D11 Traceability of Measurement

Definitions and references

Metrological traceability - (International Vocabulary of Metrology, 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."

NMI - National Metrology Institute

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

These rules on traceability of measurement apply to conformity assessment bodies (CABs) accredited to ISO/IEC 17020, ISO/IEC 17025, ISO/IEC 17065 and ISO 15189 and they comply with the requirements in this document.

This document takes into consideration ILAC P10 (ILAC Policy on Metrological Traceability of Measurement Results) and ILAC P14 (ILAC Policy for Measurement Uncertainty in Calibration).

ISAC's rules on metrological traceability

1. When metrological traceability is required, ISAC's requirement is that the equipment needing calibration shall be calibrated by one of the following.

1.1 An accredited calibration laboratory (ISO/IEC 17025) whose accreditation scope covers the measurement/calibration area required. The calibration laboratory shall be accredited by an Accreditation Body that has a multilateral or bilateral agreement with EA (European co-operation for Accreditation) for calibration, or/and is an MRA signatory to ILAC (International Laboratory Accreditation Cooperation) for calibration.

1.2 An NMI with the relevant scope recorded in BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which can be found on the BIPM website www.bipm.org.

1.3 In cases where the calibration laboratory/NMI is not available, the conformity assessment body (CAB) may employ a calibration body that can demonstrate its competence to perform the service in a manner different form the above. The following applies if this option is selected:

a) The CAB shall perform a supplier assessment of the calibration body against relevant criteria in ISO/IEC 17025. Such a supplier assessment may need to be repeated at appropriate intervals.

b) The provider of the calibration service shall, in conjunction with this supplier assessment, provide documents describing its calibration procedures, a description of the metrological traceability for what it calibrates, and an analysis and estimation of the measurement uncertainty (performed according to EA-4/02 Evaluation of the Uncertainty of Measurement in Calibration).

c) The evidence from the supplier assessment shall be available for review by ISAC´s representatives.

d) ISAC should be given the opportunity to be present on-site as an observer when the CAB performs the supplier assessment of the calibration service.

This option (1.3) can only be used when it is not possible to calibrate the equipment using existing methods at accredited calibration bodies, for example, if the equipment is so complicated that only the manufacturer or service company have the necessary technical competence to perform the required calibration.

2. If a CAB performs calibration of its own equipment ("in-house calibration"), ISAC assesses this activity according to the corresponding requirements that are set for a calibration laboratory in ISO/IEC 17025. These requirements can be summarised as follows:

- The CAB shall ensure that the personnel for the current calibration have the relevant competence.
- The CAB shall have access to a reference standard that is either tested or calibrated by an NMI or an accredited testing or calibration laboratory.
- The CAB shall have instructions for performing the calibration.
- The CAB shall have procedures for estimating/calculating the measurement uncertainty for the calibrations in question.
- The CAB shall record the calibration results together with the current measurement uncertainty.
- Based on the calibration result, the CAB shall be able to determine whether its own instrument is to be approved or rejected for its area of use. Appropriate decision-making rules shall be applied in this evaluation.
- The CAB shall have procedures in place to ensure the reliability of the results. These may include both internal and external activities depending on the complexity of the calibration.

3. If metrological traceability is obtained via reference materials, these shall be delivered by one of the following.

3.1 A reference material producer (RMP) accredited according to the requirements of ISO 17034.

3.2 An NMI with its scope recorded in BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which can be found on the BIPM website www.bipm.org.

3.3 A certified reference value published by JCTML (Medicine).

3.4 A reference material producer who can prove that the reference material (RM) is sufficiently homogeneous and stable regarding specified properties for a specific application. It is the CAB's responsibility to ensure the reference material producer's competence and that the reference material is suitable for the intended use. The basis for assessing the competence of a reference material producer shall refer to relevant requirements according to ISO 17034:2016.