National Accreditation Scheme

Metrological traceability

NAR-36
Edition 2

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Deputy Director General

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1. **Purpose of the regulation**

The primary objective of the present rules of procedure is to create a regulation framework to ensure metrological traceability.

When preparing the regulation, documents MSZ EN ISO/IEC 17025, MSZ EN ISO/IEC 15189, MSZ EN ISO/IEC 17020, ILAC-P10 (Policy on the traceability of measurement results), ILAC-P14 (Policy for uncertainty in calibration) have been considered as a basis, highlighting the changes in Standard MSZ EN ISO/IEC 17025 applicable to this area.

2. **Personal and material scope**

The **personal scope** of the present rules of procedure covers all parties involved in the accreditation procedure performed by National Accreditation Authority (hereinafter: NAH) where traceability of the measurements is a requirement.

The **material scope** of the procedure covers the accreditation, extension of scope and surveillance procedures by NAH.

3. **Definitions**

**Metrological traceability**

The property of a measurement result whereby the result can be related to a reference (SI international system of units) through a documented **unbroken chain of calibrations**, each chain link contributing to the **measurement uncertainty** calculated by using the appropriate method.

**Competent Laboratory**

The calibration laboratory satisfying the requirements of Standard MSZ EN ISO/IEC 17025, which is the basis of accreditation.

**Abbreviations**

- CIPM: International Committee for Weights and Measures
- MRA: Mutual Recognition Arrangement
- BIPM: Bureau International des Poids et Mesures (fr.), International Bureau of Weights and Measures (en)
- KCDB: Key Comparison Data Base:
- CMC: Calibration and Measurement Capabilities
- NMI: National Metrological Institute
4. Description of the regulation

4.1. Ensuring traceability in calibration and testing laboratories based on Standard MSZ EN ISO/IEC 17025

According to Standard MSZ EN ISO/IEC 17025 (hereinafter: Standard) ‘All equipment used 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 result of the measurements, calibrations or samplings shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.’

For calibration laboratories, traceability to the measurement standard achieving the base unit of the SI international system of units shall be ensured by traceability to international, national or other nation’s national measurement standard.

For testing laboratories, the requirements given under the previous point apply for equipment, tools used for measuring, unless it has been established that the calibrated status of the equipment has a negligible impact on the extended measurement uncertainty of the result, that is, the measurement uncertainty of the measuring equipment is negligible compared to the other components of uncertainty. When this situation arises, ‘the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.’

According to the standard, where traceability of measurements to SI units cannot be currently ensured, reliability of measurements can be ensured by the application of certified reference materials from competent manufacturers reliably providing the physical and chemical characteristics of the materials, or by the use of methods and/or measurement standards that the interested parties agree about.

The standard allows calibration laboratories to issue calibration certificates not including the measurement result and the measurement uncertainty – as agreed on with the customer –, but including a statement on compliance with a specified metrological requirement. In that case, for a purpose of eventual referencing later, the laboratory shall record the measured values and measurement uncertainty. When statements of compliance are made, the uncertainty of measurement shall be taken into account.

Based on ILAC-P14, when the calibration laboratory provides the result as given in the previous paragraph, the calibration certificate cannot be used to ensure further metrological traceability (for the calibration of other measuring equipment).

According to the standard, the laboratory shall ensure tractability to SI units of measurement:

- by calibration performed by a competent laboratory;
- by the certificate of certified material sample produced by a competent manufacturer traced back to SI measurement unit;
- by direct practical achievement of the SI unit through direct or indirect comparison with a national or international measurement standard.

According to the standard, where metrological traceability to SI is technically not feasible, the laboratory shall ensure traceability to an appropriate reference,

- by the documented value of certified material sample produced by a competent manufacturer;
Metrological traceability

- by measurement standards adopted as a result of a measurement procedure, specified method or agreement which are clearly defined and are appropriate for the intended purpose, and have been involved in appropriate comparisons.

In exceptional cases, Annex ‘A’ of the Standard MSZ EN ISO/IEC 17025 published in 2018 allows ensuring traceability in a case where the certificate or report of a competent laboratory does not contain the measured values and measurement uncertainty, it only contains a statement on compliance with a certain specification. In that case, in calculating measurement uncertainty, the range of compliance must be considered as follows:

- By applying appropriate decision-making rules in establishing compliance (by considering the range of compliance, the measurement uncertainty);
- By the proper treatment of the limits of specification (range of compliance) in calculating measurement uncertainty (e.g., according to OIML R 111 referenced in the next paragraph).

