TRACEABILITY OF MEASUREMENTS
(C08.01)

Approval		Effective Date
Date	01/11/19	01/11/19

SUMMARY

1- PURPOSE AND SCOPE

This document is to clarify the requirements of the SOAC traceability of measurement results, and to the attention of the applicant bodies for accreditation, accredited bodies, assessors and technical experts.

It applies to accredited bodies that carry out measures to support their activities:

- Calibration and testing laboratories: ISO / IEC 17025
- Medical Laboratories: ISO 15189
- Inspection bodies: ISO / IEC 17020
- Product certification bodies: ISO / IEC 17065
- Interlaboratory test organizers/proficiency testing providers: ISO / IEC 17043
- Reference material producers: ISO 17034

2- REFERENCES

- ILAC P10, ILAC Policy on the Traceability of Measurement Results
- ILAC P14, ILAC Policy for Uncertainty in Calibration
- ISO/IEC 17011, Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
- TP003-01 AFRAC Guidelines on the Methods of Stating Test and Calibration

3- EFFECTIVE DATE AND REVIEW

This document is applicable from the date specified on the cover page. It will be updated as necessary.

4- SUMMARY OF CHANGES

Version 00: creation.
Version 01: revision and update for some sections.

5- TERMS AND DEFINITIONS

JCGM 200 - International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)

CIPM: International Committee for Weights and Measures
MRA: Mutual Recognition Arrangement
CMC: Calibration and Measurement Capabilities
BIPM: Bureau International des Poids et Mesures **(**the intergovernmental organisation through which Member States act together on matters related to measurement science and measurement standards.)
AFRAC: African Accreditation Cooperation
MLA: Multilateral Agreement
CRM: Certified Reference Material
BIPM KCDB: BIPM key comparison database

6- INTERNATIONAL AGREEMENTS FOR THE MUTUAL RECOGNITION OF CERTIFICATES ISSUED BY THE CONFORMITY ASSESSMENT BODIES

6.1 CIPM MRA

The CIPM MRA (Mutual Recognition Arrangement for national measurement standards and for calibration and measurement certificates issued by National Metrology Institutes (NMI) is an agreement between the national metrology & measurement institutes. It is based on international key comparisons, the mutual assessment of management systems according to ISO/IEC 17025 and submission to a very strict review process of calibration and measurement capabilities (Calibration and Measurement Capabilities, CMC). The agreement, the participating laboratories, the results of measurement comparisons and CMC are documented in the International Bureau of Weights and Measures database (BIPM KCDB: BIPM Key Comparison Data Base).

6.2 AFRAC MRA

The AFRAC (African Accreditation Cooperation) is the African cooperation in accreditation covering the Africa region for the accreditation of calibration laboratories and of proficiency testing providers. The AFRAC MRA is an agreement between the members of the AFRAC for mutual recognition of accreditation certificates of conformity assessment bodies.

6.3 ILAC MRA

ILAC (International Laboratory Accreditation Cooperation) is the international group of accreditation bodies for the accreditation of laboratories and inspection bodies. Accreditation bodies (ABs) around the globe which are assessed, and whose skills are recognized by the other ABs of the same rank, signed an agreement – the ILAC Mutual Recognition Arrangement (ILAC-MRA), which promotes the acceptance of products and services across national borders. This agreement has the aim of creating an international system that promotes international trade by removing technical barriers to trade. In this way, the objective of free trade - "product tested once, accepted by all" - can be achieved.

7- TRACEABILITY OF MEASUREMENT RESULTS: THE CONCEPT

7.1 Traceability

The formal definition of traceability is given in the International Vocabulary of Metrology (VIM-2012) § 2.41 as *metrological traceability "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".*

Organisations that perform measurements are generally faced with the need to calibrate their instruments over the instruments of higher accuracy or against the standard; they must, in turn, be controlled via one or more stages of calibration relative to national or international standards.

The traceability of the measurement results is essential to ensure the validity and comparability of the results and involve a level of uncertainty.

