АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ

ATS-PA03

RULES FOR OBTAINING METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

Any differences between the Serbian and English versions of this document are not intended, but if in doubt, the Serbian version should be consulted.

1. SCOPE

This document shall lay down the policy of the Accreditation Body of Serbia (ATS) as regards requirements for metrological traceability of measurement results in testing and calibration, and refers to all other conformity assessment activities where measurement is included (medical laboratories, inspection bodies, manufacturers of reference materials, providers for proficiency testing, etc.).

ATS policy regarding requirements for obtaining metrological traceability of measurement results is based on the policy and principles of the International Laboratory Accreditation Cooperation (ILAC), laid down in a document entitled ILAC P10, ILAC Policy on Metrological Traceability of Measurement Results.

Metrological traceability requires an unbroken calibration chain and according to the stated references, all having stated uncertainities. Metrological traceability refers to reference quantity values of measurementstandards and measurement results, and not to the organization that provides them. Metrological traceability cannot be linked to a specific organization (e.g. Traceable to a specific National Metrology Institute).

This document is intended for:

- testing and calibration laboratories performing their activities in accordance with the requirements of SRPS ISO/IEC 17025:2017;
- other conformity assessment bodies, performing conformity assessment activities, where measurement is involved;
- the ATS assessors, and other engaged persons performing conformity assessment activities, decision-making and other, within accreditation procedures.

2. REFERENCE DOCUMENTS, TERMS AND DEFINITIONS AND ACRONYMS

2.1 Reference documents

- ILAC- P10:07/2020, ILAC Policy on Metrological Traceability of Measurement Results;
- VIM - International vocabulary of metrology - basic and general concepts and associated terms, 3rd edition);
- SRPS ISO/IEC 17025:2017, General Requirements for the Competence of Testing Laboratories and Calibration Laboratories;
- SRPS ISO EN 15189:2014, Medical laboratories – Particular Requirements for Quality and Competence;
- SRPS ISO/IEC 17020:2012, Conformity assessment – Requirements for the operation of various types of bodies performing inspection;
- SRPS EN ISO/IEC 17065:2016, Conformity assessment – Requirements for bodies certifying products, processes and services;
- SRPS ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing audit and certification of management systems - Part 1: Requirements;
- SRPS ISO/IEC 17024:2012, Conformity assessment – General requirements for bodies operating certification of persons;
- SRPS ISO/IEC 17043:2011, Conformity assessment – General requirements for proficiency testing.

2.2 Terms and definitions

For the purposes of this document, terms and definitions laid down in the International Vocabulary of Basic and General Terms in Metrology (VIM) shall be used.

- **metrological traceability** (VIM 3, cl. 2.41): is defined as the property of a measurement result whereby the result can be related to a reference (definition of a measuring unit, reference material, reference value, etc) through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. *Note:* standards ISO/IEC 17025 and SRPS EN ISO 15189 use the term metrological "traceability“ defined in VIM and the same is used in this document.
- **metrological traceability chain** (VIM 3, cl. 2.42): sequence of measurement standards and calibrations that is used to relate a measurement result to a reference;
- **metrological traceability to a measurement unit** (VIM 3, cl. 2.43): traceability where the reference is the definition of a measurement unit through its practical realisation. Note: the expression “traceability to the SI” means metrological traceability to a measurement unit of the International System of Units.
- RM (Reference Material) – material sufficiently homogenous and stable with respect to one or more specific properties, which has been establishment to be fit for its intended use in a measurement process (ISO 17034: 2016).
- CRM (Certified Reference Material) – reference material that charactreizes 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 measurement uncertainty and statement of metrological traceability (ISO 17034: 2016).
- RMP (Reference Material Producer) - body (organization or company, public or private) that is fully responsible for project planning and management; assignments of and decision on the property value of and relevant uncertainities, authorisation of property values and issuance of a reference material certificates or other statements for the reference materials it produces (ISO 17034: 2016).

