LA/SR02 - Supplementary Requirements on Metrological Traceability

Foreword

This Philippine Accreditation Bureau (PAB) Supplementary Requirements on Metrological Traceability was developed to provide specific guidelines as supplement with the requirements of accreditation criteria in ensuring the reliability and validity of test results or measurements.

The 3rd issuance of this document was made to reflect the following updates:

- *The phrase "on Metrological" was added to the title of the document i.e. from Supplementary Requirements for Traceability of Measurements to Supplementary Requirements on Metrological Traceability of Measurements.*
- *The reference to another clause in Section 3.3 of this document has been changed from 2.2 to 2.1.3.*
- *The latest revision of the ILAC-P10 document (ILAC-P10:07/2020) has been reflected in the References section.*

1 Terms and Definition

1.1 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.

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

Note 1 in 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."

1.2 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

1.3 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.

1.4 Certified Reference Material (VIM 3 clause 5.14)
Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures

1.5 Reference Material (VIM 3 clause 5.13)
Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

1.6 BIPM (Bureau of Weights and Measures)
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 BIPM is to ensure world-wide uniformity of measurements and their traceability to the International System of Units (SI).

1.7 CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement)
CIPM MRA is the MRA for national measurement standards and for calibration and measurement certificates issued by NMIs. 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.

1.8 JCTLM (Joint Committee for Traceability in Laboratory Medicine)
The joint committee includes the CIPM, IFCC (International Federation of Clinical Chemistry) and ILAC.

1.9 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 recognized Calibration and Measurement Capabilities (CMCs) of the participating signatories and the other containing information about the comparisons supporting these CMCs.

1.10 NMI (National Metrology Institute)

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.

2.0 Policy on Traceability when Performing Calibration

2.1 Equipment and reference standards shall be calibrated and achieved by one of the following:

2.1.1 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 BIPM KCDB which includes the range and uncertainty for each listed services.

Note: Some NMIs may also indicate that their services are 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.

In case an NMI whose service is not covered by CIPM MRA but suitable for the intended need, PAB shall ensure that the NMI indicates the traceability to international standards of measurement (SI Unit) and should provide the measurement result and associated uncertainty of measurement.

2.1.2 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 the 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 MLA may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

2.1.3 In case the laboratory has demonstrated that clause 2.1.1 and 2.1.2 of this document cannot be reasonably met or when metrological traceability to SI Units is not technically possible, it shall be required to demonstrate that there is evidence of claimed traceability and measurement uncertainty of the calibration services selected.

The evidence shall be properly documented and will be reviewed by PAB during assessment, which will add to the duration of schedule of on-site assessment visit with associated additional fees reflective of the effort required.

Appropriate evidence for the technical competence of the laboratory and claimed metrological

traceability is likely to include but not limited to the following:

- Records of calibration method validation
- Procedures for estimation of uncertainty
- Documentation for traceability of measurements
- Documentation for assuring the quality of calibration results
- Documentation for competence of staff
- Documentation for accommodation and environmental conditions
- Audits of the calibration laboratory

Generally, the laboratory shall need to have an assessment conducted by PAB similar to the assessments conducted to accredited calibration laboratory including in-house that support and/or form part of testing facility.

2.2 Statement of Traceability

2.2.1 Calibration certificates or reports must contain a traceability statement. This statement will affirm that the calibration reported was conducted using standards whose values are traceable to an appropriate national, international, intrinsic, or mutual consent standard.

For Example: If the traceability chain for a given laboratory originates at an acceptable National Metrology Laboratory to PAB, then the statement will affirm that "This instrument was calibrated using reference standard traceable to SI units as maintained by NMI" (if directly calibrated by NMI) or "This instrument was calibrated using reference standard traceable to SI units as maintained by NMI through accredited laboratory" (if calibrated by an accredited calibration laboratory).

2.2.2 To establish an audit trail for traceability, a proper calibration result should include:
- assigned or measured value
- stated uncertainty of measurement
- identification of the standards used in the calibration
- specification of any environmental conditions of the calibration where correction factors should be applied, if the standard or equipment were to be used under different environmental condition.

2.2.3 Calibration certificates and reports, which do not contain equivalent statements of traceability are insufficient to demonstrate measurement traceability.

3.0 Policy on Traceability on Testing

The ILAC Arrangement in testing covers both testing laboratories accredited to ISO/IEC 17025 and ISO 15189 (Medical Laboratories). The requirements for traceability in ISO/IEC 17025 and ISO 15189 testing laboratories are described in clause 6.5 and clause 5.3.1.4, respectively.

3.1 If the calibration of equipment used in testing results contributes significantly to the overall uncertainty and validity of the result, the same policy for traceability in clause 2 of this document applies.

3.2 If the result of calibration is not a dominant factor in testing, the laboratory shall have a quantitative evidence to demonstrate that the associated calibration contributes insignificantly to the accuracy or validity of results and associated measurement uncertainty. Therefore, traceability does not need to be demonstrated.

3.3 When traceability to SI unit is not possible, the same policy as noted in clause 2.1.3 of this document applies.

It is the responsibility of the laboratory to choose a way when traceability to SI units cannot be achieved and to satisfy the requirements and provide the appropriate evidence which shall be reviewed by PAB during the time of assessment.

4.0 Policy on Traceability Provided Through Certified Reference Materials (CRMs) and Reference Materials (RMs)

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

4.1 Traceability is considered to have been established by means of the following:

- The values assigned to CRMs are produced by NMIs and included in the BIPM KCDB or, produced by a Reference Material Producer who has been accredited for the production of reference materials listed under its accredited Scope of Accreditation to ISO 17034.

  Note: RMPs accredited by a signatory to ILAC or an ILAC recognized regional body, are considered to have established valid traceability.

- The values assigned to CRMs are covered by entries in the JCTLM database.
- The majority of RMs and CRMs are produced by other RMPs which can be considered as critical consumables and the laboratory shall demonstrate that each RMs or CRMs are suitable for its intended use.

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 15189 Medical laboratories – requirements for quality and competence

[4] National Association of Testing Authorities: General Accreditation Criteria for Metrological Traceability - October 2018