MAURITAS R3:2021
Issue No. 1: Revision No. 4
Date: December 2021

MAURITAS
R3

Traceability of measurement and measurement uncertainty in calibration

Mauritius Accreditation Service

CONTENTS

Foreword

The MAURITIUS ACCREDITATION SERVICE (MAURITAS) is a governmental body established in 1998 to provide a national, unified service for the accreditation of Conformity Assessment Bodies (CABs) such as calibration/testing laboratories, certification bodies and inspection bodies Organizations that comply with the MAURITAS requirements are granted accreditation by MAURITAS.

About MAURITAS publications

MAURITAS publications are categorized as follows:

- R series — Publications containing general policy and requirements related to MAURITAS accreditation.
- G series — Publications providing guidance on MAURITAS requirements.
- A series — Publications related to assessment procedures.
- P series — MAURITAS quality system procedures
- F series — MAURITAS Forms
- Directories — Classified listing of accredited organizations.

Mauritius Accreditation Service (MAURITAS)
4th Floor, Crescent House,
Corner Deschartes and Foucault Streets
Port Louis
Mauritius
Tel: +230 208 16 90
Fax: +230 210 61 01
Email: mauritas@govmu.org
Website: www.mauritas.org

Traceability of measurement and measurement uncertainty in calibration

1. Purpose

The purpose of this document is to:

- specify criteria for performing calibration and intermediate checks on equipment used in facilities accredited by MAURITAS.
- define the policy of MAURITAS for the estimation of uncertainty of measurement by calibration laboratories and the
- determine and specify the Calibration and Measurement Capability.

The requirements of this document applies to:

- accredited and applicant testing and calibration laboratories;
- inspection bodies;
- testing and calibration laboratories performing in-house calibration(s).

2. Scope and Responsibilities

It is the responsibility of accredited and applicant testing and calibration laboratories and inspection bodies to implement the requirements of this document. MAURITAS assessment teams shall make use of this document for assessing testing and calibration laboratories and inspection bodies.

3. References

The following documents contain provisions which, through reference in this text, constitute provisions of the MAURITAS accreditation system. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated MAURITAS references, the latest edition of the document referred to, applies. MAURITAS maintains a register of the current valid MAURITAS accreditation documents

3.1 ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

3.2 ISO 15189, Medical Laboratories – Particular requirements for quality and competence.

3.3 UKAS M 3003, The Expression of Uncertainty and Confidence in Measurement (available on www.ukas.com**).**

3.4 EURACHEM/CITAC Guide CG4, Quantifying Uncertainty in Analytical Measurement (available on www.citac.cc)

3.5 MAURITAS G Series documents

3.6 ILAC-P10, ILAC Policy on Metrological Traceability of measurement results

3.7 ILAC-P14, ILAC Policy for Measurement Uncertainty in Calibration

3.8 ILAC-G17, ILAC Guidelines for measurement uncertainty in testing

3.9 ILAC-G24, Guidelines for the determination of calibration intervals of measuring instruments

3.10 ISO 17034, General requirements for the competence of reference material producers.

3.11 EA-4/02 M, Expressions of the Uncertainty of Measurements in Calibration (including supplement 1 to EA-4/02) (previously EAL- R2)

3.12 ISO 15195, Laboratory medicine — requirements for the competence of calibration laboratories using reference measurement procedures

3.13 ISO/IEC Guide 98-3– Uncertainty of measurement – Part 3, Guide to the expression of uncertainty in measurement (GUM: 1995).

3.14 ISO Guide 35, Reference materials –GUIDANCE FOR CHARACTERIZATION AND ASSESSMENT OF HOMOGENEITY AND STABILITY

3.15 ISO/IEC Guide 99, International vocabulary of metrology - Basic and general concepts and associated terms (VIM)

3.16 ISO 80000-1, Quantities and units - Part 1: General

3.17 JCGM 100 GUM 1995 with minor corrections, Evaluation of measurement data – Guide to the expression of uncertainty in measurement. (Available on www.BIPM.org)

3.18 JCGM 200 International vocabulary of metrology – Basic and general concepts and associated terms (Available on www.BIPM.org)

4. Definitions

4.1 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."