2.3 Acronyms

The following acronyms were used in this document:

- ATS - Accreditation Body of Serbia;
- EA - European co-operation for Accreditation;
- ILAC - International Laboratory Accreditation Cooperation;
- MLA/MRA – EA MLA/ILAC MRA Multilateral Agreement;
- NMI - National Metrology Institute (note: acronym NMI in this document shall also refer to designated institutes (Designated Institutes, DI);
- CMC - Calibration and Measurement Capabilities;
- KCDB - Key Comparison Database;
- CIPM - Comité Internationale des Poids et Mesures;
- CIPM MRA - Mutual Recognition Arrangement - Arrangement for national measurement standards and calibration and measurement certificates issued by the NMI;
- BIPM - Bureau International des Poids et Mesures;
- JCTLM - The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine.

3. ACCEPTABLE METHODS TO OBTAIN TRACEABILITY

ATS shall accept calibrations of measuring equipment performed by the following entities, i.e., shall accept the following certificates:

(1) National Metrology Institute (NMI) or international organization that is a signatory to and participates in CIPM MRA. Acceptability is limited to those Calibration and Measurement Capabilities (CMCs) for which the said organizations proved their calibration competence through successful participation in key and complimentary comparisons and other CIPM activities that are an integral part of the MRA, and which are in BIPM Key Comparison Database.

The information about CIPM MRA signatories is available on the internet at the following website address https://www.bipm.org/en/member-states

The information about acceptable calibration and measurement capabilities is available on the internet at the following website address, https://www.bipm.org/kcdb/

In Serbia, the Directorate for Measures and Precious Metals, as the National Metrology Institute and a CIPM MRA signatory, can perform calibration and measurement published in the BIPM Key Comparison Database for certain sizes and ranges of measurements. *Note:* The Institute for Nuclear Sciences Vinča is a Designated Institute (DI) in the metrological system of the Republic of Serbia.

The information about acceptable calibration and measurement capabilities of the Directorate for Measures and Precious Metals is available on the internet at the following website address, https://www.bipm.org/kcdb/cmc/ or www.dmdm.rs

Acceptable evidence of metrological traceability is considered to be a calibration report/certificate of calibration, issued by DMDM for those calibration that are in the BIPM Key Comparison Database, NMI of another state or international organisation, that is a signatory of the CIPM MRA agreement. Such calibration report/certificate of calibration may or may not contain a CIPM MRA logo bearing in mind that its use is not binding. In these cases, the BIPM Key Comparison Database (BIPM KCDB) is fully credible and sufficient in such cases.

Note: NMIs from the Member States participating in the Metric Convention may take metrological traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services (including range and measurement uncertainty). Individual calibration certificates issued by BIPM are also listed.

or

(2) Accredited calibration laboratories against SRPS ISO/IEC 17025 by ATS or other national accreditation body that is a signatory to EA MLA and/or ILAC MRA agreement, and whose service is suitable for the intended use.

The list of all accredited calibration laboratories accredited by ATS is available on the internet at the following website address, www.registar.ats.rs **.**

The information about other national accreditation bodies that are signatories to EA MLA or ILAC MRA agreement is available at the following website address: **www.european-accreditation.org** in the document EA/INF-03, EA Multilateral and Bilateral Agreements, and Signatory Lists or on the website **www.ilac.org**.

Acceptable evidence of metrological traceability is considered to be calibration report/calibration certificate, issued by an accredited calibration laboratory (accredited by

ATS or accreditation body that is a signatory to EA MLA and/or ILAC MRA agreement for calibration laboratories).

