SLOVENSKA AKREDITACIJA

OA02

ACCEPTABLE METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

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1 PURPOSE AND SCOPE

This document provides the policy on ensuring metrological traceability of measurement results in conformity with the requirements for ensuring measurement traceability, as described in the relevant international standards, and in conformity with the principles of the European Co-operation for Accreditation (hereinafter called "EA"), and ILAC (International Laboratory Accreditation Cooperation), in particular with the document ILAC P10. The document also provides practical guidance, information and details necessary in addressing and ensuring metrological traceability.

The policy is intended for the following types of conformity assessment bodies (CABs):

- Calibration, testing and medical laboratories; these will use it for ensuring metrological traceability of measurement results in conformity with the requirements of the standard SIST EN ISO/IEC 17025 or SIST EN ISO 15189.
- Inspection bodies and certification bodies operating certification of products, processes and services, management systems and persons, EMAS verifiers and GHG report verifiers, who operate in conformity with the requirements of the standards SIST EN ISO/IEC 17020, SIST EN ISO/IEC 17065, SIST EN ISO/IEC 17021-1, SIST EN ISO/IEC 17024 and SIST EN ISO 14065. The requirements and procedures refer, *mutatis mutandis,* to the activities of these bodies or their subcontractors related to calibration or testing, as well as to other measurements, calibrations and tests, the results of which are used by these bodies in conformity assessment procedures.
- The policy also applies to ensuring metrological traceability of measurement results of accredited CABs with in-house calibrations, i.e. CABs who perform calibrations themselves, but they are not comprised in the scope of their accredited activity.

At the same time, this document provides guidance to the assessors of Slovenian Accreditation (hereinafter called "SA") in determining acceptable metrological traceability of measurement results in procedures for obtaining and maintaining accreditation.

2 DEFINITIONS

In addressing metrological traceability, the basic metrology definitions taken from the International Vocabulary of Basic and General Terms in Metrology (VIM) have been observed.

3 POLICY ON ENSURING METROLOGICAL TRACEABILITY

All equipment used by a CAB in calibrations, tests, investigations and measurements aimed at proving conformity with a conventional requirement – including equipment for auxiliary measurements (e.g. for measurements of environmental conditions) – which affects the accuracy or validity of calibration, test, investigation, inspection, sampling, or the result of measurement in general, shall have its metrological traceability assured (meaning that it has been adequately calibrated).

SA expects of management system certification bodies, EMAS verifiers, certification bodies operating certification of products, processes and services, as well as of GHG reports verifiers, to establish, when relevant, through audits/verifications, whether the party in certification/verification procedure has the necessary evidence of compliance of the calibrations performed.

Calibration shall be carried out in one of the following ways:

1) By the laboratories – holders of national standards in the Republic of Slovenia, or by other national and designated metrology institutes (NMI, DI), whose activity is covered by Mutual Recognition Arrangement of International Committee for Weights and Measures (CIPM MRA). Details on the extent of this activity (field, calibration capacity) are collected in the key comparison database of the International Office of Weights and Measures (BIPM KCDB; https://www.bipm.org/kcdb/).

2) Also calibration laboratories accredited by an accreditation body signatory to ILAC MRA (https://ilac.org/ilac-mra-and-signatories/) or a signatory to regional arrangements recognized by ILAC (e.g. EA MLA; https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signatories/) are considered as competent calibration laboratories.

   Only those calibration certificates bearing the accreditation mark of the accredited CAB, or any other reference to accreditation complying with the rules of the accreditation body who granted the accreditation, shall be considered as evidence of traceability.

3a) In the case that a selected NMI or DI laboratory offers calibration activity which suits the purpose but is not covered by CIPM MRA, the user shall make sure of the laboratory's competence in terms of the requirements of SIST EN ISO/IEC 17025, and provide evidence to that effect (see Annex A).

3b) In the case that a selected calibration laboratory offers calibration activity which suits the purpose but is not covered by CIPM MRA or any other regional arrangements recognized by ILAC (e.g. EA MLA), the user shall make sure of the laboratory's competence in terms of the requirements of SIST EN ISO/IEC 17025, and provide evidence to that effect (see Annex A).

Options 3a) and 3b) are used in exceptional cases, when demonstrating metrological traceability of measurement results under 1) and 2) is not possible or appropriate (see Annex A).

