SADCAS POLICY ON METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

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1. PURPOSE AND SCOPE

The purpose of this document is to describe the SADCAS policy with regard to the metrological traceability requirements in testing and calibration. This policy also applies to other conformity assessment activities where measurement is involved (e.g., medical laboratories, inspection, reference material production, proficiency testing providers). For calibrations performed by an Accredited Organization in order to establish metrological traceability for its own activities, and which are not a part of the organization's scope of accreditation, the SADCAS policy in section 3 is applicable. These internal calibrations are also known as "in-house" calibrations.

This document applies to all SADCAS accredited facilities.

2. TERMS AND DEFINITIONS

The following definitions apply throughout this document:

Accredited Organization
Throughout this document, the term "Accredited Organization", which includes CABs, is used to refer to organizations covered by the ILAC Arrangement. Whenever the term "Accredited Organization" is used in the text, it applies to both the applicant and the Accredited Organization, unless otherwise specified.

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.

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.

CRM
Certified Reference Material
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 (17034:2016[3]).

JCTLM
Joint Committee for Traceability in Laboratory Medicine

JCTLM formed by the International Bureau of Weights and Measures (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.

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).

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."

ISO/IEC 17025:2017[4] and ISO 15189:2012[5] refer to the VIM´s term of "metrological traceability".

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.

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.

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

NMI
National Metrology Institute
National Metrology Institutes (NMIs) and Designated Institutes (DIs) 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.

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 17034:2016).

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

3. SADCAS Policy on Metrological Traceability of Measurement Results

When metrological traceability is required, the SADCAS policy is that the equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) shall be calibrated by:

a) A National Metrology Institute (NMI) whose service is suitable for the intended need and is covered by the International Committee for Weight and Measures Mutual Recognition Arrangement (CIPM MRA). Services covered by the CIPM MRA can be viewed in the Bureau International des Poids et Mesures Key Comparison Database (BIPM KCDB) which includes the range and uncertainty 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

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 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:

- The combined ILAC MRA mark, or
- 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.

or

c) An NMI whose service is suitable for the intended use but not covered by the CIPM MRA. The NMI shall have participated in interlaboratory comparisons approved by the SADC Cooperation in Metrology (SADCMET) or Intra-Africa Metrology System (AFRIMETS) through which NMIs that are not yet signatory to the CIPM MRA demonstrate their calibrations and measurement capabilities and metrological traceability.

or

d) A laboratory whose calibration service is suitable for the intended use but not covered by the ILAC Arrangement or by regional arrangements recognized by ILAC.

Accredited Organizations that have demonstrated metrological traceability of their measurements results through the use of calibration services offered according to a) or b) above have made use of services that have been subject to relevant peer review or accreditation. In the situation where c) or d) applies, this is not the case, so these routes should only be applicable when a) or b) are not possible for a particular calibration. Accredited Organizations must therefore ensure that appropriate evidence for claimed metrological traceability and measurement uncertainty is available.
SADCAS shall assess this evidence that shall include the following:

- Records of calibration method validation (7.2.2.4)
- Procedures for estimation of uncertainty (7.6)
- Documentation and records for metrological traceability of measurement results (6.5)
- Documentation and records for ensuring the validity of results (7.7)
- Documentation and records for competence of personnel (6.2)
- Records for Equipment which can influence laboratory activities (6.4)
- Documentation and records for facilities and environmental conditions (6.3)
- Audits of the calibration laboratory (6.6 and 8.8)

Numbers in brackets refer to clauses in ISO/IEC17025:2017 whose requirements are assessed for competence and compliance by SADCAS.

Options a) and b) above are the preferred options for metrological traceability. Options c) and d) are only applicable when options a) and b) are not possible.

The ILAC 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:

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

or

f) 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 recognised by ILAC.

or

g) The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

Recognizing that the accreditation of RMPs is still developing, where CRMs are produced by non-accredited RMPs, Accredited Organizations shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

When metrological traceability to the SI is not technically possible, it is the responsibility of the Accredited Organization to:

h) Choose a way to satisfy metrological traceability requirements by using certified values of certified reference materials provided by a competent producer.

or

i) 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 Accreditation Body.

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: Materials sold as left over from PT Programmes may not be continuously monitored to guarantee the stability of the property value and sample matrix and so should not be considered as an alternative way to ensure the validity of results.

