	To be in line with ILAC- P10:07/2020	Full revision



1. PURPOSE

Metrological Traceability is the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or International standards, through an unbroken chain of comparisons all having stated uncertainties. This is required for testing, calibration, medical testing and inspection results.

2. SCOPE

This document covers SDAC's policy on metrological traceability concerning testing, calibration, medical testing and inspection activities, this policy applies to:

- All SDAC applicant and accredited facilities;
- All measurements, whether physical, chemical or biological;

3. REFERENCE

ISO/IEC 17025:2017	General Requirements for the Competence of Testing and Calibration Laboratories
ISO 15189:2012	Medical laboratories – Requirements for quality and competence
ISO/IEC 17020: 2012	Conformity assessment – Requirements for the operation of various types of bodies performing inspection
ILAC-P10: 07/2020	ILAC Policy on Metrological Traceability of Measurement Results

4. DEFINITIONS

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..

BIPM (International Bureau of Weights and Measures)

The BIPM is an intergovernmental organization 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).



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 organizations. The MRA provides a means of comparability of national metrology services including national measurement standards and calibration / measurement certificates issued by NMIs.

JCTLM (Joint Committee for Traceability in Laboratory Medicine)

The joint committee includes the CIPM, IFCC (International Federation of Clinical Chemistry) and ILAC.

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.

NMI (National Metrology Institute)

NMIs 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.

RMP

Reference Material Producer. a 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

5. ROLE(S) AND RESPONSIBILITY

Accredited / applicant laboratories and inspection bodies: compliance

6. POLICY ON METROLOGICAL TRACEABILITY

When metrological traceability is required, the policy is that measurement equipment 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.

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.

Or

2) 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 Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC..

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 recognized regional MRA e.g. AFRAC, ARAC, APAC etc. may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

3a) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA.

3b) A calibration laboratory whose service is suitable for the intended need but not covered by ILAC Arrangement or by Regional Arrangement recognized by ILAC.

The two options 3a) and 3b) should only be applicable when options 1) and 2) above are not possible for a particular calibration

The accredited organization must therefore ensure that appropriate evidence for claimed metrological traceability and measurement uncertainty is available and the SDAC shall assess this evidence.



It is unlikely that a decision to choose option 3a) and 3b) will be made purely on economic grounds and is more likely to be a last resort. It should be noted that choosing one of these options will require significant effort by the facility i.e. it shall be required to demonstrate that there is evidence of claimed Metrological traceability and measurement uncertainty of the calibration services provider selected. This evidence will be reviewed by SDAC at assessments of the facility (which will add to the duration of assessments with associated additional fees reflective of the effort required).

The evidence the facility must maintain of the competence 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 17025:2017):

- Audits of the calibration service provider (6.6 and 8.8)
- Documentation for competence of staff (6.2);
- Documentation for accommodation and environmental conditions (6.3);
- Records of calibration method validation (7.2.2);
- Procedures for evaluation of measurement uncertainty (7.6);
- Documentation for Metrological traceability of measurements (6.5);
- Documentation for assuring the validity of calibration results (7.7).
- Records of equipment which can influence the laboratory activities (6.3)

In practical terms, the facility would need to have evidence of an assessment of the calibration service provider similar to that which would be conducted by an accreditation body which is signatory to the ILAC MRA.

Policy for Metrological Traceability obtained through a Certified Reference Material (CRM) provided by Reference Material Producer (RMP)

4) CRM is produced by NMI using a service that is included in BIPM KCDB

Or

5) CRM produced by an accredited RMP covered by ILAC arrangement or by Regional Arrangement recognized by ILAC.

6) The values assigned to CRMs are covered by entries in the JCTLM database



Where CRMs are produced by non -accredited RMPs, the facility shall demonstrate that CRMs are produced by a competent RMP and that they are suitable for the intended use

When metrological Traceability to SI is not technically possible, it is the responsibility of the accredited organization to:

7a) Use certified values of Certified Reference Materials provided by a competent RMP

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 SDAC

7. RELATED FORMS

SDAC-F-60 Proficiency Testing plan and Metrological Traceability