Metrological traceability of measurement results can also be ensured through the use of certified reference materials (CRMs). Certified values ascribed to the CRM, shall be considered as acceptable assurance of metrological traceability, when:

4) the CRM has been produced by a National Metrology Institute (NMI, DI) and the activity is included in BIPM KCDB; or

5) the CRM has been produced by a Reference Material Producer (RMP) accredited by an accreditation body signatory to ILAC MRA (https://ilac.org/ilac-mra-and-signatories/) or signatory to regional arrangements recognized by ILAC (e.g. EA MLA; https://european-accreditation.org/ea-members/directory-of-ea-members-and-mla-signatories/); or

6) the ascribed values of the CRM are entered into the database of JCTLM (Joint Committee for Traceability in Laboratory Medicine; https://www.bipm.org/jctlm/).

When CRMs under 4), 5) or 6) are not available, and CRM is used for proving metrological traceability, the user shall:

7a) select a CRM that is produced by other producers and prove, within the scope of purchasing procedures, that the producer is adequately qualified (complying with SIST EN ISO/IEC 17034), and that the CRM is suitable for the intended use; or

7b) document the results of adequate comparison with a reference measuring procedure, with a defined method or with a conventional standard, which are clearly described and accepted as suitable means of ensuring results that meet the intended purpose.

4 CHANGES WITH REGARD TO PREVIOUS REVISION

Annex B and the sentence under paragraph 3b) which referred to that annex have been deleted.

5 CONTROL OF THE DOCUMENT

A valid document shall be located in i4 (SA information system). A clean copy shall be published on SA website, and available in printed form at SA head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies hereof shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4 or on SA website.

6 REFERENCE DOCUMENTS

- SIST-V ISO/IEC Guide 99:2012 – International Vocabulary of Metrology – Basic and general concepts and associated terms (VIM)
- ILAC P10:07/2020, ILAC Policy on Metrological Traceability of Measurement Results
- SIST EN ISO 17034:2017 Conformity assessment – General requirements for the competence of reference material producers (ISO 17034:2016)

ANNEX A

In cases where demonstration of metrological traceability in accordance with items 1) and 2) hereof should not be possible or appropriate, additional activities shall be necessary to determine the acceptability of metrological traceability of measurement results. The reasons for selecting such means of proving metrological traceability should be justified as the last or most suitable option (not as merely economic reasons).

The same applies in cases where metrological traceability of measurement results is assured through in-house calibrations in the audited CAB. This includes in particular calibrations that could usually be provided by competent external calibration laboratories, and not e.g. calibrations with reference materials, which constitute a part of testing procedures and are assessed in this context.

1. SA expects of CABs who are the users of such calibration to make sure themselves of the compliance of operators of calibration (following the requirements of SIST EN ISO/IEC 17025), and to have at their disposal documents to that effect. These documents may include (references to clauses of SIST EN ISO/IEC 17025:2017 are provided in brackets):
    a. Records of calibration method validation (7.2.2.4)
    b. Procedures and records of evaluation of measurement uncertainty (7.6)
    c. Documents and records of metrological traceability of measurement results (6.5)
    d. Documents and records of ensuring the validity of results (7.7)
    e. Documents and records of the competence of personnel (6.2)
    f. Records of the equipment that can influence laboratory activities (6.4)
    g. Documents and records of the facilities and environmental conditions (6.3)
    h. Records of calibration laboratory audits (6.6 and 8.8)

    In such cases, CAB shall pay particular attention to the integrity of information provided in reporting of the results of calibration.

2. In assessment procedures, SA assesses compliance of the selected means for ensuring traceability of measurement results. This shall be conducted by the technical assessors assessing the fields in question, provided that they have adequate competencies; when not, SA may include additional assessors or experts in the assessment.

Acceptability of ensuring traceability of measurement results shall be assessed through reviewing the documentation that the CAB disposes of; in particular cases, a part of the assessment can be carried out at the provider of the calibration in question. When necessary, SA may witness the procedure of determining the compliance of a calibration operator by the CAB.

In the case of in-house calibration, comprehensive assessment of this activity shall be carried out at least once in an accreditation cycle, taking into account the purpose of using calibration. When necessary, assessment shall also be carried out at changes or when finding significant nonconformities that could be related to in-house calibration procedures. When in-house calibrations are not particularly complex, or when assessment of minor changes in the procedure is involved, the assessor may assess through documentation only, and a visit to the CAB is not needed. When metrological traceability is ensured by CRM under 7a) or 7b) herein, the assessors shall check the documentation for compliance of the selected CRM.