QAI CLA 029

Quality and Accreditation Institute

Centre for Laboratory Accreditation

POLICY ON METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

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CHANGE HISTORY

Sl. No.	Doc No.	Current Issue No.	Revised Issue No.	Date of Issue	Reasons
1.	CLA 029	01	02	April 2021 (13 April 2021)	Aligning to the current international references

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1. Introduction

To ensure confidence in the results of accredited laboratories, QAI implement ILAC policies and use guidance documents to assist in the uniform and harmonised approach of accreditation criteria.

Metrological traceability of measurement results is a key topic for which a harmonised policy is needed if the market is to have confidence in calibrations, testing and inspections performed by accredited laboratories and inspection bodies covered by the ILAC Arrangement.

Metrological traceability requires an unbroken chain of calibrations to stated references, all having stated uncertainties – refer ISO/IEC Guide 99:2007 - International vocabulary of metrology -- Basic and general concepts and associated terms (VIM).

All equipment used for test/ calibration having a significant on the accuracy, reliability and validity of results shall be calibrated before use on any client sample.

2. Terms and Definitions

The following definitions apply throughout this document:

2.1 Metrological traceability

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.

2.2 Metrological traceability chain

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

2.3 Metrological traceability to a measurement unit

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.

2.4 National Metrology Institute (NMI)

National Metrology Institute (NMI) and Designated Institute (DI) maintain highest measurement standards in a country. These may serve specific country as well as a Region. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes as well as Designated Institute for a specific parameter.

2.5 BIPM (International Bureau of Weights and Measures)

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

2.6 Key Comparison Database (KCDB)

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 International Committee for Weight and Measures Mutual Recognition Arrangement (CIPM MRA)

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.

2.8 Certified Reference Material (CRM)

Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

2.9 Joint Committee for Traceability in Laboratory Medicine (JCTLM)

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.

3. Scope

This document describes the QAI policy with regard to the metrological traceability of measurement results. The requirements are according to ILAC P10:07/2020 "ILAC policy on traceability of measurement results".

4. QAI Policy

(A) QAI recognizes calibration of equipment and reference standards from:

(1) National Physical Laboratory (NPL, India) or any NMI whose service is suitable for the intended need and is covered by the CIPM MRA.

Note: 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.

Or

(2) An accredited calibration laboratory by an Accreditation Body covered by the ILAC Arrangement or Regional Arrangements recognised by ILAC e.g. by APAC, IAAC, EA etc. whose service is suitable for the intended need (i.e, the scope of accreditation specifically covers the appropriate calibration).

Or

(3) When the routes (1) or (2) above are not possible for a particular calibration, QAI shall accept metrological traceability of measurement results from National Physical Laboratory (NPL, NMI of India) or any other NMI whose service is suitable for the intended use.

(B) 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 characterization 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.
The situation B can only be applied in the case in which the laboratory has demonstrated that the policy A cannot reasonably be met. It is the responsibility of the laboratory to choose a way to satisfy B and to provide the appropriate evidence. This evidence shall be documented and the documentation shall be assessed QAI.

(C) If the calibration of instruments used contributes significantly to the overall uncertainty, the above policy for traceability applies.

However, if a calibration is not a dominant factor in the result, the laboratory shall have quantitative evidence to demonstrate that the associated contribution of a calibration contributes little (insignificantly) to the measurement result and the measurement uncertainty of the test and therefore traceability does not need to be demonstrated.

(D) QAI policy in regard to traceability provided through reference materials (RMs) and certified reference materials (CRMs) by RMPs–

- The values assigned to CRMs produced by NMIs and included in the BIPM Key Comparison Database (BIPM KCDB) or produced by an accredited RMP under its accredited scope of accreditation to ISO 17034, are considered to have established valid traceability

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

- 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 applicable clause(s) of respective accreditation standard.

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