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Measurement and calibration systems

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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.
- P series — MAURITAS quality system procedures
- F series — MAURITAS Forms
- Directories — Classified listing of accredited organizations.

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Measurement and calibration systems

1. Purpose

This Guidance document has been prepared to ensure that testing and calibration laboratories and inspection bodies comply with both the measurement and traceability requirements of ISO/IEC 17025, ISO 15189 and ISO/IEC 17020 as well as any other additional requirements

2. Scope and Responsibilities

This document provides guidance to laboratories and inspection bodies on the implementation of measurement and calibration systems.

Laboratories and Inspection Bodies are encouraged to follow this guidance document.

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 Guide 35, Reference materials – Guidance for characterization and assessment of homogeneity and stability

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

3.3 ISO 15189, Medical laboratories- Particular requirements for quality and competence

3.4 MAURITAS R3, Traceability of measurement

3.5 ILAC G17, Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025

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

3.7 ILAC P10, ILAC Policy on Traceability of Measurement Results

3.8 ILAC P14, ILAC Policy for Uncertainty in Calibration

3.9 GUM, Guide to the Expression of Uncertainty in Measurements

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

4. General

4.1 The Laboratory or Inspection Body should have a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards and measuring/test equipment for the performance of accredited calibrations, tests and inspections. Measurements performed by the Laboratory, Inspection Body and any sub-contractors that it uses should be covered by this system.

4.2 The system should be designed to ensure that the Laboratory or Inspection Body has the necessary procedures and resources to carry out calibrations, tests, inspections and supporting measurements within the

required time-scales and designated limits. The Laboratory or Inspection Body should set these limits and they should be consistent with the Laboratory or Inspection Body's schedule of accreditation, the relevant calibration, test or inspection specification and/or the requirements of the Client. The system should also ensure that any measuring and test equipment, and any reference material used, performs as intended.

4.3 The system should include arrangements to prevent errors that are outside specified limits of permissible error, and to provide for rapid detection of deficiencies and immediate corrective action as required by ISO/IEC 17025, ISO 15189 and ISO/IEC 17020.

4.4 The policies and procedures for this system should be documented in the Laboratory's or Inspection Body's quality manual and associated quality documentation. They should clearly define the responsibilities and duties of each member of staff involved in the activities listed in 4.1 above.

4.5 The Quality Manager should ensure that the measurement and calibration system used by the Laboratory or Inspection Body is included in the programme for management system audits, and that the results of such audits are evaluated at the Laboratory or Inspection Body's periodic review of the management system.

4.6 Laboratory or Inspection Body staff should have the qualifications, training, experience and skill to perform the tasks referred to in this document. Training should be maintained up-to-date.

4.7 As required by ISO/IEC 17025, ISO 15189 or ISO/IEC 17020, the Laboratory or Inspection Body should maintain records of training, competency, and staff authorised to use equipment and reference materials or to perform calibrations, tests, inspections, in-house calibrations and checks.

5. Planning and the selection of equipment and reference materials

5.1 The Laboratory or Inspection Body should review the requirements of the Client, and of any relevant technical specification, before commencing calibration, testing or inspection. If the work is within the capability of the Laboratory or Inspection Body, it should, before commencing, establish a programme to ensure that measurement standards/reference materials, measuring/test equipment and environmental conditions necessary for the performance of the work are available to achieve the accuracy, stability, range and resolution required. The Laboratory or Inspection Body should also ensure that it has the staff resources needed.

5.2 The Laboratory and Inspection Body should ensure that all measuring equipment needed for the work, including reference measurement standards, meet the requirements of ISO/IEC 17025, ISO 15189 or ISO/IEC 17020.

5.3 The Laboratory or Inspection Body should also ensure that, where required by MAURITAS, it uses reference materials as measurement standards to assist in the estimation of uncertainties of measurement, to calibrate measuring and test equipment, to monitor Laboratory or Inspection Body performance and to validate methods. Where required, reference materials should also be used as transfer standards to compare methods.

5.4 Wherever possible, the Laboratory or Inspection Body should use both primary pure reference materials and reference materials that have matrices matching those of the calibration/test items to take account of matrix effects.

5.5 The Laboratory or Inspection Body should also, wherever possible, use reference materials that have been certified as having been produced and characterised in a technically valid manner. The use of organisations operating as per the requirements of ISO/IEC 17034 for the production of reference materials would provide assurance of the quality of reference materials. The certificate should, wherever possible, also provide evidence of traceability to national or international standards of measurement, or to national or international standard reference materials.

5.6 Where a certified reference material is not available, reference materials with suitable properties and stability should be used. The properties required of these materials should, wherever possible, be characterised by acceptable procedures such as those recommended in ISO Guide 35. These procedures may include: analysis/testing by a definitive method; analysis/testing by a number of methods based on different physical or chemical principles; or analysis/testing by a number of laboratories using either the same or different methods.

