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Metrological traceability of measurement results to the units of the International System of Units

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1. Introduction

This document is addressed to all organisations (testing or calibration laboratories, laboratories for biomedical analysis, inspection bodies) that are accredited or candidates for OLAS accreditation, and that use analysis, testing or calibration equipment in the frame of their activities of conformity assessment. The assurance of traceability of the measurement results to the units of the International System of Units (SI) is an essential condition for the exactness of the result of an analysis, a test or a calibration.

The criteria with which the testing and calibration laboratories must comply are included in the clauses 6.4.6 and 6.5 of the standard ISO/IEC 17025:2017.

The criteria with which biomedical laboratories must comply are included in the clause 5.3.1.4 of the standard ISO 15189:2012.

The criteria with which the inspection bodies must comply are included in the clauses 6.2.6, 6.2.7, 6.2.8 and 6.2.10 of the standard ISO/IEC 17020:2012.

The criteria with which the product, process and service certification bodies must comply are included in the clauses 6.2.1 and 6.2.2 of the standard ISO/IEC 17065:2012.

This document is based on the document ILAC P10:07/2020.

2. Definitions

Metrological traceability

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.

The other definitions of fundamental and general metrological terms are available in the International vocabulary of metrology – Basic and general concepts and associated terms - JCGM200:2012 (VIM) under the following link:

https://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf

3. Policy

In order to guarantee the metrological traceability of the results, the connection of the analysis, testing and calibration equipment to the national or international measurement standards must be assured by:

1) A National Metrology Institute (NMI) where the concerned calibration is suitable for the intended use and covered by the CIPM Mutual Recognition Arrangement (CIPM MRA). Services covered by the CIPM MRA can be viewed in Appendix C of the « key comparison database » (KCDB) of the BIPM.

Note: 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.

2) A calibration laboratory where the concerned calibration is suitable for the intended use and accredited to ISO/IEC 17025 by an accreditation body covered by the EA or ILAC mutual recognition arrangement.

3) An NMI or calibration laboratory (internal or external) whose service is suitable for the intended need, but not covered neither by the CIPM MRA, nor by an accreditation to ISO/IEC 17025 for the concerned calibration from an accreditation body covered by the EA or ILAC mutual recognition arrangement.

Each calibration certificate issued by these laboratories shall contain the measurement uncertainties associated to the response of the calibrated equipment.

Organisations that have demonstrated traceability of their measurements to the International System of Units (SI) through the use of calibration services offered according to **1)** or **2)** above have made use of services that have been subject to relevant peer review or accreditation. The competence of these laboratories and the traceability of their standards to the SI system is therefore established.

In the situation **3)**, it is the responsibility of the CAB to demonstrate that the calibration is performed:

- either by a competent laboratory, or that they have themselves the competences, and
- that the standards used are themselves connected to international standards, wherever possible (see chapter 5 below).

If the calibration is carried out internally, the competence of the CAB is verified at the OLAS assessment.

If the calibration is carried out by an external provider, the evidence that the CAB shall collect and verify to demonstrate the competence of the service provider includes, but is not limited to:

- certificates proving the traceability of the used standards (whether internal or external);
- the calibration procedure;
- environmental conditions;
- uncertainty calculations;
- training of the personnel who performs the calibration.

Records relating to the demonstration of the competence of the organisation used must be available and verifiable during the OLAS assessment.

<u>If metrological traceability is provided by the use of certified reference materials (CRM), the certified values assigned to CRMs are considered to have established valid metrological traceability when:</u>

4) <u>CRMs are produced by NMIs using a service that is included in the BIPM KCDB;</u>

<u>or</u>

5) <u>CRMs are produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the EA or ILAC mutual recognition arrangement;</u>

<u>or</u>

6) <u>The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.</u>

Where CRMs are not available from accredited RMCs, it is the responsibility of the CAB to demonstrate that :

- The CRMs are suitable for the intended purpose;
- The CRMs have been supplied by a competent RMC.

4. Under what circumstances is the calibration of equipment required?

According to ISO/IEC 17025 :2017 (6.4.6), *« measuring equipment shall be calibrated when the measurement accuracy or measurement uncertainty **affects the validity of the reported results**, and/or calibration of the equipment is required to establish the metrological traceability of the reported results. »*

According to ISO/IEC 17020:2012 (6.2.6), « *where appropriate, measurement equipment having a **significant influence on the results** of the inspection shall be calibrated before being put into service, and thereafter calibrated according to an established programme. »*

According to ISO 15189:2012 (5.3.1.4), *« the laboratory shall have a documented procedure for the calibration of equipment that **directly or indirectly affects examination results** »*

According to ISO 17065:2012 (6.2.1), *« when a certification body performs evaluation activities, either with its internal resources or with other resources under its direct control, it shall meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the **applicable requirements of ISO/IEC 17025**; for inspection, it shall meet the **applicable requirements of ISO/IEC 17020**; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021.*

Calibration of an equipment is therefore required when the validity of a result may be affected by the measurement uncertainty associated with the equipment, or when metrological traceability of the results is required. Where the laboratory is able to provide quantitative evidence to demonstrate that the incidence of the equipment is not significant, particularly concerning the uncertainty calculation provided with the result, then this policy is not applicable.

5. Cases where metrological traceability of measurement results is difficult to achieve

Where the metrological traceability of measurement results by connecting analysis, testing or calibration equipment to national or international standards is difficult to achieve (for technical or cost reasons), the traceability must be ensured by:

7a) the use of reference materials or CRMs provided by a competent producer ~~comparable to reference standards associated with physical quantities~~;

or

7b) the application of specific methods (e.g. ~~inter-laboratory~~ comparison to reference methods) and/or consensus standards clearly described and agreed by all parties concerned.

~~The certified values assigned to CRMs are considered to have established valid metrological traceability when:~~

- ~~CRMs are produced by NMIs using a service that is included in the BIPM KCDB;~~
- ~~CRMs are produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the EA or ILAC mutual recognition arrangement;~~
- ~~The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.~~

~~Where CRMs are not available from accredited RMCs, it is the responsibility of the CAB to demonstrate that :~~

- ~~The CRMs are suitable for the intended purpose;~~
- ~~The CRMs have been supplied by a competent RMC.~~