1. Purpose

This document describes the DPA policy relating to traceability of measurement and using of certified reference materials.

2. Reference

- ILAC Policy ILACP-10:01/2013 "ILAC - Policy on Traceability of Measurement Results"
- S SH ISO/IEC 17025:2005, paragraph 5.6 -" General requirements for the kompetence of testing and calibration laboratories".
- S SH ISO/IEC 15189:2012, paragraph 5.6- "Medical laboratories. Special requirements for the quality and kompetence"
- ISO Guide 17034:2016–"General requirements for the competence of reference materials producers".
- BIPM KCDB - The Key Comparison Database of the BIPM;
- CIPM MRA - The CIPM Mutual Recognition Arrangement
- IFCC The International Federation of Clinical Chemistry and Laboratory Medicine
- JCTLM- Joint Committee for Traceability in Laboratory Medicine
- In ISO/IEC 17025:2005 and ISO 15189:2012 the term "traceability" is equivalent to the VIM's "metrological traceability". To avoid repetition, the term "traceability" is used henceforth in this document.
- An in-house calibration is the calibration of an Accredited CAB's own reference standards or measuring and test equipment by the laboratory's own staff for which the calibration measurement parameters ***ARE NOT*** included on their scope of accreditation

3. DPA policy related to traceability of measurement

3.1 The conformity assessment bodies accredited by DPA shall be able to demonstrate that calibration of critical equipment, and hence the calibration, inspection or test result generated by that equipment, relevant to their scopes of accreditation, is traceable to the International System of Units.
"Critical" equipment is considered to be those items of equipment necessary to perform a test, calibration or inspection in the scope of accreditation and which

have a significant effect on the uncertainty of measurement of test, calibration or inspection result.

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

3.2.1 A National Metrological Institute (NMI) whose service is suitable for the intended need and is covered by CIPM MRA. Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty for each listed service.

or

3.2.2 An accredited calibration laboratory whose scope of accreditation specifically covers the appropriate calibration, and which is accredited by Accreditation Body that is included in the ILAC Arrangement or Regional Arrangements recognized by ILAC.

or

3.2.3 A National Metrological Institute (NMI) whose service is suitable for the intended need but not covered by the CIPM MRA.

or

3.2.4 A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or Regional Arrangements recognized by ILAC.

The route 3.2.3 and 3.2.4 shall only be selected in case the routes 3.2.1 and 3.2.2 are not possible for a particular calibration either in Albania or abroad. In case of routes 3.2.3 or 3.2.4 the assessed CAB must provide appropriate evidence for the technical competence of the laboratory' and claimed traceability. Such evidence may include, but is not limited to the following (numbers refer to clauses in S SH ISO/IEC17025:2005):

- Calibration of the reference standards of the laboratory (5.6.1)
- Results from participation in interlaboratory comparisons (5.9.1)
- -Suitability of the equipment and environmental conditions (5.5.1 & 5.3)
- -Records of calibration method validation (5.4.5)
- -Procedures for estimation of uncertainty (5.4.6)
- -Documentation for assuring the quality of calibration results (5.9)
- - Documentation for competence of staff (5.2)

- -Audits of the calibration laboratory (4.6.4 and 4.14)
- - Content of the calibration report (5.10)
- Documentation of traceability of measurements (5.6)

For non-accredited laboratories it may be necessary to perform a practical assessment of the laboratory used, similar to that which would be undertaken by an Accreditation Body against S SH ISO/IEC17025, to ensure that competent work is actually being performed.

DPA recognizes that, due to the nature of some tests, it is not possible to expect traceability of measurement results against SI units. S SH EN ISO/IEC 17025 clause 5.6.2.1.2 states that "There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

- the use of certified reference materials (CRM) provided by a competent supplier to give a reliable physical or chemical characterization of a material;
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable programme of interlaboratory comparisons is required where possible.

Paragraph 5.6.3.2 of S SH ISO/IEC 17025 states the traceability requirements in relation to reference materials that "Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials".

The traceability in relation to reference materials is considered to valid established when

- The values assigned to CRMs produced by NMIs covered by the CIPM MRA and included in the BIPM KCDB
- The values assigned to CRMs produced by an accredited reference materials producer under its accredited scope of accreditation to ISO Guide 34 or ISO 17034:2016.

In case of medical laboratories or in vitro diagnostic, the traceability must be ensured through using of:

- certified reference materials (CRM) covered by entries in the JCTLM (the CIPM, IFCC and ILA Joint Committee for Traceability in Laboratory Medicine) database; or

- reference test methods covered by entries in the JCTLM. The database of JCTLM is valid in page: http://www.bipm.org/jctlm/.

When the reference materials (RM) and certified reference materials (CRM) don't fulfill the above mentioned requirements, they can be considered as critical consumables. In this case the laboratory shall demonstrate that each RM or CRM is suitable for its intended use as required by clause 4.6.2 of S SH ISO/IEC 17025 Standard and S SH ISO 15189 standard.

For all instruments calibrated in-house the following shall be in place:
a) A suitable environment for carrying out the calibration;
b) Appropriately trained personnel to both carry out and check the calibrations;
c) Reference standards, certified reference materials or reference measuring instruments that provide traceability with suitable measurement uncertainties;
d) A controlled and documented procedure for each type of calibration;
e) An appropriate means of recording and reporting the data and results of any calculations;
f) a suitable level of quality control activities and
g) A measurement uncertainty budget and procedure for calculating same.

In this case, DPA assessors will seek assurance of the laboratory's internal traceability by examining the calibration system of the laboratory/ inspection body in the course of an assessment. As well as examining the laboratory's competence to carry out the appropriate measurements, the assessors will be concerned with the suitability of any reference standards the laboratory/inspection body may hold, and with its capability to calibrate its working instruments against such reference standards.

The calibration certificates issued by equipment manufacturers or agents are not acceptable evidence of external traceability. The calibration certificates are considered valid if they are issued in accordance with point 3.2 of this policy.

The calibration certificates issued by accredited laboratories shall meet the requirements of standard S SH ISO/IEC 17025:2005, paragraph 5.10, including the accreditation symbol and uncertainty of measurements.

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