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RULES FOR ENSURING ACCEPTABLE MEASUREMENT TRACEABILITY

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1. SUBJECT AND SCOPE

The purpose of these rules is to define the policy of metrological traceability of measurement results of the Accreditation Body of Montenegro within the accreditation processes of testing/calibration laboratories and medical laboratories.

These rules are intended for ATCG staff and ATCG assessors involved in the accreditation process of testing/calibration laboratories in accordance with the requirements of standards MEST ISO/IEC 17025:2018 and MEST EN ISO 15189:2023, and they also apply to conformity assessment bodies that use measurements in conformity assessment activities.

2. ABBREVIATIONS AND DEFINITIONS

2.1 Abbreviations

SI – International System of Units
EA – European co-operation for Accreditation
ILAC – International Laboratory Accreditation Cooperation
IMB – Institute of Metrology of Montenegro
CIPM – Comité International des Poids et Mesures (International Committee for Weights and Measures)
CIPM MRA – Mutual Recognition Arrangement (arrangement for the mutual recognition of national measurement standards and calibration and measurement certificates issued by NMIs)
BIPM – International Bureau of Weights and Measures
JCTLM – Joint Committee for Traceability in Laboratory Medicine (CIPM, IFCC and ILAC)
RM – Reference Material
CMC – Calibration and Measurement Capability, available to customers under normal conditions:
(a) as stated in the laboratory's scope of accreditation, or
(b) as published in the BIPM Key Comparison Database (KCDB)
NMI – National Metrology Institute

2.2 DEFINITIONS

For the purposes of using this document and implementing the activities prescribed therein, the terms and definitions given in the International Vocabulary of Metrology (VIM) shall apply. Only selected definitions are provided in this document, as follows:

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

Metrological traceability chain
sequence of measurement standards and calibrations used to relate a measurement result to a reference

Metrological traceability to a measurement unit
traceability where the reference is the definition of a measurement unit through its practical realization
Note: The term “traceability to the SI” means metrological traceability to the units of the International System of Units.

Calibration
operation that, under specified conditions, in a first step establishes a relation between 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

Reference material (RM)
material, sufficiently homogeneous and stable with respect to specified properties, established to be fit for its intended use in measurement or in examination of nominal properties

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

Reference material producer (RMP)
body (organization or company, public or private) fully responsible for project planning and management; assignment and decision on property values and relevant uncertainties; authorization of property values; and issuance of certificates or other statements for the reference materials it produces (MEST EN ISO 17034)

CAB (conformity assessment body)
body that performs conformity assessment activities and that can be the subject of accreditation

KCDB (Key Comparison Database)
publicly available, free web resource related to the CIPM MRA, containing information on participants, results of key and supplementary comparisons, and peer-reviewed Calibration and Measurement Capabilities (CMC) (https://www.bipm.org/kcdb)

Accredited organization - the term “accredited organization”, which includes CABs, is used for organizations covered by the ILAC arrangement. It also refers to both applicants and accredited organizations, unless otherwise specified.

3. RELATION TO OTHER DOCUMENTS

ILAC P10:07/2020 – ILAC Policy on Metrological Traceability of Measurement Results
VIM (fourth edition) – International Vocabulary of Metrology: Basic and General Concepts and Associated Terms, JCGM 2021

ILAC G24:2022 – Guidelines for the Determination of Recalibration Intervals of Measuring Equipment

These documents are available on the following websites: www.european-accreditation.org and www.ilac.org

MEST EN ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories
MEST EN ISO 15189 – Medical laboratories – Requirements for quality and competence
MEST EN ISO 17034 – General requirements for the competence of reference material producers

- *Where the above documents are not indicated with a year of publication, the latest valid editions/versions shall apply, in accordance with the updated list ZPR.02.04 – Register of External Documents.*

4. DESCRIPTION OF ACTIVITIES AND RESPONSIBILITIES

4.1 Acceptable Measurement Traceability

4.1.1 Calibration Laboratories

Calibration laboratories shall have a calibration programme for equipment that ensures that all calibration and measurement results produced by the laboratory are traceable to the SI units. Additional information on metrological traceability, which is an important concept for ensuring comparability of measurement results both nationally and internationally, is provided in Annex A of MEST EN ISO/IEC 17025.

Guidance for establishing and maintaining a calibration programme can be found in ILAC G24 “Guidelines for the Determination of Calibration Intervals of Measuring Instruments”.

4.1.2 Testing Laboratories

Testing laboratories shall have a calibration programme for equipment used in testing where the contribution of calibration-related measurement uncertainty to the overall uncertainty of test results is significant and cannot be neglected.

The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, where each contributes to the measurement uncertainty, linking them to an appropriate reference.

