



## **POLICY AND PROVISIONS ON TRACEABILITY OF MEASUREMENT RESULTS**

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English translation for information only.

French and Dutch version remain the authoritative documents.

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## HISTORY OF THE DOCUMENT

Revision and date of approval	Reason for revision	Type of revision
0 CC 27.01.2011	New document	
1 Secretariat 22.05.2014	Reference to NBN EN ISO/IEC 17065 in complement to EN 45011 Update of the reference to ILAC P10:2013, without any further change of the content of the document	Point 1.2  Point 1.3
2 CC 29.06.2020	Update of references without significant change of the content Achieving traceability by means of certified reference materials	Full revision
3 Correspondence ballot 30.06.2021	Explicit statement added that critical calibrations must be performed by a laboratory <b>accredited for the relevant calibration</b> or NMI that is a signatory of the CIPM Mutual Recognition Arrangement for <b>the relevant calibration</b> . Correction of an erroneous reference (5.2 replaced by 5.1.2)	Point 5.1.2  Point 5.1.3
4 CC 26.04.2022	Adaptation of the provisions for the realization of traceability for calibrations entrusted to a third party	Point 5.1

## TABLE OF CONTENTS

1	OBJECTIVES AND NORMATIVE REFERENCES.....	4
2	RECIPIENTS.....	4
3	TRACEABILITY OF MEASUREMENT RESULTS: THE CONCEPT .....	5
3.1	Traceability .....	5
3.2	The chain of comparisons.....	5
3.3	Measurement standard .....	6
4	TRACEABILITY OF MEASUREMENT RESULTS: WHEN?.....	6
4.1	When is traceability formally required?.....	6
4.2	The determination of the traceability requirements: the responsibility of the user.....	7
5	TRACEABILITY OF MEASUREMENT RESULTS: PROVISIONS FOR THE REALIZATION.....	7
5.1	Calibrations entrusted to a third party.....	7
5.2	In-house calibrations.....	8
5.3	Traceability by means of reference materials and certified reference materials.....	10
5.4	Cases where traceability is difficult to achieve .....	10

# POLICY AND PROVISIONS ON TRACEABILITY OF MEASUREMENT RESULTS

## 1 OBJECTIVES AND NORMATIVE REFERENCES

- 1.1. This document aims to specify the requirements of BELAC on traceability of measurement results for accredited bodies, as well as for the BELAC assessors.
- 1.2. This document applies to accredited bodies that perform measurements in support of their activities:
  - Calibration and testing laboratories: EN ISO/IEC17025);
  - Medical laboratories: EN ISO15189;
  - Inspection bodies: EN ISO/IEC 17020);
  - Product certification bodies: EN ISO/IEC 17065 ;
  - Proficiency testing providers: EN ISO/IEC 17043;
  - Reference materials producers: EN ISO 17034 .

This document is also applicable on certification bodies for management systems (accredited according to EN ISO/IEC 17021-1) that assess the conformity of certified companies.

- 1.3. This document provides acceptable sources for the traceability of measurements in accordance with the following policies and principles:
  - the applicable parts of the standards, mentioned above under section 1.2;
  - document ILAC P10 "ILAC Policy on Traceability of Measurement Results";
  - document ILAC G24 "Guidelines for the determination of calibration ;
  - the relevant parts of the document "International vocabulary of metrology – basic and general concepts and associated terms (VIM)".

## 2 RECIPIENTS

- Coordination Commission
- Accreditation Board
- Secretariat
- Assessors
- (Candidate) accredited bodies

## 3 TRACEABILITY OF MEASUREMENT RESULTS: THE CONCEPT

### 3.1 Traceability

**Traceability:** property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties (VIM 2008).

Bodies that carry out measurements, are generally faced with the need to calibrate their equipment by comparing to instruments with a better accuracy or to standards, the latter must in turn be controlled by one or more calibrations with respect to national or international standards

The traceability of measurement results is essential to ensure the validation and comparability of the results and to indicate the level of uncertainty associated with it.

### 3.2 The chain of comparisons

An "**unbroken chain of comparisons**" is a logical and easily understood component of traceability. In its simplest form traceability can be wrongly seen as nothing more than a schedule or list of all the standards in the chain. One could argue that calibrations are traceable since such an enumeration / diagram of the standards used in the traceability chain is available. The concept of traceability, however, includes much more than a simple listing of this chain.