4.2 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

4.3 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.

4.4 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.

4.5 JCTLM

The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine

4.6 Calibration Laboratory

In this policy, "calibration laboratory" further means a laboratory that provides calibration and measurement services.

4.7 Calibration and Measurement Capability

In the context of the CIPM MRA and ILAC Arrangement, and in compliance with the CIPM-ILAC Common Statement, the following definition is agreed upon:

A CMC is a calibration and measurement capability available to customers under normal conditions:

a) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement; or
b) as published in the BIPM key comparison database (KCDB) of the CIPM MRA.

5. MAURITAS policy for metrological traceability

5.1 MAURITAS accepts the MAURITAS accredited calibrations of:

- the MSB Metrology Unit; and
- other accredited calibration laboratories.

5.2 MAURITAS will accept National Metrology Institutes (NMIs) which belong to the CIPM and are signatories to the CIPM MRA.

5.3 MAURITAS will also accept other accredited calibration laboratories from ILAC MRA partners equally with appropriate metrological traceability and suitable calibration and measurement capabilities (CMCs).

6. General requirements for metrological traceability

6.1 Calibration Laboratories

When metrological traceability is required, the policy of MAURITAS is that equipment [(1)] shall be calibrated by:

a) A 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.

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 need (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: 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 MLA may be included on the calibration certificate. Both of these options may be taken as evidence of metrological traceability.

or

c) (i) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA. In this case the policy of MAURITAS is that the Director of MAURITAS will consult with experts in the field of Metrology before deciding on the acceptability of the metrological traceability that is claimed.

The Director of MAURITAS shall request the following from the NMI:

- Record of calibration method validation;
- Procedures for estimation of uncertainty;
- Documentation for metrological traceability;
- Documentation for assuring the quality of calibration results;
- Documentation for the competence of staff;
- Records for equipment which can influence laboratory activities;
- Documentation for accommodation and environmental conditions; and
- Audits of the calibration laboratory.

The appropriate records will be kept for future references.

or

c) (ii) A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.
In these cases the policy of MAURITAS will be to assess the appropriate evidence for technical competence of the laboratory and claimed metrological traceability. The laboratory will be assessed based on the documents as listed at c) (i) above.

For laboratories that are using non-accredited calibration services, the onus is on the laboratories to provide the above evidence to MAURITAS.

(1) The term "equipment" is mentioned as interpreted in the ISO/IEC 17025:2017 standard (i.e. also includes standards and reference materials).

Laboratories that have demonstrated metrological traceability of their measurements through the use of calibration services offered according to 6.1a) or 6.1b) above have made use of services that have been subject to relevant peer review or accreditation. In the situation where 6.1c(i)) or 6.1c(ii)) applies, this is not the case, so these routes should only be applicable when 6.1a) or 6.1b) are not possible for a particular calibration. The laboratory must therefore ensure that appropriate evidence for claimed metrological traceability and measurement uncertainty is available and MAURITAS shall assess this evidence.

6.2 Testing Laboratories/ Inspection Bodies

The policy of MAURITAS is:

1. If the calibration of instruments used in testing/inspection contributes significantly to the overall uncertainty, the same policy for metrological traceability applies (as detailed in 6.1a-c above).

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 metrological traceability does not need to be demonstrated.

6.3 Reference Materials / Consensus Standards

The MAURITAS 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:

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

2. 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

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

Recognising that the accreditation of RMPs is still developing and CRMs may not be available from accredited RMPs, where CRMs are produced by non-accredited RMPs, Accredited Organisations shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

When metrological traceability to SI is not technically possible, it is the responsibility of the accredited organisation to:

1. Choose a way to satisfy metrological traceability requirements by using certified values of CRMs provided by a competent producer;

   Or

2. 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 MAURITAS.

   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 measurements (such as environmental conditions) are under sufficient control to provide a reliable result.

