



STANDARDS
MALAYSIA

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

**SAMM POLICY 2 (SP2) -
POLICY ON THE METROLOGICAL TRACEABILITY OF
MEASUREMENT RESULTS**

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JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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Introduction

Metrological traceability of measurement results is an important requirement to ensure confidence in calibrations and testing performed by accredited laboratories and inspection bodies.

The concept of metrological traceability requires an unbroken chain of calibrations or comparisons to stated references, all having stated uncertainties. Metrological traceability pertains to reference quantity values of measurement standards and results, not the organisation providing the results. The requirements of this document are derived from the requirements of ILAC-P10:07/2020, ILAC Policy on the Metrological Traceability of Measurement Results.

Information on the National Metrology Institute and Designated Institutes in Malaysia are as described in Annex A.

1 Scope

- 1.1 This document details the general policy of Standards Malaysia with regards to the metrological traceability requirements imposed upon applicants and laboratories accredited under the *Skim Akreditasi Makmal Malaysia* (SAMM) and where feasible and applicable, applicant and inspection bodies accredited under the Malaysia Inspection Bodies Accreditation Scheme (MIBAS).
- 1.2 This policy document should be read in conjunction with the relevant Specific Criteria, Specific Technical Requirement and policy documents governing the SAMM/MIBAS scheme.

2 Normative Reference

ILAC P10:07/2020, ILAC policy on the metrological traceability of measurement results.

3 Terms and definitions

The following definitions apply throughout this document:

3.1 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.

3.2 CAB

Conformity Assessment Body

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

3.3 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.

3.4 CRM

Certified Reference Material

Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO 17034:2016).

3.5 JCTLM

Joint Committee for Traceability in Laboratory Medicine (JCTLM) formed by the BIPM, the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC) and the International Laboratory Accreditation Cooperation (ILAC), provides a worldwide platform to promote and give guidance on internationally recognised and accepted equivalence of measurements in laboratory medicine and traceability to appropriate measurement standards.

3.6 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>.

3.7 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 realisation, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard."

In MS ISO/IEC 17025:2017 and MS ISO 15189:2012 refer to the VIM's term of "metrological traceability".

3.8 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.

3.9 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 realisation.

Note 1: The expression "traceability to the SI" means 'metrological traceability to a measurement unit of the International System of Units'.

3.10 NMI

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.

3.11 RM

Reference Material

Material, sufficiently homogenous 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).

3.12 RMP

Reference Material producer

Body (organisation or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values; and issuance of a reference material certificate or other statements for the reference materials it produces (ISO 17034:2016).

4 Policy for metrological traceability

4.1 For equipment and reference standards that must be calibrated, the policy is that the calibration shall be carried out by:

4.1.1 An NMI whose service is suitable for the intended use and is covered by the CIPM Mutual Recognition Arrangement (MRA). Services covered by the CIPM MRA can be viewed in Bureau International des Poids et Mesures Key Comparison Database (BIPM KCDB) which includes Calibration and Measurement Capabilities (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 remains the 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

4.1.2 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 Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognised 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:

- a) The combined ILAC MRA mark, or
- b) The accreditation mark of the 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 (ILAC P8).

or

4.1.3 An NMI whose service is suitable for the intended use but not covered by the CIPM MRA. In this case, the CAB shall provide appropriate evidence for the technical competence of the NMI and the claimed metrological traceability covering at least the following items (numbers refer to clauses in MS ISO/IEC 17025:2017):

- a) Records of calibration method validation (7.2.2.4)
- b) Procedures for evaluation of measurement uncertainty (7.6)
- c) Documentation and records for metrological traceability of measurements results (6.5)
- d) Documentation and records for ensuring the validity of results (7.7)
- e) Documentation and records for competence of personnel (6.2)
- f) Records for equipment which can influence laboratory activities (6.4)
- g) Documentation and records for facilities and environmental conditions (6.3)
- h) Audits of the calibration laboratory (6.6 and 8.8)

or

4.1.4 A laboratory whose calibration service is suitable for the intended use but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC. In this case, the CAB shall provide appropriate evidence for the technical competence of the laboratory and the claimed metrological traceability covering at least the same items as listed in the bullet points in 4.1.3.

4.2 The choice of route 4.1.3 or 4.1.4 shall not be made on purely economic grounds and shall only be a last resort if other routes are unavailable.

Standards Malaysia will assess the evidence as listed in 4.1.3 and the CAB's ability to evaluate it.