Besides the traceability chain, also the following components are important to achieve an acceptable "traceability" result:

- **uncertainty of measurement;** the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated;
- **documentation;** each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be recorded;
- **competence;** the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence (e.g. by demonstrating that they are accredited);
- **reference to SI units;** the chain of comparisons must, where possible, end at primary standards for the realisation of the SI units;

- **calibration intervals**; calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of the equipment).

### 3.3 Measurement standard

In the context of this document, the word "**measurement standard**" relates to:

- The metrological standards that are directly connected to a physical quantity;
- Instruments used as a reference;
- The chemical standards (i.e. pure substances);
- Biological standards (e.g. microbial strains);
- Reference materials and substances, frequently used as a standard in many technical areas.

The above list may be supplemented for specific technical areas.

## 4 TRACEABILITY OF MEASUREMENT RESULTS: WHEN?

### 4.1 When is traceability formally required?

Each measurement equipment used for calibration, testing and / or other processes and that has a **significant** influence on the accuracy or validity of the results of the calibration, testing or other process, needs to be calibrated and has to be related to national or international standards through an unbroken chain of comparison. Reference materials may also significantly impact the results of a test or other type process.

A formal traceability of the calibration is required and the requirements described in Section 5 below shall apply.

In case of calibration activities, a calibration program has also to be defined and regularly evaluated and, whenever necessary, adapted in order to maintain confidence in the calibration status. (Guidelines for the drafting of an appropriate calibration program are presented in the document ILAC G24 "Guidelines for the determination of calibration intervals of measuring instruments").

As for measuring equipment that has little or less impact on the uncertainty or the validity of the result: Regular "verifications" may suffice in this case. Verification means that evidence has to be gathered and demonstrated, in order to ensure that the equipment complies with certain well-defined requirements.

## 4.2 The determination of the traceability requirements: the responsibility of the user

In all cases, the user needs to be able to demonstrate that he has performed an analysis and has established criteria that the device must meet within the entire measurement process, in order to produce valid and traceable end results.

# 5 TRACEABILITY OF MEASUREMENT RESULTS: PROVISIONS FOR THE REALIZATION

## 5.1 Calibrations entrusted to a third party

5.1.1. The body that relies on an external service for the calibration of equipment for which formal traceability is required, has to prove that the requirements listed in point 5.1.2 are fulfilled.

5.1.2. Formal traceability is obtained when the calibration is accompanied by a certificate issued by:

- **a National Metrology Institute:**
  - SMD – ENS (FPS Economy, SMEs, Self-employed and Energy), signatory of the CIPM Mutual recognition Arrangement for the relevant calibration activity and moreover accredited according to EN ISO/IEC 17025 for the relevant calibration activity;
  - Another National Institute of Metrology signatory of the CIPM Mutual recognition Arrangement for the relevant calibration activity (for more information, see <https://www.bipm.org/en/cipm-mra>).
- **accredited calibration laboratories:**
  - Calibration laboratories accredited for the relevant calibration by accreditation bodies that are members of the mutual recognition agreements of EA and ILAC, and more specifically for Belgium, laboratories accredited by BELAC. Only calibration certificates with explicit reference to the accreditation status of the laboratory provide guarantees in terms of acceptable traceability.

5.1.3. Only if proves impracticable to use the calibration services of an body belonging to one of the above mentioned categories, can other calibration services be called upon. In that case, it must be ensured that the calibration services provided are suitable for the intended use. Ideally it should be demonstrated that the relevant parts of EN ISO/IEC 17025 concerning traceability are complied with, but in any case the calibration certificate delivered shall contain at least the following data:

- A full identification of the calibrated equipment;
- A description of the measurement standards that were used as well as their calibration status;
- A description of the traceability chain to international standards;
- The calibration method;
- The results of the calibration;
- Measurement uncertainty;
- Environmental conditions (if any);
- The calibration date;
- The signature of the person responsible for calibration;
- The name and address of the body that issued the certificate and the date of the certificate.

Such calibration services may be provided, for example, by:

- NMIs performing calibrations outside the CIPM MRA
- accredited laboratories performing calibrations outside their scope of accreditation
- calibration service suppliers which are not accredited for any service

5.1.4. In case of doubt about the validity of a certificate or for any other information regarding the possibility to perform specific calibrations, advice may always be obtained from BELAC and the National Service Standards (SMD - ENS).

5.1.5. In any case, the body shall state whether the calibration performed and, if relevant, the scope of the accreditation of the calibration laboratory, meets the requirements to perform the measurement.

## **5.2 In-house calibrations**

5.2.1. A body that itself performs the calibration of its equipment but is not accredited as a calibration laboratory shall demonstrate that it holds the technical capability and equipment for this operation.

5.2.2. Each calibration shall be described in a technical procedure appropriate with respect to the requirements of the measurement and taking into account, where possible, the relevant applicable standards and/or recommendations of the manufacturer of the equipment.

The procedure will include (amongst others):

- a) measuring instruments or group of instruments to which the procedure applies;
- b) the standards and / or reference materials used and, where appropriate, the necessary related materials;
- c) the measures to be taken during use, transportation and storage of standards and reference materials in order to safeguard their specifications;
- d) requirements for use, transport, storage and preparation of the instrument that has to be calibrated;
- e) the environmental conditions that should be under control, including the applicable limits, any adjustments depending on the environmental conditions and if required, the minimum stabilization period prior to calibration;
- f) technical instructions for the calibration, including the statement of the person or persons responsible for this task and, where appropriate, any special competence criteria for these persons;
- g) the measurement results that need to be registered;
- h) the tolerances allowed for the acceptance of calibration results;
- i) an estimate of the uncertainty of the calibration;
- j) the criteria used to decide upon and modify the calibration intervals.

5.2.3. The body shall ensure that any reference measurement equipment or metrological standards that are used, are accompanied by certificates which demonstrate traceability to national and international standards or equivalent.

The body shall verify that the certificate:

- includes a measurement range which is appropriate to the measurement and guarantees the required accuracy;
- Is issued by a body that can provide sufficient guarantees for traceability (see 5.1.2).

5.2.4. The reference measurement standards owned by the body, shall be used for calibration only and not for other purposes.

The management of the standards (storage, handling, recalibration,...) shall be documented in procedures that describe in detail the measures to be taken to maintain the specifications.

To limit the frequency of use of reference measurement standards the body may use working standards. In this case the calibration procedure shall:

- describe the measures undertaken, to guarantee the traceability of the working standards with respect to the reference measurement standards and to maintain the calibration status of the latter;

- consider the recourse to working standard as contribution for the estimation of the measurement uncertainties.

### 5.3 Traceability by means of reference materials and certified reference materials

In case a body obtains traceability by means of reference materials, it shall, whenever possible, be able to demonstrate that these materials have been produced and characterized in a technically sound way and have been duly certified ( certified reference material CRM).

The following CRM's provide a guarantee of formal traceability:

- CRM's produced by a National Institute of Metrology signatory of the CIPM Mutual recognition Arrangement (for more information, see <https://www.bipm.org/en/cipm-mra>);
- CRM's produced by a body accredited according to EN ISO 17034;
- The certified values of CRM's are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM ) database (see details under <https://www.bipm.org/jctlm>).

In case no certified reference material complying with the above mentioned categories is available, the body may consider to use other reference materials ( certified or not) , provided their composition and stability are fit for the purpose. In such a case, the body is required to define the requested characteristics of the material and to demonstrate their adequacy for the intended use. In particular, the recourse to a material previously used in a proficiency testing exercise may be an appropriate alternative, provided the necessary stability can be ensured.

### 5.4 Cases where traceability is difficult to achieve

In certain domains, where traceability to national or international standards is difficult to achieve according to the stipulations of point 5 of the present document, and particularly for testing activities, the body will ensure that:

- the components with a significant impact on the final result and on which the concept of traceability is applicable, are identified and controlled;
- the validation of the results is achieved -where possible-, through alternative approaches such as participation in proficiency testing, retesting of already examined samples, the use of multiple methods on a single sample that should lead to the same result within the limits of measurement uncertainties.