   Note 5: Surplus test materials are often available from proficiency testing (PT) providers. It should be checked whether the PT provider can provide additional stability information to demonstrate the on-going stability of the property value and matrix of the test material. If this cannot be provided, these test materials should not be considered as an alternative way to ensure the validity of results.

6.4 In-House Calibrations

In-house calibrations are considered as being those calibrations performed by a facility on their own premises on their own test and measurement equipment.

For all in-house calibrations the facility is required to maintain as a minimum the following:

a) a documented calibration procedure or method;
b) a calibration certificate or report, or some other suitable method of recording the calibration and measurement data;
c) appropriate educational and training records to demonstrate the competence of the personnel performing the calibration;
d) copies of certificates and reports to demonstrate metrological traceability to the SI system of units or RMs as per 6.1, 6.2 & 6.3 above;
e) all reference standards and measuring instruments shall be calibrated at appropriate intervals, the facility shall have and apply a procedure for establishing these calibration intervals; and
f) a procedure for the estimation of the measurement uncertainty, which shall be applied for at least each type of calibration. The uncertainty of measurement shall be taken into account when making a statement of compliance.

As calibration laboratories are accredited for the purpose of passing on metrological traceability through an unbroken chain of comparisons, in-house calibration by a calibration laboratory is only acceptable where the laboratory has been accredited for the specific in-house calibration performed.

Where equipment within a calibration laboratory is used solely as a 'transfer' device it is not necessary for the laboratory to be accredited for the calibration of this transfer device. For example, when a balance is used to calibrate weights and the process of the calibration involves the process of the comparison of two weights, the standard and the unit under test, it is not necessary that the laboratory be accredited for the calibration of the balance which is used solely as a transfer device.

MAURITAS shall assess the in-house calibration(s) performed by laboratories/inspection bodies at least once in every accreditation cycle.

6.5 Requirements for Calibration

All equipment and measuring instruments used to perform testing and measurement within a facility, including subsidiary measurements, must be calibrated unless it can be demonstrated that they have an insignificant effect on the accuracy or validity of the measurement result. Records shall be available that demonstrate this. For the purposes of interpretation any item of test and measurement equipment, the uncertainty of which contributes less than 5% to the total uncertainty of measurement would be considered as insignificant.

6.6 Intermediate Checks

Intermediate checks are those checks performed to maintain confidence in the calibration status of measuring and test equipment. Intermediate checks shall be conducted according to a defined procedure. Intermediate checks are not a substitute for calibration but may provide justification for the extension of calibration intervals, where results are favourable. When intermediate checks are performed appropriate records shall be maintained and the uncertainty of measurement shall be considered when confirming if the calibration status continues to satisfy the requirements for the test or measurement.

7. General requirements for uncertainty of measurement

7.1 MAURITAS Policy on the Estimation of Uncertainty of Measurement

7.1.1 Accredited/applicant calibration laboratories shall estimate uncertainties of measurement for all calibrations and measurements covered by the scope of accreditation/scope for which accreditation is being sought.

7.1.2 Calibration laboratories accredited shall estimate uncertainties of measurement in compliance with the "Guide to the Expression of Uncertainty in Measurement" (GUM), including its supplement documents and/or ISO Guide 35. These principles are expanded on in various interpretation documents such as EA-4/02 "Expressions of the Uncertainty of Measurements in Calibration (including supplement 1 to EA-4/02)"; UKAS M 3003 "The expression of uncertainty and confidence in measurement". In exceptional cases other internationally recognized methodologies may be applied.

7.2 MAURITAS Policy on Scopes of Accreditation of Calibration Laboratories

7.2.1 The scope of accreditation of an accredited calibration laboratory shall include the calibration and measurement capability (CMC) expressed in terms of:

a) measurand or reference material;

b) calibration/measurement method/procedure and/or type of instrument/material to be calibrated/measured;

c) measurement range and additional parameters where applicable, e.g., frequency of applied voltage;

d) uncertainty of measurement.

