ACCREDITATION UNIT

POLICY ON METROLOGICAL TRACEABILITY IN CHEMICAL MEASUREMENTS

Issued on 2007-09-01 JAS-P15, rev.h
Revised on 2021-04-05

Purpose

This policy defines the way in which laboratories will prove **metrological t**raceability of their chemical measurements**.**

Scope

This policy is intended to explain the concept of **metrological** traceability in chemical measurements as required by Accreditation Unit (**JAS-AU**), based on the definition in the International Vocabulary of Basic and General Terms in Metrology (VIM). Though it is aimed principally at testing and measurement laboratories carrying out the chemical measurement, the principles are expected to apply from routine analysis to basic research. The policy is also intended to assist laboratories in meeting the requirements on **metrological** traceability of results given in ISO/IEC 17025 or other appropriate measurement references.

Authorship

This publication has been written by the Technical Committee, and approved by the Accreditation Director.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

Copyright

Further information

This policy is mandatory for laboratories, and shall be implemented within four months from its issuance date.

For further information about this publication, kindly contact **JAS-AU**.

This document is also available on **JAS-AU website** where you can check updates directly.

Contents

1. Introduction

The quality of products and services is becoming increasingly dependent on reliable measurements. The importance attached to measurements is reflected in relevant standards by the requirement that measurements must be "traceable" to national or international standards of measurement.

Every day, thousands of chemical measurements support decisions on food safety, health and environmental protection. The global market, too, needs accurate and reliable measurements so that technical barriers to trade can be minimized. In all these sectors, the concept of "tested once, accepted everywhere" is increasingly important, and the need for reliable measurement results that can be compared across space and time has never been greater. Reliable measurements depend critically on competent **personnel**, validated and tested methods, comprehensive quality systems and traceability to appropriate measurement references. Recognition of these requirements is underscored by the increasing adoption of standards and measurement quality systems, such as laboratory accreditation against ISO/IEC 17025.

To achieve comparability of results over space and time, it is essential to link all the individual measurement results to some common, stable reference or measurement standard. Results can be compared through their relationship to that reference. This strategy of linking results to a reference is termed "traceability."

2. Terminology

2.1 Metrological Traceability

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

Notes:

1. **In ISO/IEC 17025 and ISO 15189 the term "traceability" is equivalent to the VIM's "metrological traceability". To avoid repetition, the term "traceability" is used henceforth in this document.**

2. 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.
3. Metrological traceability requires an established calibration hierarchy.
4. Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.
5. For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be **metrological** traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.
6. Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.
7. A comparison between two measurement standard**s** may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.
8. International System of Quantities and Units (SI) shows that measurements need to be expressed in agreed measurement units. The appropriate system of units for most chemical measurement is the **SI.** The SI units form a coherent system which is used almost universally in science and very widely in trade. The SI defines base units for mass (kilogram, kg), length (meter, m), time (second, s), thermodynamic temperature (Kelvin, K), electric current (Amp, A), luminous intensity (candela, cd) and amount of substance (mole, mol). It also defines many derived units in terms of the base units, and a selection of important derived units for chemical measurement is provided in **below** Table. Note that the mole is the only base unit that requires further qualification; that is, the specific substance referred to. The nature of the substance analyzed is, of course, important in all chemical measurements, whether or not they are expressed in moles. In particular, quantities such as mass fraction in chemical measurement are not 'dimensionless' in that they invariably refer to the fraction of one substance as a portion of a mixture of other substances. The implication is that for appropriate **metrological t**raceability, each measurement result should be **meteorically t**raceable to a reference for the particular substance.

Metrological Traceability in Chemical Measurement International System of Quantities and Units (SI)

Quantity	Units
molar fraction mass fraction volume fraction	**mol/mol, %** **kg/kg, %** **m^3/m^3, %**
molar concentration mass concentration volume concentration	mol/m^3 kg/m^3 $m3 /m^3$
Molality	mol/kg
pH	1 (negative logarithm of hydrogen ion activity)
Enzyme activity	katal (mol s^{-1}) (SI unit), U (**µ** mol/min)
Purity, an important characteristic for many reference materials and other substances, is generally expressed in terms of one of the fractions or concentrations above	

Quantities and units in chemical measurement

2.2 Calibration hierarchy

The Sequence of calibrations from a reference to the final measuring system, where the outcome of each calibration depends on the outcome of the previous calibration. (1)

