



**INSTITUTE FOR ACCREDITATION OF  
THE REPUBLIC OF NORTH MACEDONIA**

**Regulation on Ensuring Metrological  
Traceability of Measurement Results**



Based on Article 14, Paragraph 1, Indent 1 of the Law on Accreditation (“Official Gazette of the Republic of Macedonia”, No. 120/2009 and No. 53/2011) and Article 13, Paragraph 2 of the Statute of the Institute for Accreditation of the Republic of North Macedonia, the Council of the Institute for Accreditation of the Republic of North Macedonia at the meeting held on 12.11.2021 adopted the following:

## **R E G U L A T I O N**

### **ON ENSURING METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS**

#### **1. General provision**

##### **Article 1**

The manner of ensuring metrological traceability of measurement results (hereinafter: traceability) is prescribed by this Regulation in accordance with the principles of ensuring traceability which are defined in the relevant international standards: MKC EN ISO/IEC 17025:2018; MKC EN ISO 15189:2013 and the documents of the International Laboratory Accreditation Cooperation- ILAC.

This Regulation is intended for:

- Assessors engaged in the accreditation procedure by the Institute for Accreditation of the Republic of North Macedonia (hereinafter: IARNM);
- Testing and calibration laboratories and medical laboratories;
- Inspection bodies;
- Certification bodies for products;
- Certification bodies for management systems;
- Certification bodies for persons.
- And other conformity assessment bodies which include measurement in their activities.

#### **2. Definitions**

##### **Article 2**

##### **Metrological traceability**

The definition for metrological traceability is specified in the International Vocabulary of Basic and General Terms in Metrology ("VIM 3 point 2.41") and has the following meaning:

Metrological traceability is a 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: For this definition “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”.*

The International Vocabulary of Basic and General Terms in Metrology ("VIM") contains all terms and definitions related to traceability, in which the term “metrological traceability” is equivalent to the term “traceability” given in MKC EN ISO/IEC 17025:2018 and MKC EN ISO 15189:2013.

##### **Reference Material (RM)**



Reference Material (RM) - material, sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034:2016).

### **Certified Reference Material (CRM)**

Certified Reference Material (CRM) - reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO 17034:2016).

### **Reference Material Producer (RMP)**

Reference Material Producer (RMP) - body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces (ISO 17034:2016).

## **3. General requirements**

### **Article 3**

All equipment used by the conformity assessment bodies (testing laboratories, calibration laboratories and medical laboratories, inspection and certification bodies) for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the results of the test, calibration or sampling shall be calibrated and traceable to the International System of Units (SI) before being put into service.

In addition, the laboratory shall have a programme for calibration and ensuring traceability of its equipment.

In order to maintain traceability in calibration programs, guidance can be found in the document of ILAC-G24/OIML D 10 "Guidelines for the Determination of Calibration Intervals of Measuring Instruments".

### **3.1. Requirements for Calibration Laboratories**

#### **Article 4**

Calibration laboratories shall have a program for the calibration of their equipment, which will ensure all performed calibrations to be traceable to national and international standards.

If calibration laboratories perform internal calibrations of their own equipment, they shall have a procedure for performing calibrations and competent staff to perform the calibrations. They shall provide traceability of the reference equipment with which they perform the calibrations and express measurement uncertainty during calibrations.

Calibration laboratories ensure traceability of their own reference standards and devices to the International System of Units (SI) through a continuous calibration chain.

Reference standards held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance would not be invalidated.

Reference standards shall be calibrated after any adjustment.



### **3.2. *Requirements for Testing Laboratories and Medical Laboratories***

#### **Article 5**

The same requirements from Article 3 of this Regulation shall be applied for the measuring equipment used in testing.

If laboratories perform internal calibrations of their own equipment, they shall have a procedure for performing calibrations and competent staff to perform the calibrations. They shall provide traceability of the reference equipment with which they perform the calibrations and express measurement uncertainty during calibrations.

