

Forum Jabatan Standard Malaysia bersama Makmal
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SAMM POLICY 2 (SP2) – POLICY ON THE TRACEABILITY OF MEASUREMENT RESULTS

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SP2 - General Information & Scope

- Issue 4, 21 July 2014
- Effective date: 1 October 2014
- Applicable to Testing and Calibration Laboratories (including Medical Testing Laboratories)
- Describes SAMM Policy with regard to metrological traceability requirements from ISO/IEC 17025:2005 and ISO 15189:2012

Introduction

- Metrological traceability of measurement results is an important requirement to ensure confidence in calibrations and testing performed by accredited laboratories
- Derived from the requirements of **ILAC-P10:01/2013, ILAC policy on the traceability of measurement results**
- *(previous issued was based on ILAC-P10:2002)*

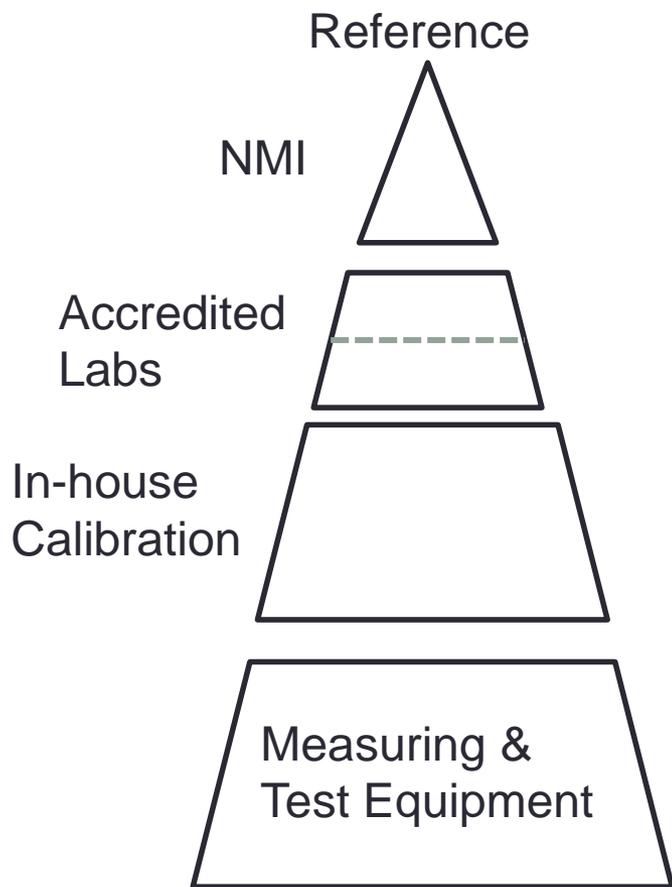
Introduction (*contd.*)

- **Metrological traceability** (Definition as in 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**.

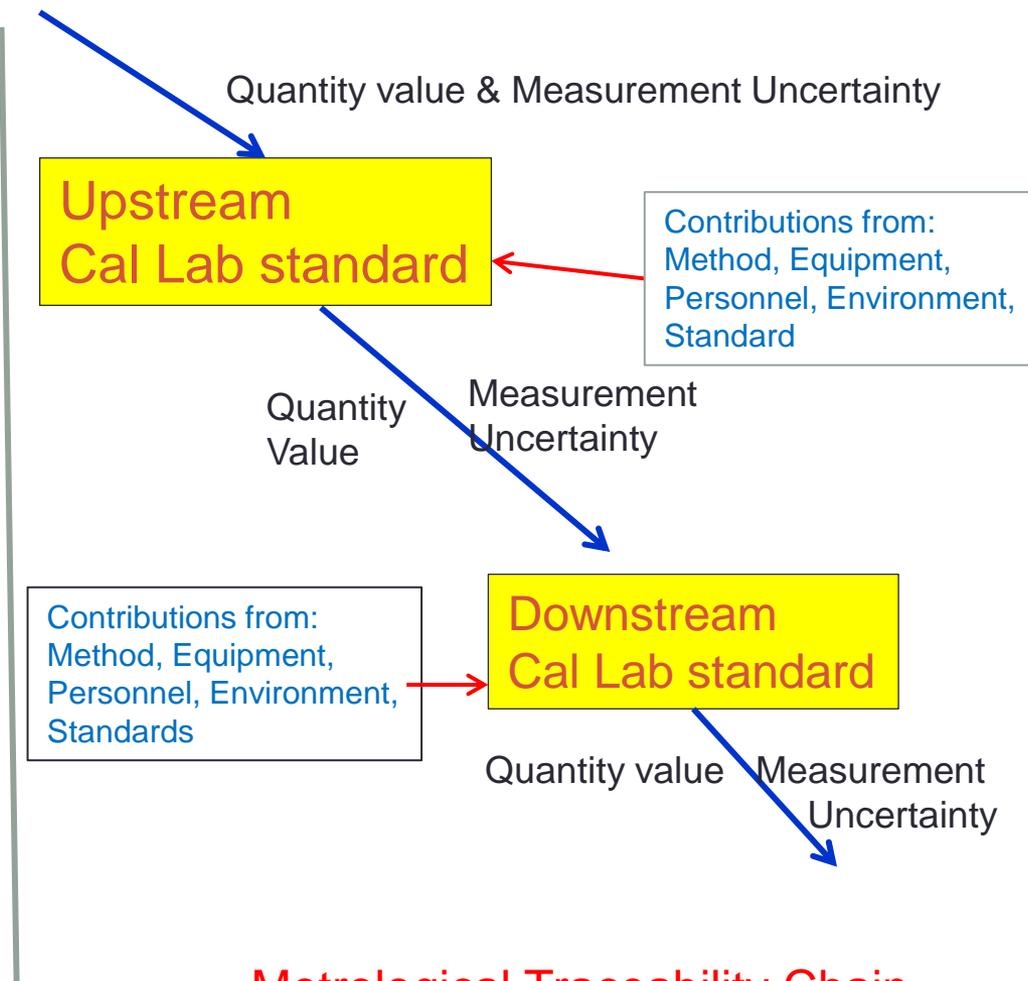
Note 1 of VIM 3 clause 2.41 states that a ‘reference’ can be a “definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.”