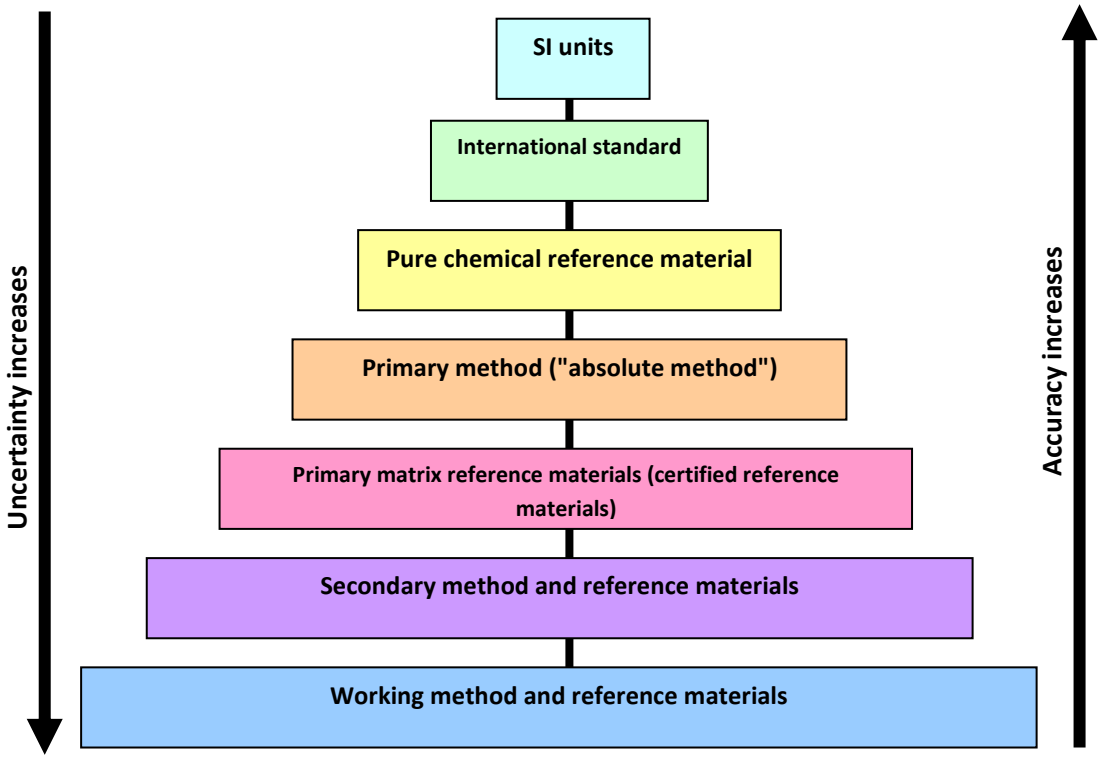

***Fig. 1: example of Calibration* hierarchy.**

2.3 Reference material (RM)

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 m**easurement **process (ISO 17034:2016)**

2.3.1 Types of reference materials

RMs are used to support measurements concerned with chemical composition, biological, clinical, physical, engineering properties and miscellaneous areas such as taste and odor. They may be characterized for 'identity' (e.g. chemical structure, fibre type, microbiological species etc.) or for 'property values' (e.g. amount of specified chemical entity, hardness etc.). Some commonly encountered types of reference materials are as follows:

1. **Pure substances characterized for chemical purity and/or trace impurities.**
2. **Standard solutions and gas mixtures, often prepared gravimetrically from pure substances and used for calibration purposes.**

3. **Matrix reference materials, characterized for the composition of specified major, minor or trace chemical constituents. Such materials may be prepared from matrices containing the components of interest, or by preparing synthetic mixtures.**
4. **Physico-chemical reference materials characterized for properties such as melting point, viscosity, and optical density.**
5. **Reference objects or artefacts characterized for functional properties such as taste, odor, octane number, flash point and hardness. This type also includes microscopy specimens characterized for properties ranging from fibre type to microbiological specimens.**

2.4 Certified Reference Material (CRM)

Reference material characterized by a metro logically 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]

2.5 Validation

Confirmation by examination and provision of objective evidence that the particular requirements of a specified intended use are fulfilled. Add the guide (ISO/IEC Guide 99:2007)

EXAMPLE:

A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum. (VIM 3rd: 2012)

2.6 Uncertainty of measurement

"Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used". [ISO/IEC Guide 99:2007]

3. Responsibilities

- It is the responsibility of **JAS-AU** assessors to evaluate the compliance of the laboratories with this policy.

- The laboratories shall have documented evidence of compliance with this policy available for the assessors at the time of assessment visit. If the documented evidence is not being available, the laboratory runs the risk of a delay in the assessment or surveillance.

4. Establishing Metrological Traceability

Essential activities in establishing **metrological t**raceability in working laboratories:

1. Specifying the measurands, scope of measurements and the **target measurement** uncertainty.
2. Choosing a suitable method of estimating the value, that is; a measurement procedure with associated calculation - an equation - and measurement conditions.
3. Demonstrating, through validation, that the calculation and measurement conditions include all the "influence quantities" that significantly affect the result or the value assigned to a standard.
4. Identifying the relative importance of each influence quantity.
5. Choosing and applying appropriate reference standards.
6. **Evaluating** the uncertainty.

