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Unclassified

Ensuring the traceability of measuring results to the International System of Units SI

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CONTENTS

1 Purpose and area of applicability of the document

Ensuring that measuring values can be traced back to standards issued by a metrology institute and the International System of Units SI as described in this document is a major prerequisite for the correctness of measuring results and the correct determination of measurement uncertainties.

This document aims to:

- Define the traceability of measurements and related terminology,
- Provide information on how to ensure the traceability of measuring results to standards issued by a metrology institute and the International System of Units SI,
- Describe the surveillance process for the traceability of measuring and test equipment,
- Provide practical tips on implementing calibration and test measures.

This document applies to all areas where it is important that measuring results can be compared. It is therefore relevant to accredited conformity assessment bodies (CABs) as well as non-accredited companies in matters relating to certification, for instance.

2 Principles

- ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*
- ISO 15189:2012 *Medical laboratories – Particular requirements for quality and competence*
- ISO/IEC 17020:2012 *Conformity assessment - Requirements for the operation of various types of bodies performing inspection*
- ISO 17034:2016 *General requirements for the competence of reference material producers*
- ISO/IEC 17043:2010 *Conformity assessment - General requirements for proficiency testing*
- ISO 9001:2015 *Quality management systems - Requirements*
- ILAC-P10:2020 *Policy on Traceability of Measurement Results*
- EA-04/14 *The Selection and Use of Reference Materials*
- ISO Guide 30: 2015 *Reference materials - Terms and definitions*
- ISO Guide 31: 2015 *Reference materials - Contents of certificates and labels*
- ISO Guide 33: 2015 *Reference materials - Good practice in using reference materials*
- ISO Guide 35: 2017 *Reference materials - Guidance for characterization and assessment of homogeneity and stability*
- EURACHEM/CITAC, Guide, 2nd Edition*, Metrological Traceability in Chemical Measurement*

3 International agreements on the mutual recognition of certificates

3.1 CIPM MRA

The CIPM MRA (*Mutual recognition arrangement for national measurement standards and for calibration and measurement certificates issued by NMIs*) is an agreement concluded between national metrology institutes for the mutual recognition of national standards as well as calibration and measurement certificates. It is based on international key comparisons of mutually assessed management systems (for METAS in accordance with ISO/IEC 17025) as well as calibration and measurement capabilities (CMC) that are subject to a strict review process. The certificates recognised within this scope carry the logo depicted on the right. The agreement, participating laboratories, results of the measurement comparisons and CMCs are documented in a database of the Bureau International des Poids et Mesures (BIPM).

http://www.bipm.org/en/cipm-mra

3.2 EA MLA

The EA (*European Cooperation for Accreditation*) is the European network of the national accreditation bodies. The EA MLA (*Multilateral Agreement*) is an agreement amongst EA members for the mutual recognition of accreditation certificates, inspection and test reports and the calibration certificates of the bodies accredited in the European member states.

http://www.european-accreditation.org

3.3 ILAC MRA

The ILAC (*International Laboratory Accreditation Cooperation*) is an international association of accreditation bodies for laboratories and inspection bodies. Accreditation bodies around the world that are assessed and found to be competent by their peers have signed an agreement – *ILAC recognition arrangement (ILAC MRA)* – that promotes the acceptance of products and services in foreign countries. The aim of this agreement is to create an international system that supports international trade by reducing technical trade barriers to realise the goal of free trade – «Once a product has been tested it is accepted everywhere».

http://www.ilac.org/

3.4 Agreements in the statutory metrology sector

The OIML (*Organisation international de métrologie légale*) is an international organisation that aims to develop harmonised statutory measuring equipment guidelines and apply them in all countries. The OIML has introduced two systems for further developing harmonisation and free trade:

The **OIML Certificate System for Measuring Equipment** is a voluntary agreement under which the members certify measuring equipment in accordance with strictly harmonised requirements, test methods and test reports. Recognition of these certificates is voluntary and based on mutual trust. However, the certificates may be used as a basis for further binding agreements of mutual recognition, especially for the OIML MAA.

