

 **APPROVED**

**Director of “National Accreditation Body” SNCO**

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**POLICY ON**

**METROLOGICAL TRACEABILITY**

**PL-06**

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**“*The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Armenian version will prevail*”**

Yerevan 2023

**POLICY ON**

**METROLOGICAL TRACEABILITY**

# Introduction

This document describes the National accreditation body (ARMNAB) policy with regard to the metrological traceability requirements in testing and calibration. This policy also applies to other conformity assessment activities where measurement is involved – i.e. medical laboratories, inspection bodies, reference material producers, proficiency testing providers, etc.

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# 2. Normative references

Only the latest publications of the documents cited without a date shall be applicable. The following documents are referred to in this document:

[1] ILAC-P10 ILAC policy on the traceability of the measurement results

[2] GOST ISO/IEC 17020 Conformity assessment. Requirements for the operation of various types of bodies performing inspection.

[3] AST 8.11 National system of ensuring the uniformity of measurements. Metrology. Terms and definitions.

[4] JCGM 200 International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

[5] ILAC-P14 ILAC policy for measurement uncertainty in calibration

[6] GOST ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

[7] EA-4/02 Expression of the uncertainty of measurement in calibration

[8] ILAC-G8 Guidelines on the reporting of compliance with specification

[9] ILAC-G24/OIML D10 Guidelines to the determination of calibration intervals of measuring devices

[10] ISO 17034 General requirements for the competence of reference material producers

[11] AST ISO 15189 Medical laboratories. Requirements for quality and competence

[12] GOST ISO/IEC 17043 Conformity assessment. General requirements for proficiency testing

EA and ILAC documents are available in the following websites:

EA: <http://www.european-accreditation.org/>, ILAC: [http://www.ilac.org](http://www.ilac.org/).

# 3. Terms and definitions

The terms and definitions used in this document (e.g., metrological traceability, calibration, measurement uncertainty, etc.) are defined in AST 8.11 standard [2] and JCGM 200 document [4]:

**Metrological traceability:** Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, contributing to the measurement uncertainty.

**Calibration**: Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

NOTE 1: a calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table.

**Internal calibration**: Calibration performed to establish the metrological traceability of its activities in relation to the scope of accreditation and that:

- does not fall within the scope of accreditation of the laboratory (and as such cannot be offered as an accredited calibration service);

- is performed by laboratory personnel and instrumentation (or under its direct control), applying technical procedures evaluated positively by ARMNAB.

# 4. Traceability elements

Metrological traceability is characterized by the following six essential elements

1) unbroken chain of comparisons which establishes the defined measurement units acceptable to a national or international reference standard,

2) documented measurement uncertainty,

3) documented measurement procedure,

4) technical competence,

5) link with the system of SI units, reference standard of measurement or reference procedure of measurement for the realization of the units of measurement,

6) calibration intervals.

The aforementioned elements are described in more detail in ILAC-P10 [1] and ILAC-G24/OIML D10 [9].

# 5. Requirements

# 5.1 Sources of traceability

5.1.1 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.

NOTE - Types of equipment having an effect on the validity of the reported results can include:

— those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;

— those used to make corrections to the measured value, e.g. temperature measurements;

— those used to obtain a measurement result calculated from multiple quantities.

5.1.2 The following are external calibration laboratories ensuring metrological traceability:

1) National Institute of Metrology (NIM), whose services are in line with the specified requirements and are included in CIPM MRA. The list of services rendered in the frames of CIPM MRA is given in Annex C of BCDC KCDB, which specifies the interval and uncertainty of each service.

2) an accredited calibration laboratory, whose accreditation scope covers the respective calibrations by the accredited National Accreditation Body or an Accreditation Body which is a signatory to ILAC agreement or signatory to a regional agreement recognized by ILAC.

3a) National Institute of Metrology (NIM), whose services are in line with the specified requirements, but are not included in CIPM MRA or

3b) accredited calibration laboratory, whose services are in line with the specified requirements, but are not accredited by the Accreditation Body[[1]](#footnote-1) which is a signatory to ILAC agreement or a signatory to a regional agreement recognized by ILAC.

