LATAK-D.034-07/07.2021

LATAK Policy for the Metrological Traceability of Measurement Results

Table of Content

Purpose

This document outlines the Policy of the State Agency "Latvian National Accreditation Bureau" (hereinafter – LATAK) with regard to metrological traceability of measurement results applicable to the conformity assessment bodies (hereinafter – Body) in the field of testing and calibration.

This Policy shall be applicable also to other conformity assessment activities involving testing and/or calibration (e.g., medical laboratories, inspection, product certification, proficiency testing providers). Calibration, which is performed by a laboratory to establish metrological traceability of own laboratory activities and does not form part of the scope of accreditation of the laboratory, shall be subject to LATAK Policy referred to in Paragraph 3. In English, the internal calibration performed by the conformity assessment body itself, is also known as the in-house calibration.

1. Terms and Definitions

BIPM
Bireau International des Poids et Mesures
International organization through which the Member States act together in matters of the science of measurements and measurement standards.

CIPM MRA
Mutual recognition arrangement of weights and measures
CIPM MRA is a mutual recognition arrangement between the national metrology institutions providing a technical basis to ensure the mutual recognition of national measurement standards and the validity of those calibration and measurement certificates issued by national metrology institutes.

CRM
Certified reference material
Reference material characterized by 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 uncertainty, and a statement of metrological traceability (ISO 17034:2016).

JCTLM
Joint Committee for Traceability in Laboratory Medicine
The JCTLM is comprised of the International Bureau of Weights and Measures (BIPM), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the International Laboratory Accreditation Cooperation (ILAC). The JCTLM provides a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements and traceability to appropriate measurement standards.

KCDB
Key Comparison Database
Publicly accessible database and a web resource related to the CIPM MRA, the use of which is free of charge. It contains information on the participants of the CIP MRA, results of key and supplementary comparisons and the updated (reviewed) calibration and measurement capabilities (CMCs) (see: http://www.bipm.org/kcdb).

Metrological traceability (VIM 3, 2.41)
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. NOTE: For the purpose of this definition, "reference" may refer to the definition of a measurement unit through its practical realization, or a measurement procedure, including the measurement unit for a non-ordinal quantity, or a measurement standard.
The standards LVS EN ISO/IEC 17025 and LVS EN ISO 15189 shall be applicable to the VIM's "metrological traceability".

Metrological traceability chain (VIM 3., Clause 2.42)
Sequence of measurement standards and calibrations used to relate a measurement result to a reference.

Metrological traceability to a measurement unit (VIM 3, Clause 2.43)
Metrological traceability where the reference is the definition of a measurement unit through its practical realization.
NOTE: The expression "traceability to the SI" shall refer to "metrological traceability to a measurement unit of the International System of Units".

NMI
National Metrology Institute
National Metrology Institute (NMI) and Designated Institute (DI) that maintain measurement standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both institutes.

RM
Reference material
Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034: 2016).

RMP
Reference material producer
Public or private company that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces (ISO 17034: 2016).

2. LATAK Policy for Ensuring the Metrological Traceability of Measurement Results

Metrological traceability is ensured through the calibration of measurement equipment

1) NMI the services of which are fit for their intended use and are included in the CIPM MRA. Information on the providers of services covered by the CIPM MRA is

available in the BIPM KCDB (http://www.bipm.org/kcdb), showing the scope and uncertainty of each service provided.

NOTE 1: Some NMIs may indicate that their services are covered by the CIPM MRA by placing the CIPM MRA logo on the certificate. However, the use of the logo is optional, and the BIPM KCDM remains the authoritative source of assurance.

NOTE 2: Those NMIs which are members of the Metre Convention may use metrological traceability directly from BIPM measurements. KCDB is a direct automatic link to the respective BIPM calibration service provider (including the scope and uncertainty). The BIPM list includes individually issued calibration certificates.

OR

2) An accredited calibration laboratory the services of which are suitable for the intended needs (i.e., the scope of accreditation includes the appropriate calibration), and the accreditation body is a signatory to the Multilateral Agreement (MLA) in the field of calibration.

NOTE 3: The calibration certificate must contain the accreditation symbol or a textual reference to accreditation. The calibration certificates (if applicable) may contain the EA MLA or ILAC MRA symbol. Both options confirm metrological traceability.

OR

3a) NMI the services of which are suitable for the intended needs but are not included in the CIPM MRA.

3b) Laboratory the calibration services of which are suitable for the intended needs, but is not accredited.

Bodies able to demonstrate metrological traceability of their measurement results, using the services referred to in Clauses (1) and (2) above, confirm their compliance with the requirements, and they are not required to undergo additional assessment, except for the cases referred to in Paragraphs 3(a) and (b), which shall be applicable only in situations where a case referred to in Clauses (1) and (2) is not available. The accredited Body shall present evidence for metrological traceability and uncertainty of measurements, whereas LATAK shall evaluate this evidence (see ANNEX to this document).

Measurement results shall be traceable to the International System of Units, applying the certified values of the certified reference materials provided by a competent producer with the established metrological traceability to the SI. The Body shall take into account the fact that reference material producers, when determining the values of certified reference materials, provide metrological traceability as follows:

4) The CRMs are produced by a NMI that uses the services included in the BIPM KCDB.

