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

SAMM POLICY 2 (SP2) – POLICY ON THE TRACEABILITY OF MEASUREMENT RESULTS

Issue 4, 21 July 2014

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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1 Introduction

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

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 requirement of ILAC-P10:01/2013, ILAC policy on the traceability of measurement results.

The information on the National Metrology Institute in Malaysia is as described in Annex A.

2 Scope

This document details the general policy of the Standards Malaysia with regard to the metrological traceability requirements from ISO/IEC 17025 and ISO 15189.

3 Terms and definitions

The following definitions apply throughout this document:

3.1 **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 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.

3.2 **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

3.3 **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
Note1: The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

3.4 **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.

3.5 **JCTLM**

The Joint Committee for Traceability in Laboratory Medicine (JCTLM) is a cooperation between the International Committee of Weights and Measures (CIPM), the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC) and the International Laboratory Accreditation Cooperation (ILAC) to promote and give guidance on internationally recognised and accepted equivalence of measurements in laboratory medicine and traceability to appropriate measurement standards.

4 Policy for traceability in calibration

4.1 The general requirement for traceability in ISO/IEC 17025:2005 is:

> *5.6.1 All equipment used for tests and/or calibrations, 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, calibration or sampling shall be calibrated before being put into service.*

It is an obligation of the laboratory to ensure the need for calibration is fulfilled as stated in ISO/IEC 17025:2005 Clause 5.6.2.1.1, *For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités).*

For reference standards the traceability requirements of ISO/IEC 17025:2005 are:

> *5.6.3.1 The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.*

In order to maintain traceability in calibration programmes, guidance can be found in ILAC G24:2007 - Guidelines for the determination of calibration intervals of measuring instruments.

4.2 Clause 5.6.2.1.1 in ISO/IEC 17025:2005 further states that "*When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability*".

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.**

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 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

4.3.2 **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.**

Note: Some calibration laboratories indicate that their service is covered by the ILAC Arrangement by including the ILAC Laboratory Combined MRA mark on the calibration certificate. Alternatively, the accreditation symbol of the accreditation body that is a signatory to the ILAC Arrangement and/or a recognised regional Multilateral Recognition Arrangement (MLA) may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

Or

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)**

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.

4.5 Clause 5.6.2.1.2 of ISO/IEC 17025:2005, states:

> *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.*

4.5.1 **Clause 5.6.2.1.2 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.**

5 Policy for traceability in testing

5.1 The ILAC Arrangement in testing covers both testing laboratories accredited to ISO/IEC 17025:2005 as well as medical laboratories accredited to ISO 15189:2012. In ISO/IEC 17025:2005, the requirements for traceability in testing laboratories are:

> *5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.*
>
> *NOTE: The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.*

In ISO 15189:2012, the requirements are:

> *5.3.1.4 Equipment calibration and metrological traceability*
> *The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects examination results. This procedure includes:*
> *a) taking into account conditions of use and the manufacturer's instructions;*
> *b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;*
> *c) verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;*
> *d) recording the calibration status and date of recalibration;*
> *e) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;*

f) safeguards to prevent adjustments or tampering that might invalidate examination results.

5.2 Standards Malaysia's policy with regards to the above clauses of ISO/IEC 17025:2005 and ISO 15189:2012 is:

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.**

5.3 In ISO/IEC 17025:2005 the further requirement for traceability for testing laboratories is:

5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

In ISO 15189:2012 the requirement for traceability is:

5.3.1.4 Where this is not possible or relevant, other means for providing confidence in the results shall be applied,
including but not limited to the following:
— use of certified reference materials;
— examination or calibration by another procedure;
— mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

In this case, the policy for traceability is identical to 4.5.1 above.

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

6.1 ISO/IEC 17025:2005 traceability requirements in relation to reference materials include:-

5.6.3.2 Reference materials
Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.

Note 1: Values associated with RMs may not be metrologically traceable. Values associated with CRMs (by definition) are metrologically traceable.

Note 2: At present, the ILAC Arrangement does not cover the accreditation of reference material producers (RMPs). At the regional level, Asia Pacific Laboratory

Accreditation Cooperation (APLAC) operates an MRA for RMPs and a number of countries operate systems for the accreditation of RMPs, and the number of accredited RMPs is therefore increasing.

6.2 The policy in regard to traceability provided by RMPs is:

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.**

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.**

Annex A

Information on the National Metrology Institute in Malaysia

The National Metrology Laboratory in SIRIM Berhad performs the functions of the National Metrology Institute in Malaysia. It is responsible for the realisation, establishment and maintenance of the Malaysian national standards of measurement based on the SI units.

In September 2001, Malaysia became a signatory of the Metre Convention. This was followed by the signing of the CIPM MRA in October 2001 by SIRIM Berhad.

Further information on the National Metrology Laboratory and the national metrology capabilities may be obtainable directly from:

National Metrology Laboratory
SIRIM Berhad
Lot PT 4803
Bandar Baru Salak Tinggi
43900 Sepang
Selangor Darul Ehsan
Malaysia.

Tel : +60-3-8778 1600
Fax : +60-3-8778 1616
Website : http://www.sirim.my

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2) ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

3) ISO 15189:2012, Medical laboratories – Requirements for quality and competence

4) JCGM 200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd edition

5) ILAC-G24:2007, Guidelines for the determination of calibration intervals of measuring instruments

6) ISO Guide 34:2009, General requirements for the competence of reference material producers