In the **OIML Mutual Acceptance Arrangement** (MAA), a group of OIML members undertakes to mutually and bindingly recognise certificates for certain measuring equipment categories. The participating laboratories must comply with the requirements of standard ISO/IEC 17025:2017, which are assessed by an international team. The aim of the MAA is to create mutual trust in construction type tests and to consequently make it easier to launch measuring equipment in the regulated sector.

http://www.metrologyinfo.org/oiml-3.html

4 Ensuring traceability

4.1 Calibration hierarchy

A company usually calibrates its measuring equipment on the basis of operating standards whose values can be traced back to national standards, and therefore the reference values of the International System of Units SI, through the use of reference standards. The values can be traced in several steps and the measurement uncertainty must be known for each one of them. The example of the Swiss metrological infrastructure in Annex 4 illustrates the hierarchy of the various bodies.

It generally has to be remembered that the selection of the calibration body depends greatly on the measurement uncertainty required with regard to the application of the measuring equipment. The higher up a body is positioned within the calibration hierarchy, in other words the fewer the steps that have to be taken to trace values so as to realise an SI unit, the smaller the measurement uncertainty allowed for the calibration of the measuring equipment.

4.2 Institutions that are able to ensure the traceability of the measuring values

- **National metrology institutes**

  In Switzerland, The Federal Institute of Metrology METAS (http://www.metas.ch) or corresponding foreign metrology institutes protect the national standards and pass on their values through calibrations and verifications to the industry, research sector and society. The CIPM MRA ensures that the certificates and reports are recognised internationally.

- **Accredited calibration bodies**

  In Switzerland, the calibration bodies of the Swiss Calibration Service SCS (http://www.sas.admin.ch) or corresponding foreign accredited bodies have the recognised power to realise traceable calibration results. The EA MLA or ILAC ensures that the certificates and reports are recognised internationally.

- **Non-accredited calibration bodies**

  If the measuring values are traced through a non-accredited body (e.g. with so-called company certificates), the client and/or owners or users of the measuring or test equipment must assess the professional competence of the calibration body. Such assessments almost always require an on-site visit and establish, in particular, if the non-accredited calibration body:

  - Keeps its instruments and equipment in good order,
  - Uses processes that are adapted to suit the planned calibration,
  - Bases its reference standards on national standards,
  - Has determined the measurement uncertainty for the planned calibration and ensured that it is suitable,
  - Has sufficient expert knowledge,

- Maintains its own management system within the meaning of ISO/IEC 17025:2017, which ensures a constant quality of its services (including, in particular, the documentation of all processes). The effect of the management part of such management system may be regarded as identical to the effect of an ISO 9001:2015 system.

If non-accredited calibration bodies are involved to ensure traceability, the SAS assessors or auditors of the certification bodies request information on and evidence of the adequate assessment made by the user of the measuring equipment. On the other hand, the accreditation ensures that the calibration body has the required competences and that it complies with the corresponding requirements of the standards. The assessment in this regard is made by an independent body.

- **Company-internal calibration bodies**

  The criteria for the assessment of the professional competences of non-accredited bodies also apply to internal, non-accredited calibration bodies. They are usually assessed as part of internal audits whose findings are also taken into consideration for the management assessment. The company's management therefore assumes full responsibility for correctly calibrating the measuring and test equipment.

4.3 Other ways to ensure traceability

- **Own primary standards**

  Calibration laboratories that maintain their own primary standards or fundamentally and consistently base their units on SI units may only claim that their units can be traced back to SI units if the standards have been compared directly or indirectly with similar standards issued by national metrology institutes (ISO/IEC 17025:2017, Section 6.5.2 c).

- **Reference materials and interlaboratory comparisons**

  (See 5.1.1, Point 4)

5 Monitoring of measuring and test equipment

5.1 Requirements of standard ISO/IEC 17025:2017

Standard ISO/IEC 17025:2017 requires in section 6.4 for all equipment used in tests and/or calibrations, including equipment used in auxiliary measurements (such as environmental conditions), with an impact on the validity of the results of the tests, calibrations or samples to be calibrated. The laboratory must have an established schedule and process for calibrating its equipment.

Note: Such schedule should comprise a system for selecting, applying, calibrating, testing, monitoring and maintaining standards and reference materials that are used as standards for test and calibration measuring equipment (ISO/IEC 17025:2017, Section 6.4.7).

5.1.1 Requirements for calibration bodies

Calibration laboratories must develop and implement the calibration schedule for equipment so as to ensure that the calibrations and measurements performed by the laboratory can be traced back to SI units. The calibration certificates issued by these laboratories must state the measurement results, including the measurement uncertainty, or a statement on compliance with a certain metrological specification (ISO/IEC 17025:2017, Section 6.5.2).

