

Policy

PL - 13

SNAS POLICY ON METROLOGICAL TRACEABILITY OF MEASUREMENT RESULTS

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PURPOSE: This document defines the SNAS policy in the field of metrological traceability of measurement results.

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1 GENERALLY

Metrological traceability is fundamental to ensure reliability and comparability of measurement results. It is one of the key elements of management systems of conformity assessment bodies (CAB) performing calibration, testing or measurement and <u>it</u> is an important factor in supplying and maintaining the market confidence in the results of activities of these bodies. SNAS considers the ensuring of acceptable metrological traceability of measurement results as one of the key elements affecting the quality of the outputs of technical activities of CAB.

Metrological traceability is a property of the measurement result, by which the result can be associated with a specified reference through a documented unbroken chain of calibrations. Each calibration in the chain contributes to the determined uncertainty of measurement. Metrological traceability requires created hierarchy of calibration, which is the sequence of calibrations from reference to the final gauge, where the result of calibration depends on the result of the previous calibration.

This document is mandatory for all already accredited conformity assessment bodies and conformity assessment bodies in the process of accreditation, such as calibration, testing or medical laboratories and if it is relevant also for organizers of proficiency testing, inspection bodies and certification bodies certifying products. The document is also mandatory for SNAS assessors, who assess the fulfillment of the requirements for metrological traceability of measurement results that are listed in the relevant standards for the accreditation.

The policy listed below applies both externally as well as internally provided metrological services, including "in-house" (in-home) calibration. Organization in order to establish metrological traceability or its own activities, and which are not a part of the organization's scope of accreditation. These internal calibrations are also known as "in-house" calibrations.

2 ABBREVIATIONS USED

BIPM - International Committee for Weight and Measures (Bureau International

des

Poids et Measures)

BIPM KCDB - Key comparison database of BIPM

CAB - Conformity Assessment Body

CIPM MRA - Mutual Recognition Arrangement of the CIPM

CRM - Certified Reference Material

ILAC MRA - Mutual Recognition Arrangement of ILAC

JCTLM - Joint Committee for Traceability in Laboratory Medicine

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NMI - National Metrology InstituteRMP - Reference Material Producer

RM - Reference Material

3 SNAS POLICY IN THE FIELD OF ENSURING METROLOGICAL TRACEABILITY THROUGH CALIBRATION

The CAB is responsible for the evaluation of need for calibration of its equipments, which are used for performing of measurements or which are related to performing of measurements. In the case that CAB determines that the calibration of the equipment is not necessary, quantitative evidence supporting this decision has to be provided. This means, that the related contribution of the calibration does not contribute significantly to the measurement result and the measurement uncertainty and therefore metrological traceability may not be proved. In the case that calibration is necessary the laboratory has to have evidence of the ensuring of acceptable metrological traceability and the proof of competence of the provider of such calibration/metrology service.

SNAS policy for equipments and measurement standards, which have to be calibrated, is that these have to be calibrated by:

3.1 A National Metrology Institute (NMI), which service is suitable for the intended use and is covered by the CIPM MRA agreement. Services covered by the CIPM MRA are listed in Appendix C of KCDB BIPM database, which includes a scope and an uncertainty for each listed service.

In the case that NMI issues the calibration certificate for performed calibration and this certificate includes the reference to the CIPM MRA agreement, it is considered as sufficient evidence of ensuring an acceptable metrological traceability.

If NMI issues the calibration certificate for performed calibration and this certificate does not include the reference to the CIPM MRA agreement, the authoritative source of information on ensuring an acceptable response is KCDB BIPM database.

NMIs from Member States participating on the Metre 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 the range and uncertainty). Individual calibration certificates issued by the BIPM are also listed.

3.2 An accredited calibration laboratory, which service is suitable for the intended use (e.g. accreditation scope specifically covers the corresponding calibration) and the accreditation body is covered by ILAC MRA agreement for the field of calibration or by regional agreement MLA recognized by ILAC for the field of calibration.

In the case that an accredited calibration laboratory issues a calibration certificate for performed calibration with the reference to accreditation, combined ILAC MRA mark or

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accreditation mark of the accreditation body which complies conditions listed above, it is considered as sufficient proof of ensuring an acceptable metrological traceability.