(In ISO/IEC 17025:2005 and ISO 15189:2012 the term “traceability” is equivalent to the VIM’s “Metrological traceability” and the term “traceability” is used throughout this document).

Metrological Traceability (contd.)



Calibration Hierarchy



Metrological Traceability Chain

Introduction (*contd.*)

- Relevant clauses of ISO/IEC 17025:2005 relating to measurement traceability:
 - 5.6 Measurement traceability
 - 5.6.1 General
 - 5.6.2.1 Calibration
 - 5.6.2.2 Testing
 - 5.6.3.1 Reference standards
 - 5.6.3.2 Reference materials
- Relevant clause of ISO/IEC 15189:2012 relating to measurement traceability:
 - 5.6.3

Policy for traceability in calibration

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

4.3.1 An NMI whose service is suitable for the intended need and is covered by the CIPM Mutual Recognition Arrangement (MRA). Services covered by the CIPM MRA can be viewed in Appendix C of the International Bureau of Weights and Measures (BIPM) key comparison database (KCDB) which includes the range and uncertainty for each listed service.

CIPM – International Committee for Weights and Measures

Policy for traceability in calibration

4.3.2 A calibration laboratory whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate calibration) and has been accredited by an accreditation body that is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.

Policy for traceability in calibration

4.3.3 An NMI whose service is suitable for the intended need but not covered by the CIPM MRA. In this case, the laboratory 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 ISO/IEC 17025:2005):

- Records of calibration method validation (5.4.5)
- Procedures for estimation of uncertainty (5.4.6)
- Documentation for traceability of measurements (5.6)
- Documentation for assuring the quality of calibration results (5.9)
- Documentation for competence of staff (5.2)
- Documentation for accommodation and environmental conditions (5.3)
- Audits of the NMI (4.6.4 and 4.14)

Policy for traceability in calibration

4.4 Standards Malaysia shall not accept the service provided by:

- a) a non-accredited calibration laboratory,
- b) an accredited calibration laboratory by Accreditation Body that is neither a signatory to the ILAC MRA nor Regional MRAs recognised by ILAC.

Policy for traceability in calibration

4.5.1 Clause 5.6.2.1.2 of MS ISO/IEC 17025 can only be applied in the case in which the laboratory has demonstrated that the policy in 4.3 cannot reasonably be met. It is the responsibility of the laboratory to choose a way to satisfy clause 5.6.2.1.2 and to provide the appropriate evidence. This evidence shall be documented and the documentation shall be assessed by Standards Malaysia.

MS ISO/IEC 17025 clause 5.6.2.1.2 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 interlaboratory comparisons is required where possible.

Policy for traceability in testing

5.2.1 If the calibration of equipment used in testing contributes significantly to the overall uncertainty, the same policy for traceability applies (as detailed under 4.3 to 4.5 above).

5.2.2 If a calibration is not a dominant factor in the testing 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.

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

6.2.1 The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO Guide 34:2009, are considered to have established valid traceability (see ILAC General Assembly resolution ILAC 8.12).

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

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

6.2.3 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 clause 4.6.2 in ISO/IEC 17025:2005 or ISO 15189:2012.