Requirements for the traceability of calibrations

The traceability of equipment and standards must be ensured as described below: Calibration by

1) A national metrology institute (NMI) that is able to perform the calibrations required within the scope of the CIPM MRA. Calibrations covered by the CIPM MRA are listed in Annex C of the CIPM MRA (BIPM Key Comparison Data Base KCDB, http://kcdb.bipm.fr/), which also states the measurement uncertainties.

   or

2) An accredited calibration laboratory that is able to perform the required calibrations (the official area of application reflects the scope of calibration) and whose responsible accreditation body has signed the ILAC MRA.

   Note: Calibration laboratories display the official accreditation mark and optionally the ILAC mark on their calibration certificates as a reference to an accredited service. This may be interpreted as a reference to full traceability.

   or

3a) A national metrology institute that, despite having suitable calibration facilities, is not covered by the CIPM MRA. See Annex 1 for such cases.

   or

3b) A calibration laboratory that, despite having suitable calibration facilities, is not covered by the ILAC Arrangement, i.e. which is not accredited for such calibration. See Annex 1 for such cases.

Laboratories that have ensured the traceability of their measuring results by using calibration services in accordance with 1) or 2) thus carry out expertly performed and traceable calibrations that are recognised through peer assessments or accreditations. This is not the case in 3a) and 3b). 3a) and 3b) should therefore only be applied if the measuring value to be calibrated cannot be established by 1) and 2).

In this case, the laboratory must ensure that there is sufficient evidence that the measuring results can be traced correctly and that the measurement uncertainty to be determined exists and has been documented. The accreditation body must check this; see Annex 1.

***Note:* Laboratory-internal calibrations**

The accredited laboratories may maintain a multi-tier calibration hierarchy for their own purposes (e.g. secondary chains) without stating the calibrations within this hierarchy in the area of application. The traceability and processes of this hierarchy must be documented and are assessed by the accreditation body. The same applies to test laboratories; see 5.1.2.

5.1.2 Requirements for test laboratories

The calibration requirements for calibration laboratories (ISO/IEC 17025:2017, Section 6.4) generally also apply for test laboratories and their measuring and test equipment with measuring functions, at least if the part of the uncertainty originating from the measuring equipment contributes to the overall measurement uncertainty contained in the test result.

The requirements stated in 5.1.1 apply if the test laboratory's equipment that is to be calibrated contributes to the overall measurement uncertainty of the test result.

5.1.3 Requirements for medical laboratories specified in standards

The requirements for medical laboratories are specified in standard ISO 15189:2012, Section 5.3.1.4:

The laboratory must have a documented equipment calibration process with a direct or indirect impact on the test. This process comprises:

a) Compliance with the manufacturer's operating conditions and instructions,

b) Recording the metrological traceability of the calibration standard and the traceable calibration of the equipment,

c) Regular tests of the required measuring accuracy and functionality of the measuring system,

d) Recording the calibration status and date,

e) Ensuring that the previous calibration factors are updated correctly if the calibration requires the introduction of correction factors,

f) Taking precautions to prevent adjustments or corruptions that may invalidate the test results.

The metrological traceability must refer to the reference materials or processes of an existing higher measuring level.

Note: Manufacturers of test systems may document the traceability of the calibration to the reference materials or processes of an existing higher measuring level. Such documentation is acceptable as long as the manufacturer's unmodified test system and calibration process is used.

If this is not possible or irrelevant, other means for building trust in the results must be used, including, but not limited to, the following:

- Use of certified reference materials,
- Tests or calibrations through other processes,
- Use of established standards or methods that have been mutually specified, signed and accepted by all participating parties.

5.2 Calibration intervals

Accredited bodies and certified companies decide themselves which measuring and test equipment is to be calibrated as well as the intervals, purpose and measurement uncertainty.

Accredited bodies specify their own calibration intervals. They are checked by the accreditation body and expert during the assessment. They have a particular process for determining suitable calibration intervals. The guidelines ILAC G24 *Guidelines for the determination of calibration intervals of measuring instruments* (http://ilac.org/publications-and-resources/) and SAS 740d *Guidelines for the determination of calibration intervals of reference standards and reference instruments* provide appropriate guidance.

6 Reference materials

Reference materials are used very frequently in chemical and biological investigations. They contribute significantly to increasing the confidence in the measurement results.

