ACCREDITATION SCHEME FOR LABORATORIES

SAC-SINGLAS 006

Traceability of Measurement

SAC-SINGLAS 006, 1 May 2021
The SAC Accreditation Programme is managed by Enterprise Singapore

1.0 Introduction

1.1 This document is intended for all calibration and testing laboratories, and inspection bodies, where testing and/or calibration is involved.

1.2 This document shall be read in conjunction with ISO 17034, ISO/IEC 17025, ISO 15189, ILAC-P10:07/2020 – ILAC Policy on the Traceability of Measurement Results, and SAC-SINGLAS 002 – Requirements for the Application of ISO/IEC 17025, ISO 15189, and other applicable Series of Technical Notes published by the respective fields under SAC-SINGLAS.

2.0 Terms and Definitions

The following definitions apply through this document:

2.1 Metrological traceability (VIM 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 in clause 2.41 interprets a 'reference' as either; "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 and ISO 15189 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this document which should be taken to mean "metrological traceability" as well.

2.2 Metrological traceability chain (VIM clause 2.42)
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 (VIM clause 2.43)
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 (SI).

2.4 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.

2.5 BIPM
The International Bureau of Weights and Measures (BIPM) is the intergovernmental organisation through which Member States act together on matters related to measurement science and measurement standards.

2.6 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.

2.7 KCDB

The Key Comparison Database (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) (http://www.bipm.org/kcdb).

2.8 JCTLM

Joint Committee for Traceability in Laboratory Medicine

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 recognised and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

2.9 CRM

Certified Reference Material

Reference material characterised 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 (ISO 17034).

2.10 RM

Reference Material

Material, sufficiently homogeneous 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).

3.0 Policy on Traceability in Calibration

3.1 The general requirements for traceability in ISO/IEC 17025 are described in Clause 6.5.

3.2 For equipment and reference standards that must be calibrated, the SAC policy is that they shall be calibrated by:

3.2.1 National Metrology Centre (NMC) Singapore, where the service is covered by CIPM MRA or traceable to NMC's primary standard covered by CIPM MRA. For NMC's other services not covered by CIPM MRA, SAC will review to accept the measurement traceability based on other information such as international comparison (if available) and technical publication.

Note: As it is not NMI's international practices to list down all the CMC of calibration services in the KCDB, it is acceptable for NMC's measurement capability that is not practical to be listed as CMC, but is traceable to NMC's primary standard covered by CIPM MRA.

3.2.2 Calibration laboratory accredited by SAC for the relevant scope of calibration activities. The calibration certificate shall be a SAC endorsed certificate with SAC Accreditation Mark.

3.2.3 An NMI whose service is suitable for the intended need and is covered by the CIPM MRA. 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. The calibration certificate must include an endorsement by the NMI.

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.

3.2.4 A calibration laboratory accredited for the relevant calibration (i.e. the scope of accreditation specifically covers the appropriate calibration) by Accreditation Body having Mutual Recognition Arrangement (MRA) with SAC. The calibration certificate shall be endorsed and included with the accreditation body's mark.

Note: For endorsed calibration certificates with unclear traceability such as:

a) traceable to NMIs with the scopes not covered by CIPM MRA, or
b) traceable to NMIs' calibration certificate without measurement uncertainty, or

c) with measurement uncertainty equal or smaller than the CMC of NMI it is traceable to.

SAC reserves the right to investigate and review before accepting these certificates on case-by-case basis.

3.3 If the laboratory has demonstrated that the policy in Clause 3.2 of this document cannot be reasonably met, or the calibration cannot be strictly made in SI units, it is the responsibility of the laboratory to provide the appropriate evidence, e.g.

a) No laboratory or NMI could fulfill the policy in Clause 3.2, and other objective evidence of measurement traceability for the calibration by the identified laboratory. This route is unlikely to be made on purely economic grounds, and is more likely to be a last resort if other routes are unavailable;
b) The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;
c) The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

This evidence shall be documented and the documentation shall be assessed by SAC.

3.4 Laboratories holding only management systems certification will be deemed to have not demonstrated the necessary technical competence.

4.0 Policy on Traceability in Testing

4.1 The ILAC Arrangement in testing covers both testing laboratories accredited to ISO/IEC 17025 as well as medical laboratories accredited to ISO 15189. In ISO/IEC 17025, the requirements for traceability in testing laboratories are described in Clause 6.5. In ISO 15189, the requirements are in Clause 5.3.1.4.

4.2 SAC policy on traceability in testing is as follows:

4.2.1 If the calibration of instruments used in testing contributes significantly to the overall uncertainty, the same policy for traceability in Clause 3 of this document applies.

4.2.2 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.

5.0 Policy on Traceability Provided Through Certified Reference Materials (CRMs) and Reference Materials (RMs)

5.1 The traceability requirements for reference materials in ISO/IEC 17025 are described in Clause 6.5.

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

5.2 SAC policy on traceability provided by reference material producers is as follows:

a) The values assigned to CRMs produced by the Health Sciences Authority (HSA), Singapore and other NMIs, which are listed in the BIPM KCDB, are considered to have established valid traceability. For values assigned to CRMs which are not covered by CIPM MRA, SAC shall review to accept the traceability based on other information such as international comparison (if available) and technical publication.
b) The values assigned to CRMs produced by an ISO 17034 accredited reference material producer (preferably with APLAC MRA for Reference Material Producer accreditation) with the relevant scope covered by the scope of accreditation, are considered to have established valid traceability.
c) The values assigned to CRMs listed in the JCTLM database are considered to have established valid traceability.
d) RMs produced by other reference material producers are considered as critical consumables and the laboratory shall demonstrate that each RM is suitable for its intended use as required by ISO 15189 or Clause 6.6. in ISO/IEC 17025.

References:

1. *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms VIM, 3rd edition, JCGM 200:2012 (JCGM 200:2008 with minor corrections) available from the BIPM homepage http://www.bipm.org or ISO/IEC Guide 99:2007 available from ISO*

2. *ILAC-P10:07/2020 – ILAC Policy on the Traceability of Measurement Results*

3. *ISO/IEC 17025: 2017 – General requirements for the competence of testing and calibration laboratories*

4. *ISO 15189: 2012 – Medical laboratories – Requirements for quality and competence*

5. *ISO/IEC 17020: 2012 – Conformity assessment -- Requirements for the operation of various types of bodies performing inspection*

6. *ISO 17034: 2016 – General requirements for the competence of reference material producers*