The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:
a) calibration provided by a competent laboratory;
b) certified values of certified reference materials with stated metrological traceability to SI units, provided by a competent producer;
c) direct realization of SI units ensured through comparison, directly or indirectly, with national or international measurement standards.

Where metrological traceability to SI units is not technically possible, the laboratory shall demonstrate traceability to appropriate references such as:
a) certified values of certified reference materials provided by a competent producer;
b) 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 ensured through suitable comparison.

Additional information on metrological traceability is provided in Annex A of MEST EN ISO/IEC 17025, as it is a key concept for ensuring comparability of measurement results at both national and international levels.

Guidance for establishing and maintaining a calibration programme can be found in ILAC G24 “Guidelines for the Determination of Calibration Intervals of Measuring Instruments”.

4.1.3 Medical Laboratories

The medical laboratory shall have a documented procedure for calibration of equipment that directly or indirectly affects examination results. The procedure shall include:
a) consideration of conditions of use and manufacturer’s instructions;
b) recording of metrological traceability of measurement standards and traceable calibration of equipment;
c) verification of required measurement accuracy and functionality of the measurement system at defined intervals;
d) recording of calibration status and recalibration dates;
e) ensuring that previous calibration factors are correctly updated when calibration indicates a series of correction factors;
f) safeguards to prevent adjustments or tampering that could invalidate examination results.

Metrological traceability shall be established to available reference materials or higher-order reference procedures.

NOTE: Documentation of traceability to reference materials or higher-order reference procedures may be provided by the manufacturer of the examination system. Such documentation is acceptable as long as the manufacturer’s system and calibration procedures are used without modification.

Where this is not possible or relevant, other means for providing confidence in results shall be applied, including but not limited to:
– use of certified reference materials;
– examination or calibration by alternative procedures;
– mutually agreed standards or methods that are clearly defined, specified, characterized and agreed upon by all relevant parties.

Guidance for establishing and maintaining a calibration programme can be found in ILAC G24 “Guidelines for the Determination of Calibration Intervals of Measuring Instruments”.

4.1.4 Other Conformity Assessment Bodies

These rules also apply to other conformity assessment bodies (e.g. inspection bodies, management system certification bodies, personnel certification bodies, etc.) for activities that include testing and calibration.

4.2 ATCG Policy on Measurement Traceability

The Accreditation Body of Montenegro applies the policy and principles defined in ILAC P10:07/2020 Policy on Metrological Traceability of Measurement Results. Measurement results shall be considered traceable if calibration is performed in one of the following ways:

1. By national metrology institutes (NMIs) that are signatories to the CIPM MRA. Acceptance is limited to calibration and measurement capabilities (CMCs) and associated uncertainties demonstrated through participation in key and supplementary comparisons and published in the BIPM KCDB database.
   Information is available at: https://www.bipm.org/en/member-state and https://www.bipm.org/kcdb

ATCG accepts calibration certificates issued by the Institute of Metrology of Montenegro and by other NMIs that are signatories to the CIPM MRA, provided the services are listed in the KCDB.

2. By calibration laboratories accredited by ATCG or by accreditation bodies that are signatories to EA MLA and/or ILAC MRA, where the scope covers the required calibration.
   ATCG accepts calibration certificates issued by such accredited laboratories, provided they meet MEST EN ISO/IEC 17025 requirements.

3a. By NMIs whose services are not listed in the CIPM MRA KCDB but are suitable for the intended purpose. In this case, the CAB shall demonstrate compliance with traceability and uncertainty requirements according to MEST EN ISO/IEC 17025.

3b. By calibration laboratories accredited by non-MLA signatory bodies. The CAB shall demonstrate compliance with traceability and uncertainty requirements according to MEST EN ISO/IEC 17025.

NOTE: Options 3a and 3b are acceptable only when options 1 and 2 are not feasible.

Suitable reference materials for traceability include:

4. Certified reference materials (CRMs) produced by NMIs with values listed in the BIPM KCDB;
5. CRMs produced by accredited reference material producers in accordance with MEST EN ISO 17034, recognized under ILAC arrangements;
6. CRMs with values included in the BIPM JCTLM database.

If non-accredited producers are used, the CAB shall demonstrate competence of the producer and suitability of the material.

Where traceability to SI units is not possible, traceability may be demonstrated through:
7a. participation in interlaboratory comparisons organized by competent bodies;
7b. use of CRMs as described above;
8. internal calibration, provided compliance with MEST EN ISO/IEC 17025 is demonstrated.

For internal calibration, the CAB shall demonstrate:
– traceability of working standards via accredited calibration;
– use of validated calibration procedures;
– competent personnel with documented training;
– inclusion of measurement uncertainty in results;
– documented and validated uncertainty calculation methods;
– complete records of all factors influencing calibration results.

5. FORMS

This document has no associated forms.