

## 1. PURPOSE

The purpose of this guideline is to regulate the measures necessary to ensure the metrological traceability of test, calibration and measurement results to national and international measurement standards and to demonstrate metrological traceability. The policies described in this guideline also apply to other conformity assessment activities (product certification, inspection, etc.), where testing and/or calibration studies take place.

## 2. SCOPE

This guideline covers measurement, calibration, testing and verification of measuring devices performed by conformity assessment bodies which are accredited or have applied to be accredited.

## 3. ABBREVIATIONS AND DEFINITIONS

**Metrological Traceability (VIM 3 Article 2.41):** "Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibration each contributing to the measurement uncertainty".

Note: "For this definition, 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 17025:2005 and ISO 15189:2007 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this Guideline.

**Metrological traceability chain (VIM 3 Article 2.42):** "Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference".

**Metrological traceability to a measurement unit (VIM 3 Article 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'". National Metrology Institute: National Metrology Institutes (NMIs) and Designated Institutes (DIs) are responsible for developing and maintaining national measurement standards in their countries or regions according to International Systems of Units (SI), ensuring equivalence to international measurement standards and providing metrological traceability to secondary (or less) level laboratories in the country. Throughout this Guideline, the term "National Metrology Institute" is used to cover both National Metrology Institutes as well as Designated Institutes.

## 4. SCOPE OF IMPLEMENTATION

The policies and requirements defined 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 service
- ISO 17034 - General requirements for the competence of reference material producers.

## 5. POLICY

NAC's policy on calibration of measurement instruments and metrological traceability of measurement results is described below. This policy is established to define NAC rules on how to fulfill metrological traceability requirements in accordance with ISO/IEC 17025:

1. In order to meet the metrological traceability requirements of the ISO/IEC 17025 standard, an organization receiving calibration service must ensure the metrological traceability of the equipment, which contributes significantly to the results of testing, calibration and sampling within the scope of accreditation, through the first and second route specified under Clause 6.
2. If an organization receiving calibration service has used non-calibrated equipment in the tests, calibrations and measurements within the scope of its accreditation, it must show to NAC that the contribution of the equipment in question to the measurement uncertainty of the results obtained is insignificant.
3. An organization receiving calibration services must keep records on the competence of the calibration provider.
4. An organization receiving calibration services must adopt a proactive approach to meet the requirements of the ISO/IEC 17025 standard for metrological traceability.
5. An organization receiving calibration services must submit its justification to NAC if it provides metrological traceability through Route-3 specified in this policy. Metrological traceability cannot be provided through Route-3, which is stated in Article 6, only for economic or logistical reasons. Foreign service providers should also be contacted if there is no service provider in the same economy that can provide metrological traceability through the first and second routes. If it is shown that the requirements for competence are met in accordance with this Guideline, the use of Route-3 is allowed. An organization receiving calibration services must submit to NAC records of the search for a metrological traceability provider that comply with this Guideline.
6. An external service provider that provides metrological traceability in accordance with Route-3 must be evaluated by the laboratory that receives the calibration service for the relevant calibration and measurement capabilities (CMCs) in the context of the standard and this guideline, and its conformity must be ensured. This assurance must be provided by an assessment to be carried out by competent persons in the relevant field in the laboratory providing the service. In such cases, in order to ensure the suitability of the external service received, NAC may supervise assessments carried out by the laboratory receiving service to ensure that the laboratory receiving the service is competent. A laboratory receiving external services must include in its contract the provisions that will allow the above-mentioned supervision in the laboratory which provides services. All records of the evaluation process must be submitted to the NAC assessment team

during the assessment process. In addition, where calibration cannot be performed according to the methods available in accredited laboratories (for example, when the equipment is too complex or only the producer has the appropriate infrastructure for calibration, etc.) use of Route-3 may be permitted.

**7.** Traceability evaluations are performed separately for each of the metrological traceability evidence claimed for all routes. If the first two routes are not possible, a laboratory that intends to provide metrological traceability through Route-3 must prove that the calibration provider from which it receives service meets the relevant requirements of the ISO / IEC 17025 standard with the minimum documents and records specified in Annex A.

**8.** An organization receiving calibration services must demonstrate evidence to NAC during the accreditation process that the external service provider providing metrological traceability through Route-3 is competent. For this purpose, NAC includes competent assessors/technical experts in the assessment team and evaluates the documented evidence and records demonstrating the competence of the external service provider used by the laboratory being assessed. An organization receiving calibration services must follow the hierarchy specified in Annex-B.

**9.** According to the Guidelines on Test Reports and Calibration Certificates with NAC Mark, a calibration laboratory accredited by NAC is required to use the accreditation mark in calibration certificates/reports as specified in this Guideline. ILAC P8 "Mutual Recognition Arrangement (Arrangement): As indicated in the General Requirements of "Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies", only reports/certificates 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.) recognized by ILAC.

Therefore, calibration certificates issued by calibration laboratories accredited by an accreditation body, other than NAC, which is covered by a recognition arrangement with ILAC or by one of the regional accreditation associations (EA, APAC, IAAC, etc.) recognized by ILAC must have the accreditation mark or reference information related to accreditation status in order for such certificates to be considered as evidence of traceability. In cases where the accreditation mark is not available, it is the responsibility of the party receiving service to show that the calibration in question has been performed by an accredited organization within the appropriate scope.

**10.** Reports / certificates issued by traceability providers who are not accredited in the field of calibration but have ISO 9001 certification, even if they are certified by an accredited certification body that provides traceability, cannot be accepted as traceability evidence.

**11.** In order to maintain the reliability of the calibration status of their calibrated equipment, organizations should regulate their calibration intervals, taking into account ILAC-G24 / OIML D 10 "Guidelines for the Determination of Calibration Intervals of Measuring Instruments".

**12.** For organizations that conduct internal calibration, the clauses of this Guideline also apply to traceability.

## Documentation on Metrological Traceability Routes, Selection and Process

Documentation on the selection and competence of the metrological traceability route must as a minimum include the following.

### Metrological Traceability Routes

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

**Route-1:** a national metrology institute that is a party to CIPM MRA Arrangement regarding the requested service and has calibration and measurement capability (CMC) published in the BIPM KCDB database. Services covered by CIPM MRA can be viewed in BIPM KCDB Annex C.

**Route-2:** A laboratory accredited according to ISO / IEC 17025 standard by an accreditation body covered by ILAC arrangement or regional arrangements recognized by ILAC in the field of calibration and has the service requested within the scope of accreditation.

**Route-3:** a) A national metrology institute whose service is suitable for the intended need but is not a party of 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 an Accreditation Body which is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

Note: Calibration activities of internal calibration organizations cannot be evaluated in the context of the routes specified in this guideline. The activities of organizations (organizations performing internal calibration) performing calibration, which is not covered by the accreditation, only to ensure their own metrological traceability are evaluated according to ISO/IEC 17025, this guideline and relevant documents.

### Selection of Route-1 or Route-2

A laboratory must verify that the calibrations provided by the organization from which the calibration service is received are in accordance with the requirements of ISO/IEC 17025 regarding metrological traceability, that they have appropriate measurement uncertainties, and that they fulfill the requirements of this guideline for the required measurement areas and intervals.

A laboratory must verify that the calibration certificates issued by the organization from which the calibration service is received fulfill the requirements of ISO/IEC 17025 for calibration certificates.

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

### Selection of Route-3

Where metrological traceability is not possible through Route-1 and Route-2, a laboratory performing testing and sampling activities and seeking to provide metrological traceability through Route-3 is required to maintain stated activities and records of these activities so as to present to NAC in order to detect the competence of the calibration provider from which the laboratory intends to receive calibration service.

It is not possible for Calibration Laboratories to be accredited using Route-3. A calibration provider, which provides metrological traceability through Route-3, must as a minimum present the documents and records specified in Annex A to demonstrate its competence. NAC may request additional documents during the assessment process.

The laboratory must provide calibrations in accordance with the requirements of ISO/IEC 17025 for metrological traceability, with appropriate measurement uncertainties, for the measurement areas and intervals it needs.

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

The laboratory must obtain and maintain the following documents and records:

- Records demonstrating that laboratories receiving calibration services from a calibration provider that provides metrological traceability through Route-3 has received this service by conducting research according to the hierarchy given in Annex-B.,
- Records of the metrological traceability of standard devices used by the calibration provider, which provides metrological traceability through Route-3,
- Records related to the evaluation with minimum documents and records specified in Annex-A, demonstrating the technical competence of the calibration provider providing metrological traceability through Route-3 and the claimed metrological traceability. The identity of the personnel should also be traceable in evaluations of personnel competence.

## **Traceability Requirements in the Absence of Direct Traceability to SI Units**

Metrological traceability to SI units may not be possible in some cases. In this case, the reasons for not fulfilling the requirements specified in this guideline must be stated together with reasons. In this case, the selection of the route that will meet the requirements of ISO / IEC 17025 for metrological traceability is the responsibility of the laboratory receiving calibration service. The laboratory receiving calibration services must provide appropriate and documented evidence of this situation. Such situations are evaluated separately in accordance with the specific circumstances of laboratories in the assessment processes.

## **Metrological Traceability Requirements under the ILAC Arrangement in Testing**

The ILAC Arrangement 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 must be taken into account.

- If the uncertainty components resulting from the calibration of the instruments used for the test significantly affect the combined measurement uncertainty of the test, the requirements in this guideline must be taken into account.
- In cases where the calibration of the instruments used for testing does not have a dominant effect on the test results, the laboratory should present quantitative evidence that the effect of uncertainty from the calibration on the measurement results is not significant.

NAC's policy on metrological traceability of certified reference materials (SRM) is as follows:

- The values assigned to CRMs produced by NMIs covered by CIPM MRA and included in the BIPM KCDB "Key Comparison Data Base" or produced by accredited reference material producers under its accredited scope of accreditation to ISO 17034 are considered to have established valid traceability (see ILAC General Assembly resolution ILAC 8.12).
- Certified reference materials entered into the JCTLM database are considered to provide valid metrological traceability of their certified values.
- Reference materials provided by other reference material producers can qualify as critical consumables. The laboratory must demonstrate that each reference material it uses is suitable for the intended use according to the ISO/IEC 17025 and ISO 15189 standards.

## 6. REVISION TABLE

| <b>Date</b> | <b>Section</b> | <b>Amendment</b>                     |
|-------------|----------------|--------------------------------------|
| 19.03.2020  | Header         | The logo is changed                  |
| 22.03.2024  | Header         | Document coding/revision no changed. |



## Annex A (MANDATORY)

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

- Validation records of calibration method
- Procedures and records used for measurement uncertainty
- Documentation and records for metrological traceability of measurements
- Documentation and records to ensure the quality of calibration results
- Documents and records related to personnel competence
- Documents and records related to accommodation and environmental conditions
- Documentation and records related to internal audit of the calibration laboratory

Other relevant documents and records requested in this guideline should also be submitted to NAC. NAC may request additional documents.

## Annex B (MANDATORY)

If metrological traceability is provided through Route-3, the organization receiving calibration services must comply with the following hierarchy.

- 1.** National metrology institute that is covered by CIPM MRA but does not have calibration and measurement capability published in KCDB for the requested calibration. In this case, the metrological traceability of the references used by the National Metrology Institute in the requested calibration service must be 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/IAAC but does not provide the requested calibration service in the scope of accreditation. The metrological traceability of the references used in the requested calibration service of the calibration laboratory that provides the service must be through Route-1 or Route-2.
- 3.** External service providers that provide metrological traceability of their services through Route-3, whose references used in the requested calibration service are metrologically traceable through Route-1 or Route-2. In this way, metrological traceability may be achieved in a few stages.
- 4.** An external service provider that claims to provide metrological traceability to national standards and whose metrological traceability is provided through Route-3 must prove that these standards meet the properties of primary standards for the realization of SI units. The laboratory must keep records that the metrological traceability chain established in the said way meets the requirements of the standard.