To apply these principles, laboratories shall follow the guidance given in clause 6 in EURACHEM / CITAC Guide "Traceability in Chemical Measurement" [2].

Also the laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide **metrological t**raceability as described in JAS-P04. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

Laboratories shall ensure that reference materials they purchase are obtained from a competent producer of reference materials.

In order to maintain traceability in calibration programs, guidance can be found in ILAC G24:2007**and** JAS-G06"Guidelines for the determination of calibration intervals of measuring instruments.

5. Requirements for achieving metrological traceability

1. The calibration program shall assure traceability of measurements, and/or verification and validation of equipment is traceable, as required in JAS-P04

   Calibration certificates, where applicable, shall indicate the measurement result and the associated uncertainty of the measurement and/or a statement of compliance with an identified metrological specification. To ensure actual traceability, the path of reference standard verification back to the NMI shall be clear. The evidence of the investigation of the path back to the NMI shall be available for verification by **JAS-AU** assessors; if applicable. The requirements for a primary reference, transfer, and working standards or reference materials shall be defined by the laboratory. When defining those requirements; the laboratory shall identify the critical characteristics that may affect the traceability for the calibration and/or test. Those characteristics include the requirements stated in ISO/IEC 17025. Critical characteristics may include handling, reporting, equipment, and methodology for using the standards etc. Depending on the level of standard and the frequency of use, transport, ownership, etc. the laboratory shall apply the appropriate degree of procedural control.

2. When traceability to NMI is not possible, the laboratory should have a procedure that will provide satisfactory evidence that the results are correlated, for example by participation in a suitable Interlaboratory comparison or proficiency testing. Other satisfactory evidence would be an internationally accepted standard in the field concerned; suitable reference material; ratio or reciprocity-type measurements; or mutual consent standards that are clearly specified and mutually agreed upon by all parties concerned.

3. Any requirements stated in the "Policy on **metrological** Traceability" shall be applied where applicable

4. **The values assigned to CRMs produced by an accredited Reference material producer (RMP) under its scope of accreditation to ISO 17034, are considered to have established valid traceability;**

5. **A wide range of other materials and formulations is available for calibration, including, for example, mixed element calibration solutions, alloys, and carefully characterized novel pharmaceutical reference materials. Without formal evidence of metrological traceability and associated uncertainty information, it must be the laboratory's responsibility to demonstrate that the materials are fit for their intended purpose. As in 7.5.4, considerable care in selection is necessary.**

6. Reporting Metrological Traceability :

It is not normal practice to give details of metrological traceability on test reports. However, where it is necessary to report evidence of **metrological traceability of results, the report will typically include:**

- **The identity of calibration standards used;**
- **Where significant, the identity of references used to control the conditions of measurement.**

7. General Guidance References

1. International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), 3rd Edition: 2012 / VIM 2.44 JCGM 200:2012 Available from the http:/www.oiml.org

2. EURACHEM / CITAC Guide "Traceability in Chemical Measurement", **2nd Edition 2019.** Available from the Eurachem secretariat, http://www.eurachem.org/, or CITAC at http://www.citac.cc/
3. JAS-P04, Policy on measurement traceability, Available from **http://www.au.gov.jo**
4. Dr. Godfrey Moses and Linda Crawford. Traceability and Uncertainty of Measurement for Medical Laboratories, version 1: 2009. Available from http://www.qcnet.com/Portals/74/pdfs/Traceability%20and%20Uncertainty%20of%20Measuremen%20for%20Medical%20Laboratories.pdf
5. ILAC-P10:**07/**20**20** "ILAC Policy on the **Metrological T**raceability of Measurement Results" Available from **https://ilac.org/publications-and-resources/ilac-policy-series/**
6. GUM: Guide to the expression of uncertainty in measurement, JCGM 100:2008.
7. Eurachem/CITAC Guide: Guide to Quality in Analytical Chemistry, 3rd edition, ~~2002.~~ 2016. Available from the Eurachem secretariat, http://www.eurachem.org/, or CITAC at http://www.citac.cc/
8. The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics. 2nd edition: 2014.
9. EA-4/14 INF: 2003: The selection and use of reference materials.
10. ILAC G24:2007 "Guidelines for the determination of calibration intervals of measuring instruments.
11. **ISO 17034:2016, General requirements for the competence of reference material producers.**
12. **ISO/IEC Guide 99:2007, International vocabulary of metrology - Basic and general concepts and associated terms (VIM).**