Document EA-04/14 INF distinguishes the following types of reference materials:

- Pure substances characterised in terms of purity and/or traces of impurities;
- Standard solutions and gas mixtures, which are often prepared gravimetrically from pure substances;

- Matrix reference materials characterised with respect to the composition of certain major, minor or trace components. Such materials may be prepared from matrices containing the components of interest or by preparing synthetic mixtures;
- Physico-chemical reference materials characterised for properties such as melting point, viscosity and optical density;
- Reference objects or artefacts characterised for functional properties, such as flavour, flash point, hardness, etc. This type also includes microscopy samples characterised for properties ranging from fibre types to microbiological samples.

The ISO standard 17034:2016 formally defines two material classes – «certified reference materials» (CRM) and «reference materials» (RM). Both terms are defined in Annex 2 of this document.

6.1 Metrological traceability through reference materials

If metrological traceability is performed by means of CRMs provided by reference material manufacturers (RMM), then the certified values of the CRMs are considered as valid means for metrological traceability if:

1) The CRM is manufactured by an NMI and is registered in the BIPM KCDB database (https://www.bipm.org/kcdb/cmc).
2) The CRM is produced by an accredited RMM within its accreditation and the relevant accreditation body is a co-signatory of the ILAC MRA.
3) The certified value of the CRM is covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database (https://www.jctlmdb.org/).

Because accreditation of RMM is still under development and required CRMs may not be available from accredited RMM, accredited conformity assessment bodies (CABs) using CRMs that are not manufactured within the accreditation of an RMM must demonstrate that the CRMs concerned have been provided by a competent RMM and that they are suitable for the intended use.

If metrological traceability to the SI is not technically possible, then the accredited CAB shall demonstrate metrological traceability to a suitable reference. This can be done by:

1) Certified values of CRMs provided by a competent RMM.
2) Results of reference measurement procedures, established procedures or consensus-based procedures. These procedures shall be accurately described and produce measurement results suitable for the intended use. They shall be backed up by appropriate measurement comparisons.

6.2 Use of reference materials

A more detailed description of the uses of RMs and CRMs can be found in ISO Guide 33 and document EA-04/14 INF. These are primarily:

- Calibration and assurance of metrological traceability.
- Validation of test methods and determination of measurement uncertainty
- Verification of test methods
- Ensuring the validity of results

Surplus test material from PTs is often available from suppliers. Consideration should be given to whether the provider of PTs can provide additional stability information to demonstrate the continued stability of the characteristic value and matrix of the test material. If this is not possible, these test materials should not be used as an alternative way to ensure the validity of the results.

Annex 1: Traceability requirements without taking into consideration CIPM MRA and ILAC MRA

Traceability on the basis of 3a) and 3b) (5.1.1) ranges from NMI calibrations outside the area of applicability of the CIPM MRA and accredited laboratories that perform calibrations outside their scope to calibrations performed by non-accredited laboratories.

To ensure traceability in such cases, sufficient evidence of the professional competence of the calibration service provider must be available. As a minimum, the following points have to be taken into consideration (the figures refer to the sections of standard ISO/IEC 17025:2017):

- Documentation of employees' competences (6.2)
- Documentation of premises and environmental conditions (6.3)
- Records of facilities that can influence the results (6.4)
- Documentation of the measurement's traceability (6.5)
- Evidence of the calibration method validation (7.2.2)
- Process for determining measurement uncertainties (7.6)
- Documentation of the validity of calibration results (7.7)
- Audit of the calibration laboratory (8.8)

For non-accredited laboratories, it may be necessary to perform assessments of the laboratory that are similar to those an accreditation body would perform in accordance with standard ISO/IEC 17025:2017 in order to prove competences.

Economic reasons should not be behind the assurance of traceability with the assistance of 3a) and 3b) (5.1.1). It should rather be regarded as a last resort when all other options are unavailable.

Annex 2: Terminology

The following collection of the most commonly used terms has been taken from these documents:

- VIM, International vocabulary of metrology Dictionary, JCGM 200:2012, https://www.bipm.org/en/committees/jc/jcgm/publications or the identical ISO Guide 99:2007,
- ISO 9000:2015, Quality management - Fundamentals and vocabulary,
- Measuring Instruments Ordinance SR 941.210.

The information in brackets refers to VIM, issue 2, 1993.