The requirements of points 3a) and 3b) shall be applied in case it is possible to fulfil the requirements of points 1 and 2 neither in the Republic of Armenia, nor abroad. In case point 3a) or 3b) are selected, the laboratory subject to assessment shall present the respective evidence on the technical competence of the calibration laboratory with respect to the latter’s metrological traceability. The respective evidence on the technical competence of the calibration laboratory with respect to the required metrological traceability includes but is not limited to the following requirements (the referenced points are from GOST ISO/IEC 17025 standard):

• Records of calibration method validation (7.2.2.4)

• Procedures for evaluation of measurement uncertainty (7.6)

• Documentation and records for metrological traceability of measurement results (6.5)

• Documentation and records for ensuring the validity of results (7.7)

• Documentation and records for competence of personnel (6.2)

• Records for equipment which can influence laboratory activities (6.4)

• Documentation and records for facilities and environmental conditions (6.3)

• Audits of the calibration laboratory (6.6 and 8.8).

The National accreditation body assess the above-mentioned evidence and the laboratory's ability to evaluate them.

In cases when traceability to national standards is not applicable in terms of SI unit system, the laboratory shall use the methods stipulated by point 6.4.1 of GOST ISO/IEC 17025 (applicable certified reference materials, stipulated methods and reference standards, etc.) in order to achieve the required metrological traceability. This option can be used in case subpoints 1 to 3 of point 5.1.2 are not applicable.

The ARMNAB policy in regard to metrological traceability provided by Reference Material (CRMs) is as follows:

Producers (RMPs) through Certified Reference Materials (CRMs) is that the certified values assigned to CRMs are considered to have established valid metrological traceability when:

a) CRMs are produced by NMIs using a service that is included in the BIPM KCDB.

or

b) CRMs are produced by an accredited RMP under its scope of accreditation and

the Accreditation Body is covered by the ILAC Arrangement or by Regional

Arrangements recognised by ILAC.

or

c) The certified values assigned to CRMs are covered by entries in the Joint

Committee for Traceability in Laboratory Medicine (JCTLM) database.

Recognizing that the accreditation of RMPs is still developing and CRMs may not be available from accredited RMPs, where CRMs are produced by non-accredited RMPs, Accredited Organizations shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

When metrological traceability to the SI is not technically possible, it is the responsibility of the Accredited Organization to:

a) Choose a way to satisfy metrological traceability requirements by using certified values of certified reference materials provided by a competent producer

or

b) Document the results of a suitable comparison to reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use. Evidence of this comparison shall be assessed by the Accreditation Body.

Note 1: When metrological traceability to solely SI units is not appropriate or applicable to the application, a clearly defined measurand should be selected. Establishing metrological traceability therefore includes both the proof of identity of the property measured and the comparison of the results to an appropriate stated reference. The comparison is established by ensuring the measurement procedures are properly validated and/or verified, that measuring equipment is appropriately calibrated and that conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result.

Note 2: Surplus test materials are often available from proficiency testing (PT) providers. It should be checked whether the PT provider can provide additional stability information to demonstrate the ongoing stability of the property value and matrix of the test material. If this cannot be provided, these test materials should not be considered as an alternative way to ensure the validity of results.

5.1.3 Reference strains serve as a primary source for microbiological tests. The metrological traceability in microbiological tests is ensured through the use of reference materials or their derivatives.

The use of reference strains of the recognized culture collections in microbiological testing is considered as the right approach to ensure metrological traceability within the frames of the testing method.

**5.2 Medical laboratories**

5.2.1 In case of accreditation of medical laboratories, the requirements of AST ISO 15189 [11] shall be fulfilled.

5.2.2 In case the given devices of measurement is deemed as not having significant impact on the results of calibration, testing or other conformity assessment activity (e.g. technical inspection), the organization using the given devices of measurement shall conduct a technical analysis to support the absence of impact on the testing, calibration results (e.g. through the estimation of the uncertainty contributions and their analysis, uncertainty budget elaborated based on the measurement equation/model).

The accredited laboratories shall calibrate the reference standards of measurement in accredited calibration laboratories having respective CMC.

Note: The management system certified with AST ISO 9001 standard does not attest that the laboratory is competent to carry out accurate calibration. The national Accreditation Body of the Republic of Armenia does not accept the traceability of results of measurement conducted by such laboratories.

The provisions on ensuring the traceability of the aforementioned tests by devices of reference materials and reference strains is stipulated in point 5.1.2 of this document.

