**1. Purpose**

This document describes the policy of the General Directorate of Accreditation regarding the requirements for traceability of measurements required by ISO / IEC 17025 and ISO 15189 standards. This policy can also be used by other conformity assessment bodies where testing / or calibration is included such as inspection, organization of PT / ILC, production of certified reference materials or product certification. This policy also includes DPA requirements related the use of certified reference materials and internal calibration.

**2. References and terms**

• ILAC Policy ILAC P10: 07/2020 “ILAC Policy on the Traceability of Measurement Results”.

• ILAC G24 / OIML D10 Guide for determining the calibration intervals of measuring instruments used in testing laboratories”.

• ISO / IEC 17025: 2017 "General requirements for the competence of testing and calibration laboratories."

• ISO / IEC 15189: 2012, “Medical laboratories. Special requirements for quality and competence "

• ISO / IEC 17020: 2012 "Conformity assessment-Requirement for the functioning of different types of inspection bodies"

• ISO / IEC 17065: 2012 “Conformity assessment-Requirements for bodies certifying products, processes and services”

• ISO Guide 17034: 2016 “General requirements for the competence of producers of reference materials.

• ISO 17043: 2010 "Conformity assessment - General requirements for proficiency tests".

• CMC- Calibration measurement capability

• BIPM KCDB- Database of key comparisons of the International Bureau of Weights and Measures

• CIPM MRA- International Committee of Weights and Measures Reciprocal Recognition Agreement.

• JCTLM- Joint Committee for Traceability in Medical Laboratories

• JCGM 200: 2012 - International Dictionary of Metrology (VIM)

• In the standard S SH ISO 15189: 2012, the term "traceability" is equivalent to the term "metrological traceability" according to VIM. The term ISO / IEC 17025: 2017 uses the term metrological traceability. The term "traceability" has been used to avoid duplication in this document.

• JCGM 100: 2008 Evaluation of measurement data - Guide for expressing measurement uncertainty (GUM).

• “Metrological traceability” is the quality of the measurement result or the value of the measurement standard, achieved through an unbroken documented chain of calibrations, each of which contributes to the uncertainty of the measurements.

• In-house calibration is the calibration of reference standards or test and measuring equipment by the staff of the conformity assessment body for which the calibration of measuring parameters is not included in the field of accreditation.

• "Reference material" is a material that is sufficiently homogeneous and consistent with respect to the specified characteristics, designed to be suitable for its intended use in the measurement or examination of nominal characteristics

• “Certified Reference Material” is a reference material, accompanied by documentation issued by an international or national body, that provides one or more of the characteristics of the specified specification with associated uncertainties and traceability using valid procedures

**3. DPA policy related the traceability of measurements**

Bodies applying for accreditation and those accredited by DPA must demonstrate metrological traceability for all equipment used for testing / calibration, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on accuracy and validity of the result of the test, calibration or sampling. Based on the definition of metrological traceability in VIM, it is more than clear that a calibration certificate in the traceability chain must contain a statement of uncertainty (or, in special cases, a statement of compliance with the specified specifications), otherwise the results presented in them do not give metrological traceability. Uncertainty assessment is normally performed in accordance with the Guidance on Expressing Uncertainty in Measurement (GUM).

3.1 For equipment and reference standards where calibration is required, the following are acceptable sources of traceability:

3.1.1 A national metrology institute whose service is suitable for the required calibration, which is a member of the multilateral recognition agreements with CIPM for the required calibration. Institutes involved in CIPM MRAs, including sizes and CMCs can be found at the link: https://www.bipm.org/en/cipm-mra/participation/signatories.html.

or

3.1.2 A calibration laboratory accredited specifically for the required calibration by an accreditation body which is a signatory to ILAC-MRA or Regional Agreements recognized by ILAC in the field of calibration.

or

3.1.3 A National Institute of Metrology, whose service is suitable for our calibration but is not a member of the Multilateral Recognition Agreements with CIPM.

or

3.1.4 A calibration laboratory whose service is suitable for the calibration required but is not accredited by an accreditation body which is a signatory to ILAC-MLA or Regional Agreements Recognized by ILAC in the field of calibration.

The routes 3.1.3 and 3.1.4 will be used only in cases when routes 3.1.1 and 3.1.2 are not possible for the required calibration both in Albania and outside its territory.

 Routes 3.1.3 and 3.1.4 are not services that are subject to peer review or accreditation, therefore the bodies using these routes must provide adequate evidence of the required traceability and measurement uncertainty. DPA will evaluate the evidence and the body's ability to evaluate it. Such evidences may include, but shall not be limited to, the reference paragraphs of S SH ISO / IEC 17025: 2017;

Copies of technical procedures and records of calibration method validation

- Procedures for estimation of uncertainty and copies of the associated uncertainty budgets.