4. REFERENCES

- SADCAS PM 01 - SADCAS Policy Manual
- SADCAS TG 01 - Information to Organizations Applying for Accreditation
- ILAC P 10: ILAC Policy on the Traceability of Measurement Results
- ILAC P 14: ILAC Policy for Uncertainty in Calibration
- 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 www.bipm.org or ISO/IEC Guide 99:2007 available from ISO.
- ISO/IEC Directives, Part 2, Principles to structure and draft documents intended to become International Standards, Technical Specifications or Publicly Available Specifications, Eight Edition 2018
- ISO 17034:2016, General requirements for the competence of reference material producers.
- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.
- ISO 15189:2012, Medical laboratories – Particular requirements for quality and competence.
- 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.
- Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability (November 2018)

APPENDIX - AMENDMENT RECORD

Revision Status	Change			Approved by	Effective Date
	Page	Clause/ Subclause	Description of Change		
Issue 1	-	-	-	CEO	2013-04-24
Issue 1	3	2	Deleted sub clause in its entirety and substituted with the following: "Equipment and reference standards used by calibration laboratories and having an impact on the accuracy and validity of measurement result shall be calibrated by: a) A National Metrology Institute (NMI) whose service is suitable for the intended need and belongs to the CIPM MRA and are signatories to its Mutual Recognition Agreement (MRA) amongst NMIs and who have approved CMCs within the BIPM Key Comparison Database (KCDB) which	CEO	2014-09-18

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			includes the range and uncertainty for each listed service. The acceptance of other NMIs other than those of the CIPM MRA partners shall be at the discretion of SADCAS Chief Executive Officer after due consultation of the appropriate Advisory Committee. b) A calibration laboratory accredited by an accreditation body covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC whose service is suitable for the appropriate calibration. c) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA. The National Metrology Institute shall have participated in the SADC Cooperation in Metrology (SADCMET) through which SADC countries that are not yet signatory to the CIPM can get their traceability. d) A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by regional arrangements recognized by ILAC. For options c) and d) appropriate evidence for the technical competence of the laboratory and claimed metrological traceability shall include the following: - Record of calibration method validation; - Procedures for estimation of uncertainty ; - Documentation for traceability of measurements; - Documentation for assuring the quality of calibration results; - Documentation for the competence of staff; - Documentation for accommodation and environmental conditions; and - Audits of the calibration laboratory.		

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			Options a) and b) above are the preferred options for metrological traceability. Options c) and d) are only applicable when options a) and b) are not possible.		
	6	3	Added to list of references "ILAC P 10: ILAC Policy on the Traceability of Measurement Results; and ILAC P 14: ILAC Policy for Uncertainty in Calibration"	CEO	2014-09-18
Issue 2	3	New Sub clause 2.1.1	After Heading of 2.1 added another heading which reads '2.1.1 Calibration laboratories"	CEO	2015-01-30
	3	Sub clause 2.1 (a) renumbered 2.1.1 (a)	2nd paragraph – Inserted "subject to satisfactory evidence of the technical competence of the laboratory using appropriate methods as outlined in the technical procedures" after "Advisory Committee"	CEO	2015-01-30
	4	New Sub clause 2.1.2	After 2.1 (d) renumbered 2.1.1 (d) added new sub clause 2.1.2 which reads "**Testing/Medical Laboratories** a) Equipment and instruments used by testing and medical laboratories and having a significant impact on the measurement results shall be calibrated by one of the processes defined in 2.1.1; b) If the calibration is not a dominant factor in the test result, traceability does not need to be demonstrated but the laboratory shall have quantitative evidence to demonstrate that the calibration contributes insignificantly to the measurement result and the measurement uncertainty of the test".	CEO	2015-01-30
	6	2.6	1st paragraph Lines 4 and 5 – Between "calibrations" and "records" inserted "and to satisfactory evidence of the technical competence of the service provider using appropriate methods as outlined in the technical procedures and"		

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			Inserted new 2nd paragraph which reads "The following methods may be used as appropriate and feasible: a) Participation in a suitable programme of inter laboratory comparisons; b) Use of suitable reference materials certified to indicate the characterization of the material; c) Examination or calibration by another procedure; d) Ratio or reciprocity type measurements; e) Mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned; and Documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer."		
Issue 3	3	2.1	a) – Deleted second paragraph. c) – Added second paragraph which reads: "The acceptance of other NMIs other than those of the CIPM MRA partners shall be at the discretion of SADCAS Chief Executive Officer after due consultation of the appropriate Advisory Committee subject to satisfactory evidence of the technical competence of the laboratory using appropriate methods as outlined in the technical procedures".	CEO	2015-05-26
Issue 4	4	2.1.3	Added new sub clause 2.1.3 "Traceability for Inspection Bodies" which reads: "Equipment used by inspection bodies and having significant impact on measurement results shall be calibrated. SADCAS accepts evidence of traceability as outlined in 2.1.1. Where traceability as stated above is not technically possible or reasonable or available, the inspection body and client and other interested parties may agree to using reference materials /certified reference materials as outlined in 2.2."	CEO	2017-06-14

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	Page	Clause/ Subclause	Description of Change		
Issue 5	4	2.1.3	Deleted 2nd paragraph and substituted with "Where traceability as stated above is not technically possible or reasonable or available, the testing/ medical laboratories and client and other interested parties may agree to using reference materials /certified reference materials as outlined in 2.2."	CEO	2017-08-10
Issue 6	All	All	Whole procedure updated to align with ILAC P10:07/2020.	CEO	2022-02-16