LAS-Q002

TTLABS GUIDE TO THE APPLICATION OF ILAC-P10
(METROLOGICAL TRACEABILITY)

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LIST OF ACRONYMS

BIPM - Bureau International des Poids et Mesures (International Bureau of Weights and Measures) see http://www.bipm.org/en/cipm-mra/

BIPM KCDB - Key Comparison Database of the BIPM; see http://kcdb.bipm.org/

CIPM - Comité International des Poids et Mesures (International Committee for Weights and Measures)

CIPM MRA - CIPM Mutual Recognition Arrangement; see http://www.bipm.org/en/cipm-mra/

CMC - Calibration and Measurement Capability

CRM - Certified Reference Material

ILAC - ILAC

JCTLM - Joint Committee for Traceability in Laboratory Medicine.

NMI - National Metrology Institutes (NMIs) and Designated Institutes (DIs) that maintain measurement standards and traceability in countries (or regions) all over the world.

RM - Reference Material

RMP - Reference Material Producer

UKAS - United Kingdom Accreditation Service

1.0 PURPOSE

This document describes the TTLABS policy on metrological traceability requirements contained within ISO/IEC 17025:2017 and ISO 15189:2012. This document gives guidance to the policies contained within ILAC document ILAC-P10: *Policy on traceability of measurement results*.

2.0 SCOPE

This policy applies to metrological traceability required for all equipment used for tests and/or calibrations, including equipment for subsidiary measurements such as environmental conditions having a significant effect on the accuracy or validity of the result of the test, calibration or sampling.

3.0 DEFINITIONS

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 (JCGM200, VIM).

Metrological traceability chain

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference (JCGM200, VIM).

NOTE 1 A metrological traceability chain is defined through a calibration hierarchy.

NOTE 2 A metrological traceability chain is used to establish metrological traceability of a measurement result.

NOTE 3 A comparison between two measurement standards 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.

Calibration

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 (JCGM200, VIM).

NOTE 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

NOTE 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

Calibration Hierarchy

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 (JCGM200, VIM).

NOTE 1 Measurement uncertainty necessarily increases along the sequence of calibrations.

NOTE 2 The elements of a calibration hierarchy are one or more measurement standards and measuring systems operated according to measurement procedures.

NOTE 3 For this definition, the 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure, or a measurement standard.

NOTE 4 A comparison between two measurement standards 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.

Measurement uncertainty

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used (JCGM200, VIM).

NOTE 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.

NOTE 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.

NOTE 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.

NOTE 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.

Uncertainty budget

Statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination (JCGM200, VIM).

NOTE An uncertainty budget should include the measurement model, estimates, and measurement uncertainties associated with the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty, and any coverage factor.

Reference Standard (reference measurement standard)

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 (JCGM200, VIM).

Reference material

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 (JCGM200, VIM).

CRM

Accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures (JCGM200, VIM).

EXAMPLE Human serum with assigned quantity value for the concentration of cholesterol and associated measurement uncertainty stated in an accompanying certificate, used as a calibrator or measurement trueness control material.

SI Unit

System of units, based on the International System of Quantities, their names and symbols, including a series of prefixes and their names and symbols, together with rules for their use, adopted by the General Conference on Weights and Measures (CGPM)

NOTE 1 The SI is founded on the seven base quantities of the ISQ and the names and symbols of the corresponding base units [contained in the following table. 1.16 (1.12) of the JCGM200:2012, VIM.

NOTE 2 The base units and the coherent derived units of the SI form

Reference measurement procedure

Measurement procedure accepted as providing measurement results fit for their intended use in assessing measurement trueness of measured quantity values obtained from other measurement procedures for quantities of the same kind, in calibration, or in characterizing reference materials (JCGM200, VIM).

International measurement standard

Measurement standard recognized by signatories to an international agreement and intended to serve worldwide (JCGM200, VIM).

EXAMPLE 1 The international prototype of the kilogram.