7.2 Elements of traceability

Traceability is characterized by a number of essential components:

- An **unbroken chain** of connection to a national or international standard;
- **Uncertainty of measurement** shall be calculated using accepted and validated methods to allow the calculation or estimation of uncertainty for the whole chain;
- **Documentation**: Each step in the chain must be performed according to documented and generally accepted procedures; the results must be recorded;
- **Competence:** laboratories or organisations involved in one or more levels of the chain of traceability shall demonstrate their technical competence;
- **Reference to International System of Units (SI):** the traceability chain shall, whenever technically possible, lead to the primary standards and refer to SI units;
- **Verification:** verifications shall be undertaken at appropriate intervals to prevent degradation of the quality of the measurement. These intervals should be selected taking into account a number of variables (e.g. the required level of uncertainty, frequency of use, wear, modes of use, the stability of the equipment).

In several areas, the reference materials are in the form of physical reference standards. It is also important that such materials are connected to the corresponding SI units.

7.3 Standard

Measurement standard: realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference.

According to this definition proposed by the VIM, in the context of this document a measurement standard means:

- the metrology standards directly related to a physical quantity;
- measuring instruments used as a reference;
- chemical standards (e.g. pure substances);
- biological standards (e.g. microbial strains);
- reference materials and substances commonly used as references in many technical fields.

The above list may need to be supplemented in the case of specific technical areas.

8- TRACEABILITY OF MEASUREMENT RESULTS: GUIDELINES FOR THE REALIZATION

Measuring equipment shall be calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or

- calibration of the equipment is required to establish the metrological traceability of the reported results.

Types of equipment having an effect on the validity of the reported results can include:
- those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;
- those used to make corrections to the measured value, e.g. temperature measurements;
- those used to obtain a measurement result calculated from multiple quantities.

8.1 Calibrations entrusted to a third party.

The organisation, using an external laboratory for the calibration of measuring instruments and reference standards, shall demonstrate that traceability requirements are established.

The formal traceability is achieved when calibration is covered by a certificate issued by:

- A National Metrology Institute (NMI) whose service is tailored to the needs provided, linked to the CIPM MRA and is part of NMIs signatories of the Mutual Recognition Agreements CIPM MRA. Calibrations covered by the CIPM MRA are listed in Appendix C of the BIPM KCDB which includes the measuring range and the CMC for each service.
- a calibration laboratory accredited by an accreditation body signatory to the ILAC Arrangement or regional arrangements recognized by ILAC or in, UEMOA area, by a laboratory accredited by SOAC, and whose service is suitable for the calibration concerned.

Only calibration certificates which explicitly refer to the laboratory accreditation give a guarantee of traceability.

However, for testing and analysis laboratories, if the calibration is not a dominant factor for the results of tests, traceability does not need to be demonstrated; nevertheless, the laboratory shall have quantitative evidence for demonstrating that the calibration contributes insignificantly to the measurement result as well as to the measurement uncertainty of the analysis.

If the body is not able to use the services of an organisation in one of the categories above, it must ensure that the issued calibration certificate contains at least the following information:
- complete identification of the object subjected to calibration;
- a description of the measurement standards used and their calibration status;
- a description of the chain of traceability to the national or international standards;
- the calibration method;
- the calibration data;
- measurement uncertainty;
- environmental conditions, if any;

- the date of calibration;
- the signature of the person responsible for calibration;
- the name and address of the organisation that produced the certificate and the date of the certificate.

These requirements apply, especially when it is essential to contact the manufacturer for calibration of a very specific instrument.

If in doubt about the validity of a certificate, or for information on possibilities of execution of a specific calibration, an opinion may be requested to SOAC.

In all cases, it is up to the **organisation** to verify that the calibration executed and, if applicable, the scope of accreditation of the concerned calibration laboratory meets the requirements of the measurement to be done.

8.2 In-house calibrations made by the organisation

The organisation that runs itself the calibration of measuring equipment but does not have an accreditation as a calibration laboratory shall be able to demonstrate that it has the technical competence and the equipment required for this operation.

Each calibration shall be documented in a technical procedure adapted to the appropriate level of requirement of the measure, taking into account wherever possible, the standards applicable in this field and/or recommendations of the equipment manufacturer.

The calibration procedure mentioned include:

a) the instrument or group of instruments to which the procedure is applicable;
b) standards and/or reference materials used and, where appropriate, the necessary auxiliary equipment;
c) the action to be taken so that during the handling, transport, storage and use of standards and/or reference materials, their characteristics are preserved;
d) the conditions of handling, transportation, storage and preparation of the instrument to be calibrated;
e) environmental conditions to respect, including applicable limitations, any corrections to be applied depending on the environmental conditions, and, if necessary, the minimum period of stabilization before proceeding to the calibration;
f) technical instructions for the execution of calibration, including the identification of those entitled to the task and; if necessary, specific qualification criteria those entitled to the task need to have;
g) recording the results;
h) the tolerance allowed for the acceptance of calibration results;
i) an estimation of the measurement uncertainty associated with the calibration;
j) the criteria used for the fixation and the possible adaptation of the intervals between successive calibrations.