The reference standards of measurement used in medical laboratories, which are mentioned in the Joint Committee for Traceability in Laboratory Medicine (JCTLM), are deemed as sufficient to ensure traceability of measurement within the frames of the testing method.

# 5.3 Confirmation of metrological traceability

Ensuring the metrological traceability stipulated by point 5.1 of this document shall be the basis for competent organizations to perform calibration of devices of measurement.

The calibration certificate shall confirm the fact that calibration has been performed.

The calibration certificates issued by accredited calibration laboratories shall serve as evidence of metrological traceability in case they contain the accreditation symbol and the calibrated devices and quantities specified in the scope of accreditation.

# 5.4 Measurement uncertainty

Measurement uncertainty, associated with the calibration of devices of measurement, is one of the elements of metrological traceability.

Measurement uncertainty shall be calculated in line with GOST ISO/IEC 17025 standard, for each type of calibration. The data based on which the uncertainty was determined, shall be documented, and the assumptions on the estimation of uncertainty shall be specified and documented.

Expression of the uncertainty of measurement in calibration is stipulated in EA-4/02 [7].

The rules for the estimation of the measurement uncertainty in calibration are stipulated in ILAC-P14 [5]:

# 5.5 Internal calibration

5.5.1 Accredited calibration, testing, medical laboratories, if applicable reference material producers, PT providers, inspection bodies in order to establish metrological traceability for its own activities, and which are not a part of the organization’s scope of accreditation, can perform an internal calibration.

5.5.2 CABs, which perform internal calibrations of their measuring devices, shall fulfil the requirements of ILAC-P10 document and listed below:

- the reference samples shall be traceable according to the indications given in 5.1.2, for the quantities, measurement fields and appropriate uncertainties;

- the reference samples shall be used only for calibrations and interim controls of the status of calibration;

- it shall operate using suitable calibration procedures and competent/qualified staff.

An internal calibration is also one performed by external staff complying with the above requirements.

5.5.3 The NAB shall assess the competence of the laboratories conducting checking (comparison), which include, but are not limited to the following:

* a documented procedure for each type of calibration;
* competence of personnel conducting the calibration;
* traceability of standards with appropriate measurement uncertainties;
* records on measurements and environmental conditions;
* records and reports on the results and data of any calculations
* procedures for evaluating measurement uncertainty/ CMCs.

**5.6 Environmental conditions**

5.6.1 For all devices checked in-house, the CAB shall have respective environment for performing the calibration and obtaining the expected metrological specifications.

5.6.2 The respective environmental conditions shall be specified in documented calibration procedures or methods applied for calibration. Those requirements shall include control and monitoring of those specifications which may affect the quality of calibration, including humidity, temperature, vibration, etc.

5.6.3 Other respective conditions such as biological sterility, dust/dirt, electromagnetic fluctuations, radiation, electrical supply, sound and vibration levels shall be subjected to control and monitoring as appropriate for the technical activities concerned. The calibration shall be halted immediately in case the environmental conditions affect the results of calibration. It is necessary to take corrective action before launching the calibration process.

**5.7 Calibration methods and procedures**

5.7.1 The CAB shall maintain and apply documented methods and procedures for the calibration of equipment, as well as records of the calibration method validation, in case of using non-standard methods.

5.7.2 Documents on calibration procedures shall be available to the entire personnel performing calibrations. All instructions, guidelines and other information regarding the use of calibration standards and the results of estimation of measurement uncertainty shall be accessible and up-to-date.

5.7.3 In case of availability of international, regional, national standards, or documents developed by other recognized organizations regarding calibrations, it is not necessary to copy them as internal procedures as they can be used directly.

6. This Policy shall be revised upon necessity.

**HISTORY OF REVISIONS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Edition** | **Amendment**  | **Amended points/word** | **Amended (previous) version** | **Signature of the person making the amendments**  |
| **No** | **Approval date** | **No** | **Approval date** |
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| 3 | 22.03.2023 |  |  | All text |  |  |
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**DOCUMENT FAMILIARIZATION SHEET**

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1. The calibration certificates issued by the calibration laboratories accredited by ARMNAB are taken as the basis for ensuring the metrological traceability of the measuring instruments used in the test laboratories, until the agreement mentioned in point 2 is concluded by ARMNAB. This reservation does not apply to the accreditation of calibration laboratories. [↑](#footnote-ref-1)