Metrological (or technical) traceability, VIM 2.41 (6.10)

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.

Calibration, VIM 2.39 (6.11)

Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

Verification, Art. 4 e of the Measuring Instruments Ordinance

Official test and confirmation that an individual measuring device meets legal requirements.

Validation, ISO 9000:2015, VIM 2.45

Verification, where the specified requirements are adequate for an intended use.

Measurement standard, VIM 5.1 (6.1)

Realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference.

National measurement standard, VIM 5.3 (6.3)

Measurement standard recognized by national authority to serve in a state or economy as the basis for assigning quantity values to other measurement standards for the kind of quantity concerned.

Note: The national standards are periodically compared with one another in collaboration with the Bureau International des Poids et Mesures (BIPM).

Primary measurement standard, VIM 5.4 (6.4)

Measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention.

The old definition was more understandable in this respect: *Standard that meets the highest metrological standards or that is largely recognised as such whose value is recognised without any reference to other standards of the same measuring value*.

Reference measurement standard, VIM 5.6 (6.6)

Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location.

Working measurement standard, VIM 5.7 (6.7)

Measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems.

Transfer measurement device, VIM 5.9 (6.8)

Device used as an intermediary to compare measurement standards.

Reference material, VIM 5.13 (6.13)

Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.

Certified reference material, VIM 5.14 (6.14)

Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

Measurement, VIM 2.1 (2.1)

Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity.

Determination, (ISO 9000:2015, 3.11.1)

Activity to find out one or more characteristics and their characteristic values.

Material measure, VIM 3.6 (4.2)

Measuring instrument reproducing or supplying, in a permanent manner during its use, quantities of one or more given kinds, each with an assigned quantity value.

Measuring instrument (calibration or test), VIM 3.1 (4.1)

Device used for making measurements, alone or in conjunction with one or more supplementary devices.

Stability of a measuring instrument, VIM 4.19 (5.14)

Property of a measuring instrument, whereby its metrological properties remain constant in time.

Measurement accuracy, VIM 2.13 (3.5)

Closeness of agreement between a measured quantity value and a true quantity value of a measurand.

Measurement uncertainty, VIM 2.26 (3.9)

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Annex 3: Abbreviations

BIPM	International Bureau of Weights and Measures	**B**ureau **I**nternational des **P**oids et **M**esures
CGPM	General Conference on Weights and Measures	**C**onférence **G**énérale des **P**oids et **M**esures
CIPM	International Committee for Weights and Measures	**C**omité **I**nternationale des **P**oids et **M**esures
CRM	**C**ertified **R**eference **M**aterial	
EA	**E**uropean Cooperation for **A**ccreditation	
EN	European standard	**E**uropäische **N**orm
EU	**E**uropean **U**nion	
IEC	**I**nternational **E**lectrotechnical **C**ommission	
ILAC	**I**nternational **L**aboratory **A**ccreditation **C**ooperation	
ILC	**I**nter**l**aboratory **C**omparison	
IRMM	**I**nstitute for **R**eference **M**aterials and **M**easurements	
ISO	**I**nternational **O**rganisation for **S**tandardisation	
JCGM	**J**oint **C**ommittee for **G**uides in **M**etrology	
JCTLM	**J**oint **C**ommittee for **T**raceability in **L**aboratory **M**edicine	
KCDB	**K**ey **C**omparison **D**ata **B**ase	
METAS	Federal Institute of **Met**rology	Institut fédéral de métrologie
MLA	**M**ulti**l**ateral **A**greement for the Recognition of Certificates	
MRA	**M**utual **R**ecognition **A**rrangement	
MS	**M**anagement **S**ystem	
NIST	**N**ational **I**nstitute of **S**tandards and **T**echnology (US metrology institute)	
NMI	**N**ational **M**etrology **I**nstitute	
OIML	International Organisation for Legal Metrology	**O**rganisation **I**nternationale de **M**étrologie **L**égale
RM	**R**eference **M**aterial	
SAS	**S**wiss **A**ccreditation **S**ervice	
SCS	**S**wiss **C**alibration **S**ervice	
SI	International System of Units	**S**ystème **i**nternational d’unités
SVS	**S**wiss **V**erification **S**ervice	
VIM	International Vocabulary of Metrology	**V**ocabulaire **I**nternational de **M**étrologie

Annex 4: Metrological infrastructure in Switzerland