It is the organisation responsible to ensure that the used reference equipment, or the metrological standards, has certificates establishing traceability to national or international standards or equivalent.

To this end, the laboratory will verify that the certificate:

- covers a sufficient measuring range compared to the considered test and ensures the accuracy required;
- was issued by an organisation which offers sufficient guarantees of traceability.

The reference standards held by the organisation shall only be used for calibration, to the exclusion of any other use.

Standards management (storage, handling, recalibration, etc.) shall be documented in procedures detailing the steps taken to ensure the maintenance of their characteristics.

The organisation may decide, to limit the frequency of use of its reference standards, to use working standards; the calibration procedure will in this case:

- document the steps taken to ensure the traceability of working standards to reference standards and maintaining the status of the latter;
- reflect the use of the working standard for the estimation of measurement uncertainty.

8.3 Where the establishment of traceability is difficult.

In the case of areas where traceability to national or international standards is difficult to establish, especially in the field of testing, the organisation will ensure when it uses of traceability, for example, relative to certified reference material (CRM), or a fixed and/or consensus standard method:

- to identify and put under control the components of the final result to which the concept of traceability is applicable;
- to establish the validity of the test results using, wherever possible, alternative approaches; the latter may be the participation in intercomparison programs, the re-examination of samples already analyzed, the application on the same sample of several test methods to lead to the same result with the same measurement uncertainty.

When traceability is established using reference materials, it is accepted if reference materials (RMs) are included in the KCDB BIPM, or have been produced by a competent Reference Material Producer (RMP). When the RMs are covered by the Joint Committee for Traceability in Laboratory Medicine (JCTLM), these are also considered to have valid traceability.

If the laboratory is brought, failing pure material, to use a complex-reference material as a measurement reference, it shall, whenever possible, refer to a material produced and characterized by a technically valid & duly certified mechanism (CRM).

When a certified reference material (CRM) is not available, a material, with composition and stability adapted to the needs (RM), can be selected or developed by the laboratory. It is then the responsibility of the laboratory to establish the characteristics and demonstrate that it is suitable for its intended use. In particular, a material having been used as part of an interlaboratory test may be a useful alternative.

8.4 Intermediate checks

The intermediate checks are these audits to maintain the confidence of the status of the calibration of measuring and test equipment. The intermediate checks are performed according to a defined procedure. The intermediate checks are not a substitute calibration but can provide a justification for the extension of calibration intervals if results are favorable.
When intermediate checks are conducted, appropriate records shall be kept and the uncertainty of measurement should be taken into consideration when confirming if the calibration status continues to meet the requirements of the test or measure.

9- TABLE OF MODIFICATIONS

No.	Source	Modification in brief (Relevant changes)
C08.00- 24 January 2019		
Creation		
C08.01- 12 September 2019		
1	§ 1	This section has been revised
2	§ 2	References have been revised in line with the wording of the standards
3	§ 3	The title has been revised
4	§ 5	The title has been revised
5	§ 6	The title has been corrected to the wording ‘’the conformity assessment bodies’’ (Table of content and clause 6.)
6	§ 6.1	Acronym corrected to the wording NMI
7	§ 7.1	This section has been updated : - the word ‘’ metrological traceability’’ is added to the definition and; - Some words have been removed in the third paragraph
8	§ 7.2	Corrections made in this section: - ‘’uncertainty of traceability’’ corrected by ‘’uncertainty of measurement’’ - the acronym ‘’International System of Units’’ (SI) used instead of (IS)
9	§ 8	This section has been updated and some details added
10	§ 8.1	The section has been revised: - The word ‘’organism’’ has been replaced by ‘’organisation’’ in all this section and; - Some words updated
11	§ 8.2	- The title has been revised and; - The word ‘’organism’’ has been replaced by ‘’organisation’’ in all this section
12	§ 8.3	The terminology of the acronym ‘’JCTLM’’ has been updated in

		this section
13	§ 8.4	- The word ‘’intermediate verifications’’ has been replaced by the word ‘’intermediate checks’’