



ACCREDITATION UNIT

POLICY ON TRACEABILITY IN CHEMICAL MEASUREMENTS

Purpose

This policy defines the way in which laboratories will prove traceability of their chemical measurements.

Scope

This policy document is intended to explain the concept of measurement 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 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.

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Further information

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

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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 staff, 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 Measurement uncertainty

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. (1)

Notes:

1. Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

2. The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.
3. Measurement uncertainty comprises in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.
4. In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

2.2 **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. 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.
2. Metrological traceability requires an established calibration hierarchy.
3. 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.
4. 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.
5. 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.

6. A comparison between two measurement standard 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.
7. The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2013).
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 bellow 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 traceability, each measurement result should be traceable to a reference for the particular substance.

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

Quantities and units in chemical measurement

Quantity	Units
molar fraction	mol/mol, %
mass fraction	kg/kg, %
volume fraction	m³/m³, %
molar concentration	mol/m ³
mass concentration	kg/m ³
volume concentration	m ³ /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	

2.3 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)

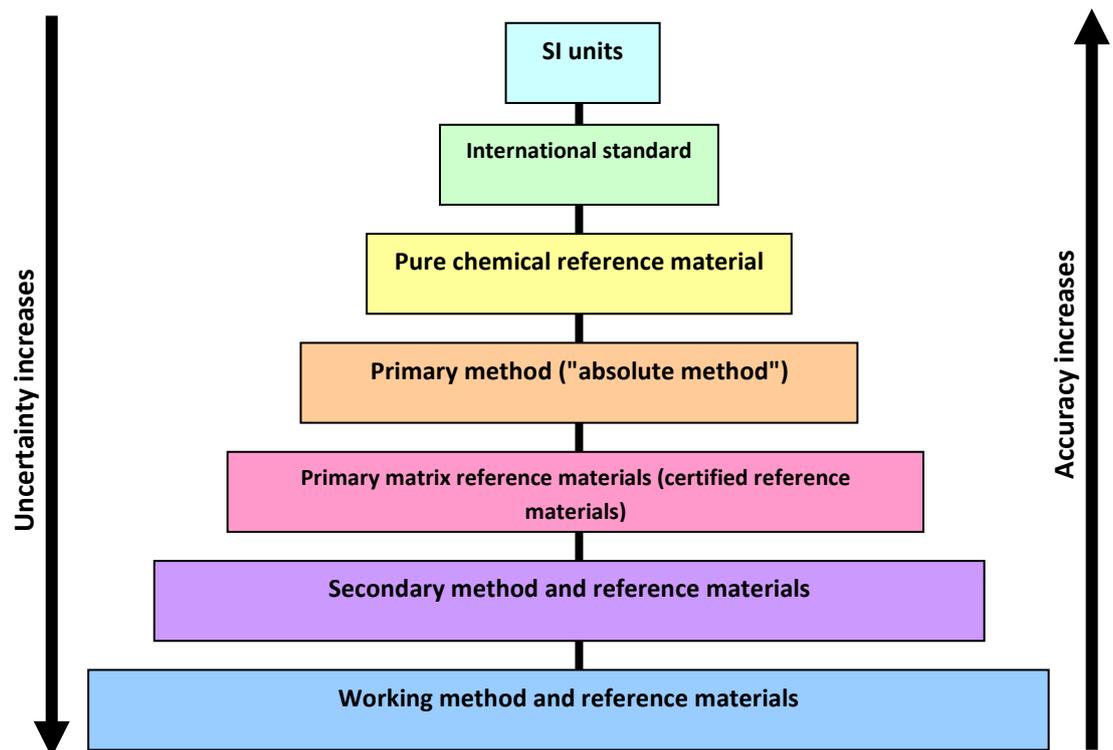


Fig. 1: example of Calibration hierarchy.

2.4 Reference material (RM)

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 **or non-nominal** properties. (1)

2.5 Certified reference material (CRM)

Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures.(1)

2.6 Intrinsic measurements standard / intrinsic standard

Measurement standard based on an inherent and reproducible property of a phenomena or substance. (1)

Notes:

1. A quantity value of an intrinsic measurement standard is assigned by consensus and does not need to be established by relating it to another measurement standard of the same type. Its measurement uncertainty is determined by considering two components: the first associated with its consensus quantity value and the second associated with its construction, implementation, and maintenance.
2. An intrinsic standard usually consists of a system produced according to the requirements of a consensus procedure and subject to periodic verification. The consensus procedure may include corrections necessitated by the implementation.
3. Intrinsic measurement standards that are based on quantum phenomena usually have outstanding stability.
4. The stability and measurement reproducibility of some intrinsic standards come from the fact that the phenomenon used is a quantum phenomenon.
5. The adjective “intrinsic” does not mean that such a measurement standard may be implemented and used without special care or that such a measurement standard is immune to internal and external influences.

2.7 Verification:

Provision of objective evidence that a given item fulfills specified requirements.

EXAMPLES

Triple-point-of-water cell as an intrinsic standard of thermodynamic temperature.

Intrinsic measurement standard of electric potential difference based on the Josephson Effect.

Intrinsic measurement standard of electric resistance based on the quantum Hall effect.

A Sample of copper as an intrinsic measurement standard of electric conductivity.

2.8 Validation

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

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)

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 Traceability

Essential activities in establishing traceability in working laboratories:

1. Specifying the measurands, scope of measurements and the required 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. Estimating 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 traceability 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.

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

5. Requirements for achieving 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.

Where intrinsic standards are used, the laboratory should demonstrate by measurement-assurance techniques, interlaboratory comparison **with an accredited lab**, or other suitable means that its intrinsic-measurement results are correlated with NMI.

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 Measurement Traceability" shall be applied where applicable.

6. 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", 2003.
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-P10:01/2013 "ILAC Policy on the Traceability of Measurement Results" Available from <http://ilac.org/>
6. GUM: Guide to the expression of uncertainty in measurement, JCGM 100:2008.
7. Eurachem/CITAC Guide: Guide to Quality in Analytical Chemistry, 2002.
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.