



**Accreditation Education Research & Scientific Service Center,
Nepal**

Policy on Metrological Traceability

Document No. – AERSSC 20

Issue No.: 11

Issue Date: 31st March 2024

Amendment No.: 0

Amendment Date:



Amendment Records

S. No.	Page No.	Section No.	Issue Date	Issue No.	Revision Detail



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1. Introduction

To ensure confidence in the results of accredited CABs, AERSSC implements ILAC policies and uses guidance documents to assist in the uniform and harmonised approach of accreditation criteria.

Metrological traceability of measurement results is a key to providing confidence in testing, medical testing by accredited CABs covered by the ILAC Arrangement. A harmonized policy for Metrological traceability for accredited CAB is thus imperative.

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

All equipment used for tests including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, or sampling shall be calibrated before being put into service.

2. Terms and Definitions

The following definitions apply throughout this document:

2.1 Bureau International BIPM

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

2.2 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.

2.3 Certified Reference Material (CRM)

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.

2.4 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.

2.5 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>)

2.6 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.

2.7 Metrological traceability chain

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

2.8 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

2.9 National Metrology Institutes (NMI)

National Metrology Institutes (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 National Metrology Institutes as well as Designated Institutes.

3. Scope

This document describes AERSSC policy with regard to the Metrological Traceability of Measurement Results. The Metrological Traceability requirements mentioned in this document are according to ILAC P10:07/2020 "ILAC Policy on Traceability of Measurement Results".

4. Policy

4.1. For achieving Metrological Traceability to the International System of Units (SI), measuring equipment (including standards and reference materials) shall be calibrated by:

- a. Any NMI whose service is suitable for the intended use and is covered by the CIPM MRA.

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Note: Services covered by the CIPM MRA can be viewed in the BIPM KCDB which includes CMCs for each listed service.

Or

- b. 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 Accreditation Body is covered by the ILAC arrangements or by Regional Arrangements recognized by ILAC.

Note: Conformity Assessment Bodies (CABs) can indicate that their service is covered by the ILAC Arrangement by using AERSSC Symbol or AERSSC Accredited CAB Combined ILAC MRA Mark on the certificate/ report.

- c. In cases when services of any NMI is not covered by the CIPM MRA and/or Conformity Assessment Bodies service is not covered by the ILAC Arrangements or by Regional Arrangements recognized by ILAC then, In this case, the AERSSC shall ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025

Note 1: The situation c can only be applied when 1) or 2) are not possible for a particular calibration.

- 4.2. 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.

- 4.3. AERSSC policy in regard to metrological traceability provided by Reference Material Producers (RMPs) through Certified Reference Materials (CRMs) is that the certified values assigned to CRMs are considered to have established valid metrological traceability when

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

Or

- b) CRMs are produced by an accredited RMP under its accredited scope of accreditation and the accreditation body is covered by the ILAC Arrangements or by Regional Arrangements recognized by ILAC.

Or

- c) The certified values assigned to CRMs are covered by entries in the JCTLM database.

Note: It is recognized that all CRMs may not be available from NMIs and/ or accredited RMPs but are produced by other organizations. In such cases, the conformity assessment body shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

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- 4.4. When metrological traceability to the SI is not technically possible, it is the responsibility of the conformity assessment body to
- a) Choose a way to satisfy metrological traceability requirements by using certified values of certified reference materials 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.

Note: 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 measurand 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 the measuring equipment is appropriately calibrated and that conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result.