7.2.2 There shall be no ambiguity on the expression of the CMC on the scopes of accreditation and, consequently, on the smallest uncertainty of measurement that can be expected to be achieved by a laboratory during a calibration or a measurement. Particular care should be taken when the measurand covers a range of values. This is generally achieved through employing one or more of the following methods for expression of the uncertainty:

a) A single value, which is valid throughout the measurement range.

b) A range. In this case a calibration laboratory should have proper assumption for the interpolation to find the uncertainty at intermediate values.

c) An explicit function of the measurand or a parameter.

d) A matrix where the values of the uncertainty depend on the values of the measurand and additional parameters.

e) A graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the uncertainty.

Open intervals ((example 1) "0 < U < x", or (example 2) for a resistance interval of 1 to 100 ohms, the uncertainty stated as "less than 2 μΩ/Ω") are incorrect in the expressions of CMCs.

7.2.3 The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percent. Usually the inclusion of the relevant unit gives the necessary explanation. Because of the ambiguity of definitions, the use of terms "PPM" and "PPB" are not acceptable.

Note 6: The term "best existing device" is understood as a device to be calibrated that is commercially or otherwise available for customers, even if it has a special performance (stability) or has a long history of calibration.

Note 7: When it is possible that the best existing device can have a contribution to uncertainty from repeatability equal to zero, this value may be used in the evaluation of the CMC. However other fixed uncertainties associated with the best existing device shall be included.

Note 8: In exceptional instances, such as evidenced in very limited number of CMCs in the KCDB, it is recognized that a "best existing device" does not exist and/or contributions to the uncertainty attributed to the device may significantly affect the uncertainty. If such contributions to uncertainty from the device can be separated from other contributions, then the contributions from the device may be excluded from the CMC statement. For such a case, however, the scope of accreditation shall clearly identify that the contributions to the uncertainty from the device are not included

7.2.4 Where laboratories offer services such as reference value provision, the uncertainty covered by the CMC shall include factors related to the measurement procedure as it will be carried out on a sample, i.e., typical matrix effects, interferences, etc. shall be considered. The uncertainty covered by the CMC will not generally include contributions arising from the instability or inhomogeneity of the material. The CMC shall be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

Note 9: The uncertainty described by the CMC for the reference value measurement is not identical with the uncertainty associated with a reference material provided by a reference materials producer. The expanded uncertainty of a certified reference material will in general be higher than the uncertainty described by the CMC of the reference measurement on the reference material.

7.3 MAURITAS Policy on Statement of Uncertainty of Measurement on Calibration Certificates

7.3.1 ISO/IEC 17025 requires calibration laboratories to report, in the calibration certificate, the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

Accredited calibration laboratories shall report the measured quantity value and the uncertainty of measurement, in compliance with the requirements in 7.3.2 – 7.3.5 of this section.

7.3.2 The measurement result shall normally include the measured quantity value y and the associated expanded uncertainty U. In calibration certificates the measurement result should be reported as y ± U associated with the units of y and U. Tabular presentation of the measurement result may be used and the relative expanded uncertainty U / |y| may also be provided if appropriate. The coverage factor and the coverage probability shall be stated on the calibration certificate. To this an explanatory note shall be added, which may have the following content:

"The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %."

Note 10: For asymmetrical uncertainties other presentations than y ± U may be needed. This concerns also cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units.

7.3.3 The numerical value of the expanded uncertainty shall be given to, at most, two significant digits. Where the measurement result has been rounded, that rounding shall be applied when all calculations have been completed; resultant values may then be rounded for presentation. For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided i.e in Section 7 of the GUM.

Note 11: For further details on rounding, see ISO 80000-1.

7.3.4 Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device. Where applicable the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device. Therefore, reported uncertainties tend to be larger than the uncertainty covered by the CMC. Random contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties attributed by the laboratory, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.

7.3.5 As the definition of CMC implies, accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

7.3.6 As required in ISO/IEC 17025, accredited calibration laboratories shall present the measurement uncertainty in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent).

Appendix A: Amendment Table

SN	Section	Amendment