If an accredited calibration laboratory issues a calibration certificate for performed calibration without the reference to accreditation, combined ILAC MRA mark or accreditation mark it is not considered that metrological service was performed by competent provider (for more information see 3.3).

3.3 A NMI, which service is suitable for the intended use, but is not covered by CIPM MRA or calibration laboratory, which service is suitable for the intended use, but is not covered by ILAC MRA agreement or regional agreement of MLA recognized by ILAC for the field of calibration.

In this case, CAB has to ensure the appropriate proof of required metrological traceability and measurement uncertainty and the accreditation body will assess this proof.

It is required from CAB to the possibility 3.3:

- the performing of customer audit with the presence of SNAS representative or another accreditation body, which is signatory of ILAC MRA (recognized regional MLA) in the field of calibration and
- output record/certificate of performed calibration, including at least:
- date of calibration.
- identification of the object on which the calibration was performed,
- measured values and results, including uncertainty,
- information about metrological traceability (or a reference to where the data can be found).

As appropriate proofs are considered to the possibility 3.3, for example:

- the results of interlaboratory comparisons in corresponding field,
- demonstration of internationally agreed consensus standard/standard,
- records of validation of calibration method,
- procedures and records about estimation of the uncertainty of measurement results,
- documentation relating to metrological traceability of measurements, assuring quality of calibration results, competence of staff, premises, environment equipments.
- audits of calibration/testing laboratory, etc.

The possibility in 3.3 can be used only in the case that the calibration can not be ensured in the way given in 3.1 and 3.2 or services given in 3.1 and 3.2 are not available in the Slovak Republic or in neighboring countries.

In the case that it is evident that the possibilities 3.1 - 3.3 are unavailable or not relevant, metrological traceability may be ensured, for example through certified reference materials, agreed methods and/or accepted consensus standards and if it is possible. participation of CAB in appropriate programs comparisons/proficiency testing is required or in the way, that is specified in the relevant standards used for the accreditation.

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It is required from CAB to the possibility 3.4:

- to justify, that the policy referred in the possibilities No. 3.1 3.3 can not be reasonably fulfilled or is not important,
- to provide the evidence of the appropriate way of compliance of the policy listed in the possibility No.3.4.

4 SNAS POLICY IN THE FIELD OF ENSURING METROLOGICAL TRACEABILITY THROUGH REFERENCE AND CERTIFIED REFERENCE MATERIALS

Values associated with the reference materials (RM) may not be metrologically traceable. Values associated with certified reference materials (CRM) are metrologically traceable.

SNAS policy in the given field is the following:

4.1 Values of CRM produced by NMI which are included in the database BIPM KCDB, or values of CRM specified in the database JCTLM on BIPM website,

or

- **4.2** Values of CRM produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangement recognized by ILAC.
- **4.3** If neither of the options described in point 4.1 or 4.2 can be used, an RM manufactured by a non-accredited RMP may be used. However, the CAB must demonstrate that the RMs have been provided by a competent RMP and that they are suitable for the intended use.

It is required from CAB to the possibility 4.3:

- demonstration of the appropriateness of RM,
- participation in proficiency testing or other appropriate mutual comparison,
- mutual comparison among CAB in the event of unavailability of official comparisons,
- comparison of used RM with CRM meeting the possibility 4.1 or 4.2,
- comparison of RM from different producers,
- the use of two independent methods to confirm the values of RM
- comparison of newly used RM with already used one which was tested by the above listed methods, etc.

5 RELATED DOCUMENTS

ISO/IEC 17011 General requirements for accreditation bodies accrediting assessment bodies

ISO 17034 General requirements for the competence of reference material producers

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ISO/IEC 17025 calibration	General requirements for the competence of testing and laboratories
ISO 15 189	Medical laboratories – Particular requirements for duality and competence.
ILAC P10	ILAC Policy on the Metrological Traceability of Measurement Results.
ILAC P4	ILAC Mutual Recognition Arrangement: Policy and Management.
ILAC P8	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies.