

1. PURPOSE

The purpose of this Guideline is to regulate measures required to ensure and demonstrate the metrological traceability of testing results, calibrations and measurements to national and international measurement standards. The policy established in this Guideline may also be applied to other conformity assessment activities where testing and/or calibration is involved (e.g., inspection and product certification).

2. SCOPE

This Guideline covers measurement, calibration, and validation of test and measurement instruments by conformity assessment bodies which have been accredited or have filed an application for accreditation.

3. ABBREVIATIONS AND DEFINITIONS

3.1 Abbreviations:

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| APAC | : Asia Pacific Accreditation Cooperation |
| BIPM | : International Bureau of Weights and Measures |
| CMC | : Calibration and Measurement Capability |
| CRM | : Certified Reference Material |
| EA | : European Co-operation for Accreditation |
| EN | : European Standard |
| IAAC | : Inter American Accreditation Cooperation |
| IEC | : International Electrotechnical Commission |
| ISO | : International Organization for Standardization |
| JCTLM | : Joint Committee for Traceability in Laboratory Medicine |
| KCDB | : Key Comparison Database |
| MLA | : Multilateral Recognition Arrangement |
| MRA | : Mutual Recognition Arrangement |
| NMI | : National Metrology Institute |
| RM | : Reference Material |
| RMP | : Reference Material Producer |
| SI | : International System of Units |
| VIM | : International Vocabulary of Metrology. |

3.2 Definitions

3.2.1 Metrological traceability (VIM 3 clause 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: Clause 2.41 states that a 'reference' can be a "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."

In ISO/IEC 17025 and ISO 15189 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "metrological traceability" is used throughout this Guideline.

3.2.2 Metrological traceability chain (VIM 3 clause 2.42)

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

3.2.3 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" means metrological traceability to a measurement unit of the International System of Units.

3.2.4 National Metrology Institute

National Metrology Institutes (NMIs) and Designated Institutes (DIs) are responsible for realizing and maintaining national measurement standards in their countries or regions in accordance with the definition in the International System of Units (SI), ensuring these standards' equivalence to international measurement standards and providing metrological traceability to secondary and lower level laboratories within the country. Throughout this Guideline, the term "National Metrology Institute" is used to cover both National Metrology Institutes as well as Designated Institutes.

4. APPLICABILITY

The policies and requirements in this Guideline apply to accreditation processes where the following standards are used as criteria:

- ISO/IEC 17025-General requirements for the competence of testing and calibration laboratories
- ISO 15189-Medical laboratories – Particular requirements for quality and competence
- ISO/IEC 17020-Conformity assessment – Requirements for the operation of various types of

bodies performing inspection

- ISO/IEC 17043-Conformity assessment – General requirements for proficiency testing
- ISO/IEC 17065-Conformity assessment – Requirements for bodies certifying products, processes and services
- ISO 17034-General requirements for the competence of reference material producers

5. POLICY

NBE's policy on calibration of measurement instruments and metrological traceability of measurement results is described below. This policy is established to define NBE rules related to how the metrological traceability requirements defined in ISO/IEC 17025 standard will be fulfilled:

1. An organization using external calibration services shall ensure metrological traceability of the equipment which contributes significantly to the results of tests, calibrations and samplings through Route-1 or Route-2 listed under Clause 6 of this policy in order to fulfil the metrological traceability requirements defined in ISO/IEC 17025 standard.

2. Where an organization using external calibration services has used non-calibrated equipment in tests, calibrations and measurements within the scope of its accreditation, it shall demonstrate to NBE that the equipment in question contributes insignificantly to the uncertainty of measurement results.

3. An organization using external calibration services shall retain the records on the competence of the calibration provider.

4. An organization using external calibration services shall adopt a proactive approach to fulfil the metrological traceability requirements defined in ISO/IEC 17025 standard.

5. An organization using external calibration services shall present NBE with justification where it ensures metrological traceability through Route-3 described in this policy. Solely economic or logistic reasons do not constitute justification to ensure metrological traceability through Route-3 under Clause 6. If a service provider which ensures metrological traceability according to the first or second route cannot be found within the same economy, foreign service providers should also be contacted. Where it is demonstrated that competence requirements are fulfilled to this Guideline, the use of Route-3 is allowed. The organization receiving the calibration service shall present to NBE the records that the metrological traceability provider is searched in accordance with this Guideline.

6. The external service provider providing metrological traceability according to Route-3 shall be assessed by the laboratory receiving the calibration service for the relevant calibration and

measurement capabilities (CMCs) in the context of the standard and this Guideline. In addition, its conformity to the standard and this Guideline shall be ensured. This assurance shall be ensured with an assessment by the competent person in the laboratory providing the service. In such cases, NBE may supervise the assessments carried out by the laboratory using external services in order to ensure the competence of the laboratory using external services. The laboratory using external services shall define terms in the contract such that the service provider laboratory will enable the above-mentioned oversight. All records of the evaluation process shall be presented to the NBE assessment team during the assessment process.

7. Assessments of traceability are carried out separately on each metrological traceability evidence alleged for all routes.

If the first two routes are not possible, a laboratory intending to provide metrological traceability via Route-3; shall demonstrate the calibration provider from which it receives service meets the relevant requirements of ISO/IEC 17025 standard with the minimum documents and records specified in Annex A.

8. An organization using external calibration services shall demonstrate the evidence for the competence of external service provider providing metrological traceability via Route-3 to NBE during the accreditation process. NBE shall include competent assessor(s) in the assessment team to that end, and assess the documented evidence and records demonstrating the competence of the external service provider used by the laboratory being assessed. The organization receiving the calibration service must follow the hierarchy specified in Annex B.

9. According to the clauses of G-2-18 NBE Marked Laboratories Test and Calibration Reports, a calibration laboratory accredited by NBE pursuant to the aforesaid document shall use the accreditation symbol in its calibration certificates/reports.

As indicated in General Requirements of ILAC P8 “Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies”, only certificates/reports that have the accreditation symbol/logo/mark may fully benefit from the recognition accorded by the ILAC MRA and Regional Arrangements (EA, APAC, IAAC etc.) recognised by ILAC.

Therefore, calibration certificates issued by calibration laboratories accredited by an accreditation body other than NBE, which is covered by the ILAC Arrangement or by Regional Arrangements (EA, APAC, IAAC etc.) recognised by ILAC shall have the accreditation mark or the reference information to accreditation status in order for such certificates to constitute an evidence of traceability. Where the accreditation symbol is missing, it is the responsibility of the organization using external calibration services that the calibration in question has been provided by an organization accredited in the relevant scope.

10. Reports / certificates issued by traceability providers that are not accredited in the field of calibration but are certified to ISO 9001, even if the traceability provider is certified by an accredited certification body, are not recognized as evidence of traceability,

11. In order to maintain confidence in the calibration status of the equipments, CABs should consider ILAC-G24/OIML D 10 (E) Guidelines for the Determination of Calibration Intervals of Measuring Instruments document.

12. The clauses of this Guideline apply also to traceability in respect of organizations using internal calibration.

6. METROLOGICAL TRACEABILITY ROUTES, SELECTION AND DOCUMENTATION

The documentation on the selection and competence of the **metrological traceability routes** shall as a minimum include the following.

6.1 Metrological Traceability Routes

The ILAC P10 evaluated the routes related to metrological traceability under three routes as follows.

Route-1: A national metrology institute whose service is suitable for the intended need and is covered by the CIPM MRA and whose calibration and measurement capability (CMC) is published on BIPM KCDB. Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB.

Route-2: A laboratory accredited according to ISO/IEC 17025 by the Accreditation Body which is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC in the field of calibration, providing the intended calibration service in the scope of accreditation.

Route-3:

- a)** A national metrology institute whose service is suitable for the intended need but is not covered by the CIPM MRA.
- b)** A calibration laboratory whose service is suitable for the intended need but is not accredited according to ISO/IEC 17025 by the Accreditation Body which is covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC.

NOTE: The calibration activities of the organizations performing internal calibration cannot be evaluated in the context of the routes specified in this Guideline. Organizations that perform calibration in the areas not covered by the accreditation in order to ensure only their metrological traceability (organizations performing internal calibration), shall be assessed according to ISO/IEC 17025, this Guideline and other relevant documents.

6.2 Selection of Route-1 or Route-2

621 The laboratory shall verify that the calibrations provided by the calibration organization, are in compliance with the requirements of ISO/IEC 17025 for metrological traceability, have appropriate measurement uncertainties and meet the requirements of this Guideline for required measurement areas and ranges.

622 The laboratory shall verify that the calibration certificates issued by the organization from which the calibration service is received meet ISO/IEC 17025 requirements on calibration certificates.

Note: The scope of such a verification process may include the examination of a database on the Web, evaluation of the documentation for accreditation, and review of the scope of the calibration laboratory.

6.3 Selection of Route-3

In cases where it is not possible to provide metrological traceability through Route-1 and Route-2, a laboratory carrying out test and sampling activities and seeking to provide metrological traceability through Route-3, shall maintain records of activities stated in Clause 5 for the purpose of determining the competence of the calibration provider from which the laboratory is planning to obtain the calibration service and the records for the evaluation of these activities in order to present them to NBE.

The calibration provider providing metrological traceability through Route-3 shall at least provide documents and records as specified in the Annex A to demonstrate competence. NBE may request additional documents during the assessment process.

631 The laboratory shall provide calibrations that meet metrological traceability requirements of ISO/IEC 17025 for the needed measurement services and ranges with appropriate measurement uncertainties.

632 The laboratory shall ensure that the content of the calibration certificate issued by the calibration provider providing metrological traceability through Route-3 complies with the ISO/IEC 17025 requirements for calibration certificates.

633 The laboratory shall obtain and keep the following documents and records:

- Records that the laboratories receiving calibration services from calibration provider that provide metrological traceability through Route-3 have received this service by researching according to the hierarchy given in Annex-B,
- Records of the metrological traceability of standard devices used by the calibration provider providing metrological traceability through Route-3,
- Minimum documents and records in Annex A demonstrating the technical competence and the claimed metrological traceability of the calibration provider providing metrological

traceability through Route-3 in addition to the records concerning the evaluation of the above-mentioned records. In the evaluations of staff competence, the identity of the staff should be traceable.

7. TRACEABILITY REQUIREMENTS IN THE ABSENCE OF DIRECT TRACEABILITY TO SI UNITS

In some cases, metrological traceability to SI units may not be possible. In this case, it shall be stated with justifications that the requirements in Clause 6 of this Guideline cannot be met.

In this case, the selection of the route to meet the requirements of ISO/IEC 17025 regarding metrological traceability is the responsibility of the laboratory that receives the calibration service. The laboratory receiving the calibration service should provide appropriate and documented evidence. Such situations are evaluated separately in accordance with the specific circumstances of the laboratories in the assessment processes.

8. METROLOGICAL TRACEABILITY REQUIREMENTS UNDER THE ILAC ARRANGEMENT IN TESTING

The ILAC Arrangement in testing covers testing laboratories accredited according to ISO/IEC 17025 and medical laboratories accredited according to ISO 15189. Considering ISO/IEC 17025 and ISO 15189 standards the following requirements shall be taken into account.

- a) If the calibration of instruments used in testing contributes significantly to the overall uncertainty, the requirements in Clauses 6 and 7 of this Guideline shall be taken into account.
- b) If a calibration is not a dominant factor in the testing result, the laboratory shall present quantitative evidence to demonstrate that the effect of the uncertainty from the calibration on the measurement results is not significant.

9. REQUIREMENTS FOR TRACEABILITY PROVIDED THROUGH CERTIFIED REFERENCE MATERIALS (CRMs)

NBE's policy on metrological traceability of reference materials is as follows:

9.1 CRMs, produced and have their values assigned by a national metrology institute covered by the CIPM MRA and whose services are published on BIPM KCDB; or produced by an accredited reference material producer under its accredited scope of accreditation to ISO 17034 are considered to have established valid metrological traceability (see ILAC General Assembly resolution ILAC 8.12).

9.2 The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid metrological traceability.

9.3. The reference materials produced by other reference material producers can be considered as critical consumables. The laboratory shall demonstrate that each RM is suitable for its intended use according to ISO/IEC 17025 and ISO 15189 Standards.

ANNEX A

(MANDATORY)

Minimum documents and records to be presented for the technical competence of the calibration service provider and the claimed metrological traceability:

- ✓ Records of calibration method validation
- ✓ Procedures and records for estimation of measurement uncertainty
- ✓ Documentation and records for metrological traceability of measurements
- ✓ Documentation and records for assuring the quality of calibration results
- ✓ Documentation and records for competence of staff
- ✓ Documentation and records for accommodation and environmental conditions
- ✓ Documentation and records for internal audit of the calibration laboratory

Other documentation and records stipulated in this Guideline shall also be presented to NBE. NBE may request additional documents.

ANNEX B

(MANDATORY)

When metrological traceability is provided through Route-3, an organization using external calibration services shall comply with the following hierarchy:

- 1)** A national metrology institute which is covered by the CIPM MRA but whose calibration and measurement capability is not published on KCDB for the intended calibration service. In such cases, the references used by such national metrology institutes for the intended calibration service shall be metrologically traceable through Route-1 or Route-2.
- 2)** A laboratory which is accredited to ISO/IEC 17025 Standard by an accreditation body signatory to the Recognition Arrangement with at least one of EA, ILAC, APAC or IAAC, but does not provide the intended calibration service in the scope of accreditation. In such case, the references used by such laboratory offering calibration service shall be metrologically traceable through Route-1 or Route-2.
- 3)** External service providers that provide metrological traceability of their services through Route-3, whose own references used in the intended calibration service are metrologically traceable through Route-1 or Route-2. Such metrological traceability may be obtained through several stages.
- 4)** A calibration service provider that has demonstrated metrological traceability of its measurements through the Route-3, which claims metrological traceability to national standards shall prove that such national standards fulfil the properties of primary standards for the realization of SI units. The laboratory shall maintain records that the metrological traceability chain established in this way meets the requirements of the standard.