The extent to which testing and medical laboratories should meet these requirements largely depends on the relative contribution of the calibration uncertainty to the total measuring uncertainty. If the contribution of the measuring equipment calibration uncertainty is very negligible to the total measurement uncertainty, the laboratories shall provide documented proof thereof. If the measuring uncertainty of the measuring equipment calibration is the dominant factor in the total measuring uncertainty, the requirements from point 3.1 shall be strictly observed.

### **3.3 *Requirements for Inspection and Product Certification Bodies***

#### **Article 6**

When inspection bodies, which operate in conformity with the MKC EN ISO/IEC 17020:2012 standard and product certification bodies, which operate in conformity with the MKC EN ISO/IEC 17065:2012 standard perform testing and/ or calibration, they shall meet all requirements of the MKC EN ISO/IEC 17025:2018 standard.

Tests and calibrations of the measuring equipment which is used in the inspection or certification shall fulfill the requirements from points 3.1 and/ or 3.2 of this Regulation.

### **3.4 *Requirements for Certification Bodies for Management Systems***

#### **Article 7**

The management systems certification bodies, operating in accordance with the MKC EN ISO/IEC 17021-1:2016 standard, shall check the fulfillment of the requirements for traceability of the measuring devices of the bodies being certified in the process of verification/audit and certification. The traceability shall be ensured in the same manner as presented in points 3.1 and/or 3.2 of this Regulation.

### **3.5 *Requirements for Persons Certification Bodies***

#### **Article 8**

The persons certification bodies operating in accordance with MKC EN ISO/IEC 17024:2012 standard shall respect the traceability requirements according to points 3.1 and/ or 3.2 of this Regulation, if the certification scheme for evaluation of persons contains testing and/ or calibration results.



#### 4. Methods for determination of acceptable traceability

##### A) Ensuring traceability through calibration

###### Article 9

When conformity assessment bodies use external calibration services, the traceability of the measurement equipment shall be assured by the use of calibration services from qualified and competent laboratories that can demonstrate measurement capability and traceability.

###### Article 10

The laboratories accredited by accreditation bodies which are MLA (Multilateral Agreement within the EA) signatories in the field of calibration, the laboratories accredited by accreditation bodies which are MRA (Mutual Recognition Arrangement within the ILAC (International Laboratory Accreditation Cooperation)) signatories in the field of calibration and the laboratories accredited by IARNM, are considered as qualified and competent laboratories for performing calibration.

Information about the EA MLA signatories is available on the following link of the EA web site: [Directory of EA Members and MLA signatories - European Accreditation \(european-accreditation.org\)](http://european-accreditation.org), also in the document [EA-INF/03](#) (Signatories to the EA Multilateral and Bilateral Agreement).

Information about the MRA signatories is available on the web site: [» Recognised Regional Cooperation Bodies International Laboratory Accreditation Cooperation \(ilac.org\)](http://ilac.org).

###### Article 11

IARNM acknowledges the traceability of National Metrology Institutes (NMIs) or international organizations that are signatories to CIPM MRA (Mutual Recognition Arrangement (MRA) for national measurement standards and calibration and measurement certificates issued by the NMIs). Acceptability is limited to those Calibration and Measurement Capabilities (CMCs) and levels of measurement uncertainty for which the above named institutes and organizations proved their calibration competence through successful participation in key and supplementary comparisons and in other CIPM activities that are an integral part of the MRA, and which are in the BIPM Key Comparison Database (KCDB).

*Note 2: National metrological institutes of member - countries participating in the Metric Convention may also provide metrological traceability directly through measurements made at the International Bureau of Weights and Measures (BIPM). The Key Comparison Database provides an automated link to relevant BIPM services with expressed CMC scopes and values.*

Information about the CIPM MRA signatories is available on the web site: <http://www.bipm.org/en/cipm-mra/participation/signatories.html>.

Information about acceptable Calibration and Measurement Capabilities (CMCs) of national metrology institutes is available on the web site: <http://kcdb.bipm.org/AppendixC/>.