The specification used as the basis of assessment of compliance indicates a measurement range with the correct value laying in it with a determined probability, with attention to the systematic errors and measurement uncertainty (e.g.: some class accuracy weights according to requirement OIML R 111 used in the calibration of balances).

4.2. Ensuring traceability in medical testing laboratories based on Standard MSZ EN ISO 15189

Based on Standard MSZ EN ISO 15189 all equipment influencing test results used in medical laboratory tests, which have a major impact on the accuracy or validity of measurements, and their results, shall be calibrated according to the technical specific rules in ILAC-P10 prior to putting into operation. The medical laboratory shall have an established programme and procedure for the calibration of its equipment. Furthermore, if traceability according to ILAC P10 is ensured by the supplier or manufacturer, NAH checks at the site audit or at the time of double-checking corrective actions if documentation of statements regarding reagents, procedures or testing systems are available.

For medical testing laboratories, the requirements given in 4.1 are applicable to equipment used in measurement, unless it has been established that the calibrated status of the equipment has a negligible impact on the expanded measurement uncertainty of the result. When this situation arises, ‘the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.’

4.3. Ensuring traceability in measurements of inspection bodies

In inspection activities, the measurement uncertainty related to the given test usually gives limited information in respect of the validity of the final result of inspection. If the test does not produce numerical results, traceability is usually less significant.

According to Standard MSZ EN ISO/IEC 17020, the full calibration programme of the equipment shall be planned and operated with a view to ensure the traceability of measurements performed by the inspection body in the given case to the national or international measurement standards, if there are any. Where traceability to national or international measurement standards cannot be applied, the inspection organisation shall demonstrate the correlation or accuracy of the inspection results.
Standard MSZ EN ISO/IEC 17020 requires that the performance of the equipment and the reference standard applied should be traceable. Traceability requirements according to the sources of measurement uncertainty:

- traceability of reference standards, reference materials applied and the calibrated status of equipment applied shall be ensured,
- environmental conditions can be monitored by calibrated equipment with traceability, as appropriate.

Measurement uncertainty can also be considered by the determination of the inspection method in detail, selection of the level of acceptability and limitation on the environmental conditions.

4.4. Organisations providing traceability

A laboratory providing traceability shall satisfy the requirements of these rules of procedure. Several methods can be used for the verification thereof, e.g., recognition by a third party (by an accreditation organisation), by customer audit and by self-certification.

4.4.1. Internationally recognised organisations (based on ILAC-P10):

- National metrological institutes or notified organisations whose activities have undergone compliance assessment under CIPM MRA. Their services can be found in Annex C of BIPM KCDB, together with their calibration and measurement capabilities (https://kcdb.bipm.org/appendixc/)
- Calibration laboratories accredited by accreditation organisations, signatories to ILAC MLA or ILAC recognised Regional Agreement, which laboratories give evidence to the metrological traceability and whose services, together with their calibration and measurement capabilities can be found on the public websites of the national accreditation organisations;
- Reference material producers who are in compliance with Standard MSZ EN ISO 17034;
- If none of the three previous options can be achieved, ILAC-P10 allows the use of such NMI service which is not under CIPM MRA but is in compliance with the planned demands. It allows the use of a service of an accredited laboratory which service is not under the scope of the ILAC Agreement or Regional Agreement recognised by ILAC, but is in compliance with the planned demands.

In the latter case, that is, when none of the previous three conditions are met, NAH establishes the following requirements:

- Documented, validated calibration procedure shall be available including the calculation of measurement uncertainty according to the current Standard ‘ISO/IEC 17025’;
- Educated, authorised personnel;
- Traceable working standards in compliance with the demands;
- Ensuring environmental conditions suitable for the measurement task and their registration;
- Ensuring documented quality of the results;
- Evidenced proficiency of the laboratory in the given activity.

4.4.2. Requirements applicable to the calibration of measurement standards of accredited testing laboratories and calibration laboratories of their own within their own competence

In respect of the calibration of their own measurement standards performed within their own competence, both testing and calibration laboratories shall verify if the above requirements of NAH are met.

A testing laboratory does not need to get accreditation as a calibration laboratory, but when a testing laboratory is being accredited, it must be reviewed whether the above requirements of NAH are met.

5. Related rules of procedure and rules of law

- VIM: International vocabulary of basic and general terms in metrology (current valid version to be found at: https://www.bipm.org/en/publications/guides/vim.html)
- MSZ EN ISO/IEC 17025
- MSZ EN ISO 15189
- MSZ EN ISO/IEC 17020
- ILAC-P10 Policy on the traceability of measurement results
- ILAC-P14 Policy for uncertainty in calibration

6. Annexes

No annex is attached to these Rules of procedure.

7. Forms

No form is attached to these Rules of procedure.