ASCLD/LAB-*International*

ASCLD/LAB Policy on Measurement Traceability

ASCLD/LAB-*International* is a program of the
American Society of Crime Laboratory Directors / Laboratory Accreditation Board
ASCLD/LAB

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NOTE Guidance documents are available from ASCLD/LAB to assist customers with better understanding and implementing ASCLD/LAB policies. While customers are encouraged to review and consider information from the guidance documents, guidance documents issued by ASCLD/LAB do not contain or create any additional accreditation requirements. The companion guidance documents for this policy are:

- AL-PD-3058 *ASCLD/LAB Guidance on Measurement Traceability*
- AL-PD-3059 ASCLD/LAB *Guidance on Measurement Traceability – Measurement Assurance*

Document History / AL-PD-3057

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December 31, 2014	1.3	Added information on the BIPM key comparison database (KCDB) for NMI calibration capability	ASCLD/LAB Executive Director	December 31, 2014

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1 Purpose

Measurement traceability[1] is a requirement for ISO/IEC 17025:2005[2] accreditation and an important tenet of the laboratory's management system.[3] The purpose of this document is to state how ASCLD/LAB will interpret, apply and assess measurement traceability requirements from ISO/IEC 17025:2005.

2 Scope and Concept

This policy is intended for laboratories that are accredited or that are seeking accreditation under either the ASCLD/LAB-*International* Testing or Calibration Program.

This policy covers the traceability of measurements.

2.1 Measurement traceability, more precisely known as metrological traceability, can be characterized by the following essential elements:[4]

(a) Unbroken Chain of Comparisons - A documented system of comparisons with each step having the essential elements of metrological traceability going back to a stated reference acceptable to the parties, usually a national or international standard;

(b) Documented Measurement Uncertainty - The measurement uncertainty for each step in the traceability chain must be calculated according to defined methods and must be stated so that an overall uncertainty for the whole chain may be calculated;

(c) Documented Measurement Procedure - Each step in the chain must be performed according to documented and generally accepted procedures and the results must be documented;

(d) Technical Competence - The laboratories or bodies performing one or more steps in the chain must maintain and supply evidence of technical competence (e.g., by maintaining appropriate training records, participating in inter-laboratory comparisons, and by demonstrating that they are accredited by a recognized accreditation body);

(e) Realization of SI Units – The chain of comparisons must, where possible, end at the realization of the International System of Units (SI);

(f) Documented Calibration Intervals - Calibrations must be repeated at established and appropriate intervals to preserve metrological traceability; and

(g) Measurement Assurance - A proper measurement assurance program [however named] must be established to ensure the validity of the measurement process and to ensure the calibration status of equipment, reference standards and reference materials.

The vocabulary and definitions of traceability concepts may be found in the International Vocabulary of Metrology (VIM).[5]

3 General Requirements

The general requirements in ISO/IEC 17025:2005 for measurement traceability are found in Section 5.6 of that standards document.

Based on the general requirements for measurement traceability:

3.1 Traceability of a measurement is required for all measurements where measurement uncertainty is estimated.[6] Additionally, for testing laboratories, traceability of a measurement is required where the measurement result has a significant impact on the final test result.

3.2 Equipment

For establishing measurement traceability through the calibration of equipment used in the measurement process, the applicable general requirements in ISO/IEC 17025:2005 are:

5.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.

5.6.2.1 Calibration

5.6.2.1.1 …the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Système international d'unités).....When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability.

5.6.2.2 Testing

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

Based on these general requirements:

3.2.1 A program and procedure for the calibration of laboratory equipment shall be documented and include a list of the equipment requiring calibration, specifications for the calibration laboratory, specified requirements for the calibration, and the interval of calibration.

3.2.1.1 Once established, any extension in the interval of calibration shall be based on documented empirical data.

3.2.2 If available, calibration laboratories shall use a supplier of external calibration services for all calibrations of equipment where the calibration of the equipment has a significant effect on the accuracy or validity of:

(a) sampling, or
(b) the calibration results

that is either:

1) a National Metrology Institute (NMI) that is a signatory to the BIPM - CIPM[7] Mutual Recognition Arrangement with the calibration to be performed listed in Appendix C of the BIPM key comparison database (KCDB)[8]

or

2) a service supplier accredited to ISO/IEC 17025:2005 by an accrediting body that is a signatory to the IAAC[9] Multilateral Recognition Arrangement or the ILAC[10] Mutual Recognition Arrangement, with the calibration to be performed listed in a scope of accreditation.

3.2.3 If available, testing laboratories shall use a supplier of external calibration services for all calibrations of equipment where the calibration of the equipment has a significant effect on:

(a) the accuracy or validity of sampling or a test result, or
(b) the total uncertainty of the test result

that is either:

1) a National Metrology Institute (NMI) that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the calibration to be performed listed in Appendix C of the BIPM key comparison database (KCDB)

or

2) a service supplier accredited to ISO/IEC 17025:2005 by an accrediting body that is a signatory to the IAAC Multilateral Recognition Arrangement or the ILAC Mutual Recognition Arrangement, with the calibration to be performed listed in a scope of accreditation.

3.2.4 For equipment where the calibration does not have a significant effect on sampling, the test result, or the calibration result, the laboratory must determine if a calibration will be performed and what constitutes a reliable calibration laboratory.

3.2.5 When used for measurement traceability, suppliers of external calibration services that do not meet either Clause 3.2.2 or 3.2.3 of this policy must be evaluated with competence, measurement capability and traceability confirmed by the laboratory. Objective evidence of the confirmation shall be readily available for review in the laboratory. (See Section 5 of this policy)

3.2.6 As an alternative to Clauses 3.2.2 and/or 3.2.3 of this policy, calibration or testing laboratories accredited by ASCLD/LAB may perform calibrations on the equipment used to make measurements in the laboratory only when the laboratory:

(a) obtains and maintains accreditation in the field of calibration, with an appropriate scope for the equipment being calibrated (e.g., balances, pipettes, thermometers, etc.), and
(b) the accreditation is granted by an IAAC or ILAC recognized accrediting body with an appropriate scope of recognition.

3.3 Reference Materials

For establishing measurement traceability through reference materials used in the measurement process, the applicable general requirement in ISO/IEC 17025:2005 is:

5.6.3.2 Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

Based on this general requirement:

3.3.1 If a certified reference material (CRM)[11] is changed in a way that alters the traceable measurement value, then the equipment used to alter the CRM shall be evaluated per Section 3.2 of this policy.

3.3.2 When a CRM is used in conjunction with a measuring system[12] for establishing measurement traceability, the measuring system itself will not be subject to the requirements in Section 3.2 of this policy.

3.3.2.1 The laboratory is still responsible for evaluating the other measuring and/or sampling equipment used in the test or calibration method to determine the applicability of Section 3.2 of this policy.

3.3.3 Certified reference material is considered to have valid measurement traceability when supplied by a National Metrology Institute (NMI) and included in a BIPM key comparison database (KCDB) or from an accredited Reference Material Producer (RMP) that is accredited to ISO Guide 34:2009[13] by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the CRM.

3.3.4 Measurement traceability established through the use of a certified reference material acquired from an RMP that does not meet Clause 3.3.3 of this policy must be evaluated with competence and traceability confirmed by the laboratory. Objective evidence of the confirmation shall be readily available for review in the laboratory. (See Section 5 of this policy)

3.4 Reference Standards

For reference standards, the applicable general requirement in ISO/IEC 17025:2005 is:

5.6.3.1 Reference standards

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 5.6.2.1. 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.

Based on this general requirement:

3.4.1 Section 3.2 of this policy must be followed for all reference standards requiring calibration.

3.5 Measurement Assurance

Once established, measurement traceability shall be maintained through a measurement assurance[14] program (however named).

The general requirements in ISO/IEC 17025:2005 that relate to measurement assurance are:

5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

5.6.3.4 Transport and storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

Based on these general requirements:

3.5.1 A laboratory shall determine if intermediate checks are needed to maintain confidence in the calibration status of equipment, reference standards and reference materials. If needed, these checks shall be carried out according to a defined procedure and schedule.

3.5.2 Once established, any extension in the interval of calibration status checks shall be based on documented empirical data.

4 Supplier Evaluation Requirements

4.1 When used to establish and/or maintain measurement traceability, calibrations, reference standards, and reference materials shall be viewed as critical consumables, supplies, and services per Clause 4.6.4 of ISO/IEC 17025:2005.

The applicable requirement in ISO/IEC 17025:2005 for evaluating suppliers of critical consumables, supplies and services is:

4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

Based on this general requirement:

4.2 The laboratory shall evaluate suppliers of calibrations of equipment or reference standards, suppliers of reference standards and suppliers of reference materials to confirm that the supplier meets the specifications of the laboratory and this policy. (See Clauses 3.2.2 through 3.2.6 of this policy for equipment and/or reference standards) (See Clauses 3.3.3 and 3.3.4 of this policy for reference materials)

Objective evidence of each supplier evaluation and a list of approved suppliers shall be readily available for review in the laboratory. (See Section 5 of this policy)

5 Record Requirements

Laboratory records will be assessed by ASCLD/LAB as a part of determining conformance with the requirements of ISO/IEC 17025:2005 (cited above) and the provisions of this policy.

NOTES – All links last confirmed on December 30, 2014

[1] "Measurement traceability" refers to "metrological traceability."

VIM Definition - 2.41 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

Source: Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections).

[2] International Organization for Standardization (ISO), *ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories* (Geneva, Switzerland: ISO, 2005). Available for purchase at http://www.iso.org/iso/home/store/catalogue_ics.htm or from other authorized distributors.

Additional information about ISO is available at http://www.iso.org/iso/home.html.

[3] ISO, *ISO/IEC 17025:2005 – Clause 1.4 – Note 1: "The term 'management system' in this International Standard means the quality, administrative and technical systems of a laboratory."*

[4] Adapted from:

National Institute of Standards and Technology (NIST), *GMP 13 Good Measurement Practice for Ensuring Metrological Traceability*, (Gaithersburg, Maryland, September 2014). Available for download at http://www.nist.gov/pml/wmd/labmetrology/upload/GMP_13_20140911.pdf

[5] Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections). Available for download at http://www.bipm.org/en/publications/guides/vim.html.

Even though the electronic version of the 3rd edition of the VIM is available free of charge on the BIPM's website, copyright of that document is shared jointly by the JCGM member organizations (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, and OIML).

[6] American Society of Crime Laboratory Director / Laboratory Accreditation Board (ASCLD/LAB): *ASCLD/LAB Policy on Measurement Uncertainty,* Section 3 *(AL-PD-3060) (*Garner, North Carolina: ASCLD/LAB, 2013*).* Available at: www.ascld-lab.org

[7] International Bureau of Weights and Measures (BIPM): More information about the BIPM is available at: http://www.bipm.org/en/cipm-mra/

[8] International Bureau of Weights and Measures (BIPM) key comparison database (KCDB), Appendix C: Available at: http://kcdb.bipm.org/appendixC/

[9] Inter American Accreditation Cooperation (IAAC): More information about the IAAC is available at http://www.iaac.org.mx/English/Index.php

[10] International Laboratory Accreditation Cooperation (ILAC): More information about ILAC is available at www.ilac.org

[11] VIM Definition - 5.14 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 traceabilities, using valid procedures

Source: Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections).

[12] VIM Definition – 3.2 measuring system: set of one or more measuring instruments and often other devices, including any reagent and supply, assembled and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds

Source: Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections).

ASCLD/LAB NOTE: For interpreting and applying 3.3.2 of this policy, a gas chromatograph is an example of a measuring system.

[13] International Organization for Standardization (ISO), *ISO Guide 34:2009 General requirements for the competence of reference material producers* (Geneva, Switzerland: ISO, 2009). Available for purchase at http://www.iso.org/iso/home/store/catalogue_ics.htm or from other authorized distributors.

[14] ASCLD/LAB Definition - measurement assurance: Practices put in place to monitor a testing or calibration process and to ensure the calibration status of equipment, reference standards or reference materials used in a measurement process.

The National Institute of