Calibration report/calibration certificate shall contain all elements in line with SRPS ISO/IEC 17025. It should also contain an accredited symbol (ATS or other accreditation body signatory of EA MLA and/or ILAC MRA agreement for calibration laboratories, or a combined ILAC MRA mark or otherwise acceptable reference to accreditation), confirming that calibration was performed within accredited operations.

or

(3a) NMI (including DMDM), whose calibration services are suitable for intended purposes, but are not included in the CIPM MRA Key Comparison Database. In this case, the conformity assessment body using the said NMI services shall establish a procedure to demonstrate that these services meet the relevant criteria for metrological traceability and uncertainty of measurement in accordance with SRPS ISO/IEC 17025 standard. The established procedure shall be subject to assessment by ATS, which may include additional assessors having appropriate competence.

or

(3b) Calibration laboratories, whose calibration services (including certificates showing the symbol of accreditation) are suitable for intended purposes but are not covered by an ILAC MRA agreement or regional arrangements recognized by ILAC. In this case, the conformity assessment body using those services shall establish a policy to ensure that these services meet the relevant criteria for metrological traceability and measurement uncertainty in accordance with SRPS ISO/IEC 17025 standard. The established procedure shall be subject to assessment by the ATS, which may include additional assessors having appropriate competence.

Note: Proving metrological traceability stated in (3a) and (3b) shall only be accepted when obtaining calibration service stated in options (1) or (2) is not possible.

With regard to metrological traceability provided by the RMPs through CRMs, it is considered that the certified values assigned CRMs are considered to have established valid metrological traceability when:

(4) CRM sare produced by NMIs using a service that is included in the BIPM KCDB database.

or

(5) CRMs are produced by an accredited RMPs under its scope of accreditation and that Accreditation body is signatory of the ILAC MRA agreement or of any of the regional arrangements recognized by ILAC.

or

(6) Certified value assigned to CRMs are covered by entries in the JCTLM database (Joint Committee for Traceability in Laboratory Medicine).

If, for justified reasons, CRMs produced by a non-accredited RMPs are used, accredited organizations must demonstrate that the CRMs were provided by a competent RMPs and are suitable for the intended purpose.

(7) When metrological traceability to the SI units is not possible, the responsibility of the accredited organization is to:

7a) Choose a way to satisfy metrological traceability requirements by using certified values of CRMs provided by a competent producer.

or

7b) Document the results of suitable comparisons with reference measurement procedures, specified methods, or consensus standards, which are clearly described and accepted as provide measurement results fit for their intended use.

In this case, the chosen method must be specified and it must be shown that the laboratory cannot achieve traceability in the manner described in clauses from (1) to (3) of these Rules in a satisfactory manner, and ATS shall assess the chosen method.

or

(8) Accredited conformity assessment body performing "in-house" calibration of measuring equipment for their own needs as a support to their accredited activities and that may serve as evidence to ATS that they meet the requirements of SRPS ISO/IEC 17025 and ATS rules for respective calibrations and measurements.

In cases when traceability is obtained by in-house calibration or in a mode stated in (3a) and (3b) conformity assessment body shall demonstrate its technical competence for all such calibrations, which will be checked by ATS during the assessment, or as a minimum, it shall ensure that the conformity assessment body:

- uses verified standard calibration methods or documented and validated methods used to perform certain calibrations;
- applies procedure for estimation of measurement uncertainty for those calibrations. Records on calculations of measurement uncertainty must be made and stored for each calibration type;
- possesses adequate conditions to perform calibrations;
- has staff that is trained and competent to perform calibrations and keep adequate records thereof;
- has appropriate equipment that affects laboratory activities;
- obtains metrological traceability for all reference standards, measuring equipment and reference materials that are used in case of those calibrations in accordance with previously stated points. Calibration must be repeated at appropriate intervals so as to ensure reliable values achieved by reference standards;
- has evidence of ensuring the validity of results through participation in proficiency testing or inter-laboratory comparisons other than proficiency testing;
- keeps the records of calibrations performed in such a way. The records may be in the form of reports on calibration, certificates, stickers, etc., and they must be kept for a certain period of time;
- includes in-house calibrations in internal audits.

Note: In order to establish and maintain a calibration program, recommendations can be found in ILAC G24:2007 Guidelines for the determination of calibration intervals of measuring instruments.