

## D11e Traceability of Measurement

**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 Institutes

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

This policy of traceability of measurement is for CABs accredited to ISO 17020, ISO 17025, ISO 17065 and ISO 15189 and they must fulfil its requirements. This document takes into consideration ILAC P10 and ILAC P14.

### ISAC's policy on Metrological traceability

1. When metrological traceability is required, ISAC's policy is that the equipment needing calibration shall be calibrated by:
  - 1.1 An accredited calibration laboratory (ISO/IEC 17025) whose accreditation scope covers the measurement/calibration area required. The calibration laboratory must be accredited by an Accreditation Body who 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 of a country with its scope reported in BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which can be found under the BIPM website [www.bipm.org](http://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 which can otherwise show its competence to perform the service. The following applies if this option is selected:

The CAB needs to 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.

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

The evidence from the supplier assessment needs to be available for review by ISAC's representatives.

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 an example if the equipment is so complicated that only manufacturer or service company have the needed technical competences to perform needed 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 summarized as follows:
  - The CAB shall ensure that the personnel for the current calibration have relevant competence.
  - The CAB must have access to a reference standard that is either tested or calibrated by an NMI or accredited testing or calibration laboratory.
  - The CAB must have instructions for performing calibration.
  - The CAB must have procedures for estimating/calculating the measurement uncertainty for the calibrations in question.
  - The CAB shall report the calibration results together with the current measurement uncertainty.
  - Based on the calibration result, the CAB must be able to determine when its own instrument is to be approved or rejected for its area of use. Appropriate decision rule shall be applied in this evaluation.
  - The CAB must have procedures in place to ensure the reliability of the results. Can include both internal and external activities depending on the complexity of the calibration.
  
3. If metrological traceability is obtained via reference material, ISAC's policy is that these are delivered by:
  - 3.1 An accredited reference material manufacturer (RMP) according to the requirements of ISO 17034
  - 3.2 An NMI of a country with its scope reported in BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which can be found under the BIPM website [www.bipm.org](http://www.bipm.org)
  - 3.3 Certified reference value published by JCTML (Medicine)
  - 3.4 A reference material manufacturer 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 manufacturer's competence and that the reference material is suitable for the intended use. The basis for assessing the competence of a reference material producer is referred to relevant requirements according to ISO 17034: 2016.