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Traceability of measurement

Mauritius Accreditation Service

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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 and are entitled to use the MAURITAS Accreditation symbol.

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.
- Directories — Classified listing of accredited organizations.

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Traceability of measurement

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. This document also defines the policy of MAURITAS for the estimation of uncertainty of measurement by calibration laboratories and the determination and specification of the Calibration and Measurement Capability. The requirements of this document applies to both accredited and applicant testing and calibration laboratories as well as inspection bodies. This document is also applicable to all accredited/applicant testing and calibration laboratories performing their internal calibration.

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 assessors 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 Traceability of Measurement Results.

3.7 ILAC-P14, ILAC Policy for Uncertainty in Calibration

3.8 ILAC-G17, Introducing the concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025

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, 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 reference measurement laboratories

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 – General and statistical principles for certification

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 measurement traceability

5.1 MAURITAS accepts the MAURITAS accredited calibrations of:

- the MSB Metrology Division; 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 traceability and suitable calibration and measurement capabilities (CMCs).

6. General requirements for measurement traceability

6.1 Calibration Laboratories

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

a) 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.

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

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: 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 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 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 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.

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.

Laboratories that have demonstrated 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 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 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 traceability does not need to be demonstrated.

6.3 Reference Materials / Consensus Standards

MAURITAS recognises that it is not always possible or realistic to expect all measurements to be traceable to the International System of Units (SI), for example, traceability may be to a Certified Reference Material (CRM), or a specified method and/or consensus standard. Participation in a suitable program of inter-laboratory comparisons / proficiency testing is a requirement.

Where traceability is established through the use of reference materials, traceability is accepted if the Reference Materials (RMs) are included in the BIPM KCDB, or have been produced by a competent Reference Material Producer (RMP) A competent RMP is one which operates as per the requirements of ISO 17034.

Where RMs are covered by the Joint Committee for Traceability in Laboratory Medicine (JCTLM), these are also considered as having established valid traceability.

Where reference materials do not meet the above criteria, they are required to be treated as critical consumables, and the facility is required to demonstrate that each RM is suitable for its intended use.

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 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 internal –calibration 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 (e.g., " U < x") are not allowed in the specification of uncertainties.

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.

7.2.4 Calibration laboratories shall provide evidence that they can provide calibrations to customers in compliance with 7.2.1 b) so that measurement uncertainties equal those covered by the CMC. In the formulation of CMC, laboratories shall take notice of the performance of the "best existing device" which is available for a specific category of calibrations.

A reasonable amount of contribution to uncertainty from repeatability shall be included and contributions due to reproducibility should be included in the CMC uncertainty component, when available. There should, on the other hand, be no significant contribution to the CMC uncertainty component attributable to physical effects that can be ascribed to imperfections of even the best existing device under calibration or measurement.

It is recognized that for some calibrations a "best existing device" does not exist and/or contributions to the uncertainty attributed to the device 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.

NOTE: 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.

7.2.5 Where laboratories provide services such as reference value provision, the uncertainty covered by the CMC should generally 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 should be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

Note: The uncertainty covered 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 covered 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.

By exception, and where it has been established during contract review that only a statement of compliance with a specification is required, then the measured quantity value and the measurement uncertainty may be omitted on the calibration certificate. The following shall however apply:

- The calibration certificate is not intended to be used in support of the further dissemination of metrological traceability (i.e. to calibrate another device);
- As specified in ISO/IEC 17025:2005 clause 5.10.4.2, the laboratory shall determine the uncertainty and take that uncertainty into account when issuing the statement of compliance; and
- The laboratory shall retain documentary evidence of the measured quantity value and the uncertainty of measurement, as specified in ISO/IEC 17025 clauses 5.10.4.2 and 4.13, and shall provide such evidence upon request.

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 $y \pm U$ 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: For asymmetrical uncertainties other presentations than $y \pm U$ 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 figures. Further the following applies:

a) The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.

b) 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: For further details on rounding, see ISO 80000-1:2009

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.