- Documentation for traceability of measurement results,

- Evidence of staff competence and authorization

- Documentation to assuring the validity of calibration results.

- Documentation for accommodation and environmental conditions

- On-site audit of the calibration laboratory

The General Directorate of Accreditation recognizes the case, that due to the nature of some tests it is not technically possible to ensure traceability of measurement results against the SI system. Paragraph 6.5.3 of ISO / IEC 17025: 2017 requires that the laboratory must demonstrate traceability through:

- certified values ​​of certified reference materials (CRM) obtained from competent producer

- the results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and provided by suitable comparison.

Traceability through certified reference materials is accepted established when:

- The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its scope of accreditation to ISO 17034.

- certified reference materials (CRM) listed in the JCTLM database;

If the reference materials (RM) and certified reference materials (CRM) do not meet the above requirements, in this case the body must demonstrate that each RM or CRM is suitable for the intended use as required by ISO / IEC 17025 and ISO 15189.

Calibration certificates issued by manufacturers or their agents are not acceptable indicators of external traceability. Calibration certificates are accepted only if they are issued in accordance with point 3 of this policy.

Calibration certificates issued by accredited laboratories must meet the requirements of paragraph 7.8 of the ISO / IEC 17025: 2017 standard, must bear the symbol of the accreditation body and must declare the measurement uncertainty.

**4. in house calibration**

In-house calibration means calibrations performed by the conformity assessment body to establish the metrological traceability of its own activities, and which are not a part of the scope of accreditation. The body performs in-house calibration to support its own measurement activities instead of seeking the services of an accredited calibration laboratory. Calibration activities in support of accredited measurement activities shall be performed competently and shall ensure adequate traceability of results. Conformity assessment bodies performing in-house calibrations are required to ensure that the traceability of their calibrations meets the requirements of this policy and the relevant requirements of ISO / IEC 17025 and ISO 15189.

For instruments calibrated by the conformity assessment body itself (in-house calibration), it must provide:

a) A suitable environment in which conduct the calibration

b) Competent and authorized personnel to conduct and check the calibrations

c) Reference standards, certified reference materials or reference measuring instruments that provide traceable results with suitable measurement uncertainties

d) A documented and controlled procedure for each type of calibration

e) A means of recording, analyzing and reporting the data and results for any calibrations

f) A suitable level of quality control activities

g) Calculation of the uncertainty budget and the procedure for its calculation for each calibration.

The conformity assessment body that performs in-house calibrations in support of their accredited activities are required to provide details the competence of the personnel performing the calibration, the methodology involved, the traceability arrangements and the uncertainty budgets of these calibrations to DPA. Normally this information shall be sent to DPA when the body applies for initial accreditation, re-accreditation or extension of accreditation. These details shall be sent even in cases when the body makes changes in them in accordance with the contract with DPA.

DPA will use this information to ensure that persons with appropriate competence are included in the assessment team to assess these activities. If necessary, DPA will use calibration assessors / experts for internal calibration assessment.

The assessment of in-house calibrations will be part of the assessment of traceability and calibration aspects during regular assessment and surveillance visits. But when needed extra time can be planned in the assessment plan for assessing the in-house calibrations. The assessment will include documentation review and on-site witnessing. On-site witnessing of in-house calibration activities can be expected at least at initial assessment and re-accreditation visits.

The ability of the conformity assessment body to perform in-house calibration will not be included in the scope of accreditation.

A conformity assessment body may be required to participate in an internal audit program for in-house calibration activities if it is determined that:

-In-house calibrations are performed for a large number of accredited activities and they significantly affect the uncertainty budget.

- an assessment has identified concerns about the performance of, or deficiencies in, the conduct of in-house calibrations

- The conformity assessment body has identified non-conforming work in its accredited activities (e.g. poor performance in a proficiency test) and it is reasonable to suspect that the in-house calibration may have contributed to the poor performance.

**5. Maintenance of traceability**

In order to maintain traceability on continuous basis, reference standards and measuring equipment shall be subject to calibration on going basis, according to the calibration program established by the conformity assessment body. The intervals between calibrations depend on various factors, including but not limited to:

- Measurement uncertainty required

- The past history of the equipment, including calibration results and frequency of any maintenance required

- Frequency of use of the equipment

- Frequency of cross –checking against other equipment and of intermediate checks

- Manufacturer's recommendations

- Environmental conditions in which the equipment is exposed including any effects due to transportation.

It is recommended that conformity assessment bodies should be based on ILAC G-24 and DPA-IN-011 guidelines regarding calibration interval.

**Date: 26.04.2021 General Director**

 **Armond HALEBI**