5.7 Where the Laboratory or Inspection Body prepares standards from materials of known properties, or purchases uncertified standards such as chemical standards, the Laboratory or Inspection Body should verify that the standards are of acceptable quality and suitable for the purpose. Standards should be purchased, where possible, from suppliers as detailed in 5.5 above.

6. Uncertainty of measurement

6.1 The Laboratory or Inspection Body is required to produce an estimate of the uncertainty of its measurements (as detailed in ILAC G17 and GUM), to include the estimation of uncertainty in its methods and procedures for calibration, testing and inspection, and to report the uncertainty of measurement in calibration certificates and in, test and inspection reports, where relevant.

6.2 Estimates of uncertainty of measurement should take into account all significant identified uncertainties in the measurement, testing and inspection processes, including those attributable to measuring equipment, reference measurement standards (including material used as a reference standard), staff using or operating equipment, measurement procedures, sampling and environmental conditions.

6.3 In estimating uncertainties of measurement, the Laboratory or Inspection Body should take into account data obtained from internal quality control schemes and other relevant sources. The Laboratory or Inspection Body should also ensure that any requirement for the estimation of uncertainty and for the determination of compliance with specified requirements as stated in the relevant MAURITAS publications, are complied with at all times.

6.4 In setting the acceptance limits for the calibration of measuring and testing equipment, the Laboratory or Inspection Body should ensure that the limits chosen allow for the conditions under which the equipment or reference material is to be used. Such limits may be significantly different to those applicable during the calibration process.

7. Calibration procedures

7.1 The Laboratory or Inspection Body should use methods and procedures for the calibration of measuring equipment, reference measurement standards (including reference materials) and test equipment used in calibration and testing laboratories and inspection bodies that comply with the requirements of ISO/IEC 17025, ISO 15189 or ISO/IEC 17020. The methods and procedures should include, but not be limited to:

a) identification of the instrument, gauge or test equipment, or group of such items to which the procedure is applicable;

b) identification of all measurement standards/reference materials and associated equipment used to perform the calibration;

c) the procedures to be adopted for handling, transporting, storing and using measuring equipment and reference materials used for calibration, including details of shelf life and measures to prevent contamination or loss of determinant;

d) the procedures to be adopted for handling, transporting, storing and preparing items for calibration;

e) the environmental conditions that must be used, the limits applicable, the procedure for any corrections that may have to be made as a result of the environmental conditions and, where relevant, the minimum period of stabilisation before calibration;

f) the method or procedure for calibration in the form of written instructions and diagrams where appropriate;

g) details of the measurement or calibration data to be recorded and the method for presentation and analysis of this data;

h) the limits of acceptance for the calibration data for the item or type of item being calibrated;

i) the estimation of the uncertainty of measurement of the calibration process (see 7.2 below);

j) the procedures to be adopted for selecting calibration intervals when the equipment/reference material is being used by the Laboratory or Inspection Body to perform calibrations or tests;

k) the procedures for checking equipment and reference materials between calibrations;

l) an identification number, number of pages, date of issue and name of person authorising issue and use of the procedure.

7.2 In its procedures for estimating the uncertainty of the calibration process, the Laboratory or Inspection Body should take into account the cumulative effect of the uncertainties of measurement of each successive stage in the chain of calibrations for each measurement standard and item of equipment calibrated. The Laboratory or Inspection Body should take action when the total uncertainty of measurement is such that it significantly compromises its ability to make measurements within the limits of permissible error.

7.3 Where the Laboratory or Inspection Body uses the services of an external organisation to calibrate measuring and test equipment, the requirements of MAURITAS R3 should be met.

8. Records

8.1 The Laboratory or Inspection Body should maintain records for each item of measuring equipment, including reference measurement standards and reference material standards and test equipment, used in the performance of calibrations, tests or inspections. The records should show, either through in-house documentation or calibration certificates from external organisations that each calibration in the chain of traceability has been carried out.

8.2 The Laboratory or Inspection Body should ensure that the records contain detailed information of the equipment/reference material used for calibrations, and that there is also a full and up-to-date history of the calibration of this equipment/reference material (see ISO/IEC 17025, ISO 15189 or ISO/IEC 17020).

8.3 The records should provide sufficient information to demonstrate the measurement capability and traceability of each item of measuring equipment and the range of use of each reference material, its shelf life and required storage conditions.

8.4 Each record should include or refer to

a) the date on which each calibration was performed;

b) the calibration results obtained after and, where relevant, before any adjustment and repair;

c) the specified calibration interval (as detailed in ILAC G24);

d) reference to the calibration method or procedure used and any relevant standard or specification;

e) the specified limits of permissible error;

f) calibration certificates meeting the requirements for traceability specified in document MAURITAS R3;

g) certificates, or other documentation, for all reference materials used for calibration, providing evidence of characterisation of the material, and evidence of traceability to national or

international standards of measurement, or to national or international standard reference materials;

h) the environmental conditions at the time of calibration and the corrections made, where necessary, for such conditions;

i) a statement of the uncertainties of measurement involved in the calibration and of their cumulative effect;

j) any design or performance specifications met;

k) name of persons performing the calibration and checking the results;

l) any limitations in use resulting from the calibration data obtained;

m) details of any maintenance carried out in accordance with the requirements of ISO/IEC 17025, ISO 15189 or ISO/IEC 17020 and of any servicing, adjustment, repair or modification, particularly at the time of calibration.