5) The CRMs are produced by an accredited RMP in accordance with the granted accreditation, and the accreditation body granting the accreditation is a signatory to the Multilateral Agreement (MLA) in the field of reference material production.

6) The certified values assigned to the CRM are covered by entries in the JCTML database.

The RMP accreditation is now in its development stage, and the CRM are not always provided by accredited RMPs. Furthermore, if the CRMs are produced by a non-accredited RMP, the Body must demonstrate that the CRMs have been provided by a competent RMP and are fit for their intended use.

If metrological traceability to the SI is not possible in technical terms, the Body shall:

7a) Choose the way to ensure the compliance with the requirements for metrological traceability, using the certified values of certified reference materials provided by a competent producer.

OR

7b) Document the results obtained through appropriate reference measurement procedures, established methods or approved standards. The comparisons made shall be recorded/ described, and it shall be confirmed that the issued measurement results are fit for their use. These confirmation approvals shall be evaluated by LATAK.

NOTE 4: If metrological traceability to the SI alone is not appropriate or fit for use, the selected measurand shall be clearly defined. The established metrological traceability shall include both the confirmation of the accuracy of the measurand and the comparison of the results against the respective established reference. The confirmation shall be made, implementing a validated or verified procedure, properly calibrating measurement equipment and ensuring controlled measurement conditions (e.g., environmental conditions), thus assuring reliable results.

NOTE 5: Given that the proficiency testing providers provide only the remains of test materials, it is important to verify whether the proficiency testing provider is able to provide further information of the values of the test material properties and constant stability of the matrix. Otherwise, these test materials cannot be evaluated as an alternative method, in order to make sure the results are reliable.

3. In-House Calibration of Laboratory Equipment

Bodies may calibrate their own equipment, if they are able to demonstrate appropriate competence and traceability of measurement results. These activities must meet all requirements outlined in the binding documents of LATAK and the standard LVS EN ISO/IEC 17025:2005, which are applicable to calibration laboratories. These activities are assessed by LATAK in the same way as assessing the accredited calibration laboratories, and the assessment panel may involve the respective technical expert or assessor.

ANNEX

If the traceability has been established in accordance with Paragraphs 3(a) and (b) of the Policy, the Body shall undertake the necessary measures, as specified in this Policy, which shall be taken in account by LATAK during the ordinary assessment.

Sufficient evidence for the technical competence of the laboratory and its entitlement to metrological traceability may include, but is not limited to, the following (see the respective clauses of the standard LVS EN ISO/IEC 17025:2017 in parenthesis):

- records on the validity of the calibration method (7.2.2.4);
- procedures for the evaluation of measurement uncertainty (7.6);
- documentation and records on the metrological traceability of measurement results (6.5);
- documentation and records on ensuring the validity of calibration results (7.7);
- documentation and records on the personnel competence (6.2);
- records on the equipment that can affect the laboratory activities (6.4);
- documentation and records on facilities and environmental conditions (6.3);
- audits of calibration laboratories (6.6 and 8.8).

Those non-accredited laboratories offering their services shall take into account the fact that they may need to undergo the practical assessment of the laboratory, similarly to that performed by an accreditation body when assessing the conformity with the requirements laid down in the standard LVS EN ISO/IEC 17025, in order to make sure that the respective service is provided with relevant competence.

The application of Paragraphs 3(a) and (b) shall not be justified by financial considerations – it shall be the last resort, if no other approaches are feasible.

References

1. International Vocabulary of Metrology – Basic and General Concepts and Associated Terms VIM, 3rd edition, JCGM 200:2012 (JCGM 200:20008 with minor corrections) available from the BIPM homepage www.bipm.org or ISO/IEC Guide 99:2007 available from ISO.

2. LVS EN ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories (ISO 17025:2017).

3. LVS EN ISO 15189:2013 – Medical laboratories – Requirements for quality and competence (ISO 15189:2012).

4. LVS EN ISO/IEC 17043:2015 – Conformity assessment – General requirements for proficiency testing (ISO/IEC 17043:2010).

5. ILAC-P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results.

6. LVS ISO 17034:2017 – General requirements for the competence of reference material producers (ISO 17034:2016).

Register of Changes

Version	Scope of changes	Date
07	Structural changes where the requirements are applied to all fields in general, while retaining the basic information.	1 July 2021
	Removal of the reference to LVS EN ISO/IEC 17025:2017 in the Policy. The Policy was developed independently so that it would be applicable also in case of other accreditation standards (e.g., ISO/IEC 17020).	
	Throughout the text, the term “traceability” has been replaced by the term “metrological traceability”.	
	Addition of the definitions of CIPM MRA, KCDB, RMP and CRMP in the section “Definitions”.	
	Removal of the text of ISO/IEC 17025:2005, updating of the information with regard to the new version of LVS EN ISO/IEC 17025:2017 and addition of LVS ISO 17034:2017.	
	Annex with regard to the Paragraphs 3(a) and (b) for illustrative purposes	