###### Article 12

Only the calibration certificates issued by calibration laboratories specified in Article 10, bearing the accreditation mark or reference to accredited status of the laboratory represent evidence of ensured traceability.

*Note 3: Some metrological institutes may point out that their services are covered by the CIPM MRA agreement (Article 11) by affixing the CIPM MRA logo to their certificates, but in*



any case, relevant evidence of this is the CMC data contained in the Key Comparison Database (BIPM KCDB).

### Article 13

Calibration certificates issued by calibration laboratories not covered by ILAC agreements or by Regional agreements recognized by ILAC and the National Metrology Institutes not covered by the CIPM MRA do not represent evidence of ensured traceability.

## B) Ensuring metrological traceability through Certified Reference Materials (CRM)

### Article 14

When traceability is ensured by usage of certified reference materials (CRM), the conformity assessment body shall make a selection and evaluation of the appropriateness of the certified reference material.

The values assigned to CRMs produced by NMIs and included in the BIPM KCDB (Key Comparison Database) or produced by an accredited Reference Material Producers (RMP) in accordance with ISO 17034:2016, are considered to have established valid traceability.

The values assigned to CRMs covered by entries in the ILAC Joint Committee for Traceability in Laboratory Medicine (JCTLM) database are considered to have established valid traceability.

*Note 4: Given that the accreditation of Reference Material Producers (RMP) is an area that is still being developed, if CRMs from non-accredited producers are used, the Conformity Assessment Body shall demonstrate that the CRMs have been obtained from competent Reference Material Producers and are suitable for the purpose.*

## C) Rules if metrological traceability to SI units cannot be provided

### Article 15

If the requirements of Article 3 of this Regulation are not relevant to conformity assessment bodies, i.e. if metrological traceability to SI units is not technically possible, conformity assessment bodies shall apply other methods of ensuring confidence in the results including, not limited to, the following:

- use of appropriate certified reference materials (in accordance with Article 14),
- participation in appropriate proficiency testing (PT) programs, interlaboratory comparisons (ILC) and programs for external quality assessment (EQA),
- comparison with another reference procedure, specified methods or mutually accepted standards by all stakeholders that are appropriate for the purpose, under strictly defined conditions that ensure reliable results,
- use of surplus test materials available from PT providers (if the provider provides appropriate information on the stability of the sample),
- documented statements regarding reagents, procedures or test systems where traceability is provided by the supplier or manufacturer.

### Article 16

An integral part of this Regulation is the list of reference documents given in the Annex 1 of this Regulation.



## **5. Transitional and final provisions**

### **Article 17**

With the entry into force of this Regulation, the Regulation on Ensuring Manner of Measurement Traceability in the Republic of Macedonia adopted by the Council of IARNM on 30.10.2014 shall cease to be valid.

### **Article 18**

This Regulation shall enter into force on the day of its adoption.

Date:  
12.11.2021

Chairman of the Council  
  
Prof. Dr. Pavle Sekulovski



## **ANNEX 1**

### **Reference Documents**

The documents that are relevant to the measurement traceability used in the accreditation procedure are listed below. Any document alteration is controlled by IARNM.

<b>VIM III</b>	<i>International Vocabulary of Metrology - Basic and General Concepts and Associated Terms, JCGM 200:2012</i>
<b>MKC EN ISO/IEC 17025:2018</b>	<i>General requirements for the competence of testing and calibration laboratories</i>
<b>MKC EN ISO 15189:2013</b>	<i>Medical laboratories – Particular requirements for quality and competence.</i>
<b>ILAC P10:07/2020</b>	<i>ILAC Policy on the Traceability of Measurement Results</i>
<b>EA-4/14</b>	<i>The Selection and Use of Reference Materials</i>
<b>ILAC-G24/OIML D 10</b>	<i>Guidelines for the determination of calibration intervals of measuring instruments</i>
<b>ISO 17034:2016</b>	<i>General requirements for the competence of reference material producers</i>
<b>ILAC P14:09/2020</b>	<i>ILAC Policy for Measurement Uncertainty in Calibration.</i>