4.3 When metrological traceability to the SI is not technically possible, it is the responsibility of the CAB 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. Evidence of this comparison shall be assessed by the Standards Malaysia.

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 Policy for traceability provided through reference materials (RMs) and certified reference materials (CRMs)

- 5.1 The policy in regard to traceability provided by RMPs through Certified Reference Materials (CRMs) is that the certified values assigned to CRMs are considered to have established valid metrological traceability when:
- 5.1.1 CRMs are produced by NMIs using a service that is included in the BIPM KCDB; or
- 5.1.2 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 Arrangements recognized by ILAC; or
- 5.1.3 The certified values assigned to CRMs covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.
- 5.2 Recognising 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, CABs shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.
- 5.3 Standards Malaysia will assess the above evidence and the CAB's ability to evaluate it.

Annex A

Information on the National Metrology Institute and Designated Institutes in Malaysia

The National Metrology Institute of Malaysia (NMIM) is responsible for the realisation, establishment and maintenance of the Malaysian national standards of measurement based on the SI units.

On 3 September 2001, Malaysia became a signatory of the Metre Convention. This was followed by the signing of the CIPM MRA on 4 October 2001 by SIRIM Berhad. On 23 July 2007, the Malaysian Nuclear Agency (Nuclear Malaysia) is accepted as a Designated Institute for ionizing radiation followed by Department of Chemistry Malaysia on 26 September 2017 for amount of substance: high-purity chemicals for organic compounds; food for preservatives and alcoholic beverages.

Further information on the national metrology capabilities of the National Metrology Institute of Malaysia and the Designated Institutes, information may be obtained directly from:

1. National Metrology Institute of Malaysia (NMIM)

Lot PT 4803,
Bandar Baru Salak Tinggi,
43900 Sepang,
Selangor Darul Ehsan,
Malaysia.

Tel : +603-8778 1600

Fax : +603-8778 1616

Website : <http://www.nmim.gov.my>

2. Malaysian Nuclear Agency (Nuclear Malaysia)

43000 Kajang, Selangor.

Tel : +603-8911 2000

Fax : +603-8911 2153

Website : <http://www.nuclearmalaysia.gov.my>

3. Department of Chemistry Malaysia

Jalan Sultan
46661 Petaling Jaya, Selangor.

Tel : +603-7985 3000

Fax : +603-7985 3092

Website : <http://www.kimia.gov.my>

Bibliography

- 1) ILAC G24:2007, Guidelines for the determination of calibration intervals of measuring instruments.
- 2) ILAC P8:03/2019, ILAC mutual recognition arrangement (arrangement): supplementary requirements for the use of accreditation symbols and for claims of accreditation status by accredited conformity assessment bodies.
- 3) ILAC P15:05/2020, Application of ISO/IEC 17020:2012 for the accreditation of inspection bodies.
- 4) ISO/IEC 17034:2016, General requirements for the competence of reference material producers.
- 5) JCGM 200:2012, International vocabulary of metrology - Basic and general concepts and associated terms (VIM), 3rd edition.
- 6) MS ISO 15189:2012, Medical laboratories - Requirements for quality and competence.
- 7) MS ISO/IEC 17020:2012, Conformity assessment - Requirements for the operation of various types of bodies performing inspection.
- 8) MS ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.

Revision Table

The table provides a summary of the key changes to this document from the previous version.

Section	Amendment
1. Introduction	Amendment on ILAC P10 documents and add Designated Institute.
2. Scope	No amendment.
3. Terms and definitions	Definitions for BIPM, CAB, CIPM MRA, CRM, KCDB, RM and RMP and RMP has been added.
4. Policy for metrological traceability	The policy has been updated to comply with ILAC P10:07/2020 requirements. The clause 4.1.1, 4.1.2 and 4.1.3 of the policy remains practically unchanged.
5. Policy for traceability provided through reference materials (RMs) and certified reference materials (CRMs)	The policy has been updated to comply with ILAC P10:07/2020 requirements.
Annex A	Information about Designation Institute has been added.
Bibliography	Updated.
Revision table	Revision table added.

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6. Mr. Nazri Marzuki National Metrology Institute of Malaysia (NMIM)
7. Mr. Chen Soo Fatt Department of Standards Malaysia (Assessor)
8. Mr. Wong Siew Kwan Department of Standards Malaysia (Assessor)
9. Ms. Wong Fei Ting Department of Standards Malaysia
10. Mr. Ainol Azizul Rosli Department of Standards Malaysia