EGAC Policy on Metrological Traceability for Measurement Results R2G

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Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
1.1/ Mar 2019	Quality manager	5/7	Modification in clause 4.5
Annual Doc. Revision Jan 2021	Quality Manager	All Pages	Annual revision for this document, Conducted by Ashraf Saif Quality General Manager. And no changes needed.
2 / Jun 2021	Quality Manager Calibration Manager	All	Modification according to the new ILAC-P10:7-2020: - Small change in the regulation name. - Some Adjustment to the regulation Index. - In whole regulation replace Metrological Traceability instead of traceability. - The scope is adjusted to include other conformity assessment standards. - Add item 3 “abbreviations” to clear the abbreviations used in this regulation. - Updates the policy to match with new ILAC-P10:7-2020 - Update the edition of new ILAC-P10:7-2020 & GUM-6:2020, in any part of the regulation. - The references are adjusted to include other conformity assessment standards. - Add informative Appendix as a guideline.

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1. SCOPE

This policy specifies the forms of objective evidence, by which the proof of metrological traceability in context of accreditation process is provided by testing laboratories, calibration laboratories, medical laboratories, inspection bodies, forensic service providers, biobanks, proficiency testing providers, reference material producers, and internal calibration by accredited CABs.

2. TERMS AND DEFINITIONS

2.1 BIPM (Bureau International des Poids et Mesures)

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

2.2 CAB (Conformity Assessment Body)

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

2.3 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.

2.4 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[3]).

2.5 JCTLM (Joint Committee for Traceability in Laboratory Medicine)

JCTLM formed by the 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.

2.6 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).

2.7 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 procedure including the measurement unit for a non- ordinal quantity, or a measurement standard”.

ISO/IEC 17025:2017[4] and ISO 15189:2012[5] refer to the VIM´s term of “metrological traceability”.

2.8 **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.

2.9 **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’.

2.10 **NMI (National Metrology Institute)**

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

2.11 **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).

2.12 **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).

2.13 **Calibration intervals**

Calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of the equipment, intermediated check, Accuracy of equipment).

3. ABBREVIATION:

3.1	SI units	:	International System of Units
3.2	CMC	:	Calibration and Measurement Capability
3.3	ILAC	:	International Laboratory Accreditation Cooperation
3.4	NIS	:	National Institute of Standards
3.5	AB	:	Accreditation Body

4. EGAC POLICY ON METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

EGAC will apply the principles of ILAC P10:07/2020, ILAC Policy on Metrological Traceability of Measurement Results to the assessment and accreditation of testing laboratories, calibration laboratories, medical laboratories, inspection bodies, forensic service providers, biobanks, proficiency testing providers, reference material producers, and internal calibration by accredited CABs.

They shall be able to demonstrate that measurement results obtained under their scopes of accreditation are traceable to the international system of units (SI units).

The following certificates / reports are recognized as proof of the metrological traceability for the accreditation of them if the measuring equipment shall be calibrated by:

1. NIS whose service is suitable for the intended use and covered by CIPM MRA which can be viewed in BIPM KCDB (which includes CMCs 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 remainsthe authoritative source of verification.

Note 2: NMIs from Member States participating in the Metre Convention may take metrological 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 use (i.e. the scope of accreditation specifically covers the appropriate calibration) and the AB is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

Note 3: Only certificates bearing the accreditation symbol or a text reference to the accreditation of the calibration laboratory can benefit fully from the recognition that the ILAC MRA and its regional counterparts bring.

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

- *The combined ILAC MRA mark, or*
- *The accreditation mark of the AB (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.

Or

3. a) NIS whose service is suitable for the intended use but not covered by the CIPM MRA. In this case EGAC policy (Appendix 1) shall apply, to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025.

   Or

   b) A laboratory whose calibration service is suitable for the intended use but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC. In this case, EGAC policy (Appendix 1) shall apply, to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC17025.

Accredited Organizations that have demonstrated metrological traceability of their measurements results 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 3.a) or 3.b) applies, this is not the case, so these routes should only be applicable when 1) or 2) are not possible for a particular calibration.