8.5 Similar records, as appropriate, should be maintained for any checks carried out on equipment or reference materials between calibrations.

9. Calibration intervals

9.1 The Laboratory or Inspection Body should have documented criteria for the selection of calibration intervals for all measuring and test equipment used based on information provided in ILAC G24 Document.

9.2 Reference measurement standards should be calibrated at approved intervals. Reference materials should be checked for deterioration and, if necessary, replaced.

9.3 All other measuring and test equipment should be calibrated at intervals determined by the following factors:

a) the uncertainty of measurement required or declared by the Laboratory or Inspection Body;

b) risk of a measuring instrument exceeding the limits of the maximum permissible error when in use;

c) the requirements of any relevant standard specifications for the measurements/tests involved;

d) the recommendation of the equipment manufacturer;

e) the type and stability of the equipment;

f) the extent and severity of use;

g) the influence of the environmental conditions (eg temperature, humidity, vibration and dust);

h) the accuracy of measurement needed for the calibration or test concerned;

i) trends determined by examination of records of previous calibrations;

j) evidence obtained from service and maintenance records;

k) any known or observed tendency for the equipment to exhibit wear or to drift in performance;

l) the frequency of, and information from, in-house checks, using known standards.

9.4 When selecting intervals for the maintenance and calibration of measuring and test equipment, the Laboratory or Inspection Body should take into account all of the relevant factors in 9.3 above. It should do so in such a way as to minimise the risk that the results of any calibrations/tests performed between calibrations may be affected because some of the measuring or test equipment used has failed to perform to specified requirements. For certain types of measurement, such as chemical analysis using chromatographs or spectrometers, calibration is necessary as part of normal operations using appropriate chemicals or certified reference materials.

9.5 When selecting intervals for the maintenance and calibration of new measuring and test equipment, the Laboratory or Inspection Body should ensure that, where only limited information is available, the interval initially selected is shorter than the expected eventual interval. The interval may then be adjusted at a later date as a result of information obtained from further calibrations and checks.

9.6 The Laboratory or Inspection Body should have procedures for the periodic review of maintenance and calibration intervals to take into account the variation in the type, frequency and conditions of use of any measuring or test equipment. When the performance of measuring and test equipment deviates from the specified requirements, the requirements of ISO/IEC 17025, ISO 15189 or ISO/IEC 17020 should be met and the maintenance and calibration intervals should be reviewed immediately and modified where necessary. Such equipment should not be returned to service until the reason for the deviation has been eliminated and the equipment has been re-calibrated.

9.7 The Laboratory or Inspection Body should shorten the intervals between calibrations (and maintenance where appropriate) when the results of preceding calibrations or intermediate checks indicate that the measuring and test equipment is no longer performing in accordance with the specified requirements.

9.8 The Laboratory or Inspection Body should increase the interval between calibrations only when the results of preceding calibrations, and any intermediate checks or quality control data, indicate that the performance of the measuring and test equipment is likely to remain within the specified requirements throughout the new period between calibrations.

10. Sealing of calibrated equipment

The Laboratory or Inspection Body should have procedures to prevent adjustable devices on measuring and test equipment (other than those intended for the user), whose setting affects the performance, being altered by unauthorised staff. Where seals (labels, solder, wire, paint etc) are used, they should be designed to indicate clearly when unauthorised adjustment has been made. The procedures should ensure that, where a seal has been damaged or broken, the requirements of ISO/IEC 17025, ISO 15189 or ISO/IEC 17020 are met.

11. Labelling of calibrated equipment and reference materials

11.1 The requirements for labelling, codifying, or otherwise identifying the status of calibration of measuring and test equipment used by the Laboratory or Inspection Body are given in ISO/IEC 17025, ISO 15189 or ISO/IEC 17020.

11.2 When equipment has been calibrated, or reference materials certified by an external organisation, the Laboratory or Inspection Body should ensure that the equipment/reference material is fit for use, is labelled and that it has a certificate (or notification, where a certificate might be delayed) to indicate the results of the calibration.

11.3 Labels, or other methods of codifying or identifying the equipment/reference material, should, as well as indicating calibration status, clearly indicate to the staff using the equipment/reference material, any limitations of the calibration and/or any restrictions on the use of the equipment/reference material.

11.4 Any item of measuring or test equipment, or any reference material, that is not calibrated, should not be used for accredited calibration/testing/inspection. If there is any possibility that staff might at any time use such equipment or material for accredited calibration/testing/inspection before it has been calibrated, it should be appropriately identified and, if possible, segregated.