EXAMPLE 2 Chorionic gonadotrophin, World Health Organization (WHO) 4th international standard 1999, 75/589, 650 International Units per ampoule.

EXAMPLE 3 VSMOW2 (Vienna Standard Mean Ocean Water) distributed by the International Atomic Energy Agency (IAEA) for differential stable isotope amount of substance ratio measurements.

National measurement standard

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 (JCGM200, VIM).

Primary measurement standard

Measurement standard established using a primary reference measurement procedure, or created as an artefact, chosen by convention (JCGM200, VIM).

Secondary measurement standard

Measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind (JCGM200, VIM).

NOTE 1 Calibration may be obtained directly between a primary measurement standard and a secondary measurement standard, or involve an intermediate measuring system calibrated by the primary measurement standard and assigning a measurement result to the secondary measurement standard.

NOTE 2 A measurement standard having its quantity value assigned by a ratio primary reference measurement procedure is a secondary measurement standard.

Working measurement standard

Working measurement standard working standard measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems (JCGM200, VIM).

NOTE 1 A working measurement standard is usually calibrated with respect to a reference measurement standard.

NOTE 2 In relation to verification, the terms “check standard” or “control standard” are also sometimes used.

4.0 REFERENCES

4.1 ISO/IEC 17025:2017 - General Requirements for the competence of testing and calibration laboratories, clauses:

- 6.4; 6.5; 6.6;

4.2 ISO 15189:2012, Medical laboratories – Requirements for quality and competence, clauses:

- 4.6; 4.9; 4.13 i); 4.13 j);
- 5; 5.3; 5.3.1.4; 5.8.3 i)

4.3 ILAC, ILAC P10:01, ILAC Policy on the Traceability of Measurement Results.

4.4 Joint Committee for Guides in Metrology, JCGM 200, International vocabulary of metrology - Basic and general concepts and associated terms (VIM).

4.5 Joint Committee for Guides in Metrology, JCGM 100, Evaluation of measurement data - Guide to the expression of uncertainty in measurement (GUM).

4.6 United Kingdom Accreditation Service, TPS 41: UKAS policy on metrological traceability.

4.7 ILAC, ILAC-G24, Guidelines for the determination of calibration intervals of measuring instruments.

5.0 GUIDE

5.1 Laboratories are expected to comply with the requirements and policies laid out in ILAC P10 ILAC Policy on the Traceability of Measurement Results.

5.2 Laboratories are required to identify all measurements that affect the validity of results and therefore ensure all equipment that make such measurements are calibrated and satisfy metrological traceability requirements.

5.3 It is acknowledged that accredited calibration service providers in Trinidad and Tobago are limited at this time. However laboratories are expected to apply either policy Section 2, 3a) or 3b) as defined in ILAC P10:01/2013 ILAC Policy on the Traceability of Measurement Results to ensure that the calibration service provider is meeting metrological traceability requirements. Annex A of ILAC P10:01/2013 ILAC Policy on the Traceability of Measurement Results applies in such situations.

5.4 For testing and medical laboratories, TTLABS acknowledges the challenges faced by these organisations for the achievement of metrological traceability. However for the calibration of instruments ILAC policies 1, 2, 3a), 3b) and 4 from ILAC P10:01/2013 ILAC Policy on the Traceability of Measurement Results applies, unless the laboratory has quantitatively demonstrated that such calibration is not a major contributor to the testing result.

5.5 TTLABS requires testing and medical laboratories to establish metrological traceability through the use of reference materials and certified reference materials. These can be produced by NMIs and reputable Reference Materials Producers (RMPs).

NOTE: These can be accredited to *ISO 17034 – General requirements for the competence of reference material producers* or as listed in the JCTLM database.

5.6 Since reference and certified reference materials are critical consumables, the laboratory needs to demonstrate that these consumables are suitable for the intended use as required by the relevant clause(s) of ISO/IEC 17025 and/or ISO 15189.