Accredited Organizations must therefore ensure that appropriate evidence for claimed metrological traceability and measurement uncertainty is available and the EGAC shall assess this evidence.

The ILAC policy in regard to metrological traceability provided by RMPs through CRMs is that the certified values assigned to CRMs are considered to have established valid metrological traceability when:

4. CRMs are produced by NMIs using a service that is included in the BIPM KCDB.

   Or

5. CRMs are produced by an accredited RMP under its scope of accreditation and the AB is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

   Or

6. The certified values assigned to CRMs are covered by entries in JCTLM database.

Recognizing that the accreditation of RMPs is still developing and CRMs may not be available from accredited RMPs, where CRMs are produced by non-accredited RMPs, Accredited Organizations shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

When metrological traceability to the SI is not technically possible, it is the responsibility of the Accredited Organization to:

7. a) Choose a way to satisfy metrological traceability requirements by using certified values of CRM provided by a competent producer.

   Or

   b) 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 the EGAC.

Note 4: When metrological traceability to solely SI units is not appropriate or applicable to the application, a clearly defined measurand should be selected. Establishing metrological traceability therefore includes both the proof of identity of the property measured and the comparison of the results to an appropriate stated reference. The comparison is established by ensuring the measurement procedures are properly validated and/or verified, that measuring equipment is appropriately calibrated and that conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result.

Note 5: Surplus test materials are often available from proficiency testing (PT) providers. It should be checked whether the PT provider can provide additional stability information to demonstrate the ongoing stability of the property value and matrix of the test material. If this cannot be provided, these test materials should not be considered as an alternative way to ensure the validity of results.

5. APPENDIX 1

Guidelines for considerations when metrological traceability is not established through the CIPM MRA and the ILAC Arrangement

When metrological traceability is established through either 3a) or 3b) of the policy, this necessitates action, in the first instance, from AB that must address this situation in its policy for metrological traceability; secondly, for the Accredited Organizations who will then need to comply with this policy; and finally for peer evaluators who will assess the effectiveness of this policy during peer evaluations of AB. It is recognized that metrological 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 any calibration service suppliers which are not accredited for any service (for whatever reason).

Appropriate evidence for the technical competence of the calibration service supplier and claimed metrological traceability is likely to include but not be restricted to the following: (numbers refer to clauses in ISO/IEC17025:2017):

The CAB shall introduce the evidence for the following:-

- Records of calibration method validation (7.2.2.4)
  - Calibration /Test method.
  - Procedure of validation method.
  - Result of implementation.
  - Analysis of results.
  - Validity of decision.
- Procedure for evaluation of uncertainty (7.6)
  - Uncertainty Budget and CMC for Calibration
- Documentation and records for metrological traceability of measurement results (6.5)
  - Evidence for traceable of Calibration certificate for reference equipment used
- Documentation and records for ensuring the validity of results (7.7)
- Documentation and records for competence of personnel (6.2)
  - Job description, training certificate, evaluation, monitoring, education and authority
- Record for equipment which can influence laboratory activities (6.4)
  - Record of intermediate check for equipment
- Documentation and records for facilities and environmental conditions (6.3)
- Audits of the calibration laboratory (6.6 and 8.8)
  - Record of audits new (last audit report and corrective action, list of auditors)

6. REFERENCES

- ILAC P10-07/2020 “Policy on Metrological Traceability for Measurement Results”.
- International vocabulary of metrology – Basic and general concepts and associated terms VIM:2012.
- Guide to the Expression of Uncertainty in Measurement GUM-6:2020.
- ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories.
- ISO 15189:2012 – Medical laboratories - Particular requirements for quality and competence.
- ISO 17020:2012 – Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- ISO/IEC 17043:2010 - Conformity Assessment - General Requirements for Proficiency Testing;
- ILAC G19:2014 - Modules in a Forensic Science Process;
- ISO 17034:2016 - General Requirements for the Competence of Reference Material Producers.