Policy on Metrological Traceability of

Measurement Results

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1. Introduction

1.1 Testing and calibration laboratories, medical testing laboratories as well as other conformity assessment activities where testing and/or calibration is involved (e.g., inspection and product certification) applying for NSC-ONSC accreditation have to meet these criteria of traceability before being granted accreditation.

1.2 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, these criteria of traceability are applicable. Internal calibrations are also known as "In-house calibrations".

2. Terms and definitions

2.1 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.

2.2 BIPM

Bureau International des Poids et Mesures

BIPM is the intergovernmental through which Member States act together on matters related to measurement science and measurement standards.

2.3 CAB

Conformity Assessment Body

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

2.4 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.

2.5 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).

2.6 JCTLM

Joint Committee for Traceability in Laboratory Medicine

JCTLM formed by 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.

2.7 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)

2.8 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 producer including the measurement unit for a non-ordinal quantity, or a measurement standard”

ISO/IEC 17025:2017 and ISO 15189:2012 refer to the VIM’s term of “metrological traceability”

2.9 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.

2.10 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.

2.11 NMI

National Metrology Institute

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.

2.12 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)

2.13 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)

3. Metrological Traceability Policy

3.1 When metrological traceability is required, the measuring equipment shall be calibrated by one of the following:

3.1.1 An NMI whose service is suitable for the intended use and is covered by the CIPMMRA. Services covered by the CIPM MRA can be viewed in Appendix C of the BIPMKCDB which includes the range and uncertainty for each listed service.

Notes: (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.

(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.

3.1.2 An accredited calibration laboratory whose service is suitable for the intended use (i.e. the scope of accreditation specifically identifies the appropriate calibration) and the accrediting body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

Note: Only certificates bearing the accreditation symbol or text reference to the accreditation of calibration laboratory can benefit fully from the recognition that the ILAC MRA and its regional counterparts bring.

Calibration laboratories can indicate that their services is covered by ILAC Arrangement by including on the calibration certificate:

- The combined ILAC MRA mark, or
- The accreditation mark of 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.

3.1.3 The following two options should only be applicable when options 3.1.1 and 3.1.2 above are not possible for a particular calibration.

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

b) A laboratory whose calibration services is suitable for the intended use but not covered by the ILAC Arrangement or Regional Arrangements recognized by ILAC.

It should be noted that the accredited organizations shall be required to demonstrate that there is evidence of claimed traceability and measurement uncertainty of the calibration services selected. This evidence will be reviewed and notified by relevant Laboratory Accreditation Subcommittee. The evidence must maintain of the competence and claimed metrological traceability is likely to include but not be limited to the following:

- Records of calibration method validation
- Procedures for evaluation of measurement uncertainty
- Documentation and records for metrological traceability of measurement results
- Documentation and records for ensuring the validity of results
- Documentation and records for competence of personnel
- Records for equipment which can influence laboratory activities
- Documentation and records for facilities and environmental conditions
- Audits of the calibration laboratory

3.2 Where in-house calibrations are performed, NSC-ONSC assessors will seek assurance of the laboratory's internal traceability by examining the laboratory's calibration system and the laboratory's competence to carry out the appropriate measurements during the assessment or surveillance visit.

3.3 If the result of a calibration is not a dominant factor in the test or measurement result, the laboratory shall have 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.

3.4 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference such as:

3.4.1 Certified reference material values provided by a competent producer;

Note : Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

3.4.1 Results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted by an appropriate authoritative body as providing measurement results fit for their intended use and ensured by suitable comparison.

3.5 When the traceability obtained through a reference material (RM) and certified reference material (CRM), NSC-ONSC has policies that

3.5.1 The values assigned to CRMs are produced by NMIs and included in the BIPM KCDB

3.5.2 The value assigned to 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 Arrangement recognized by ILAC.

3.5.3 The values assigned to CRMs are covered by entries in the JCTLM database.

3.5.4 The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the facility shall demonstrate that each RM or CRM is suitable for its intended use.

4. References

1. ILAC-P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results
2. ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories
3. ISO/IEC 15189:2012 Medical laboratories - Requirements for quality and competence
4. ISO 17034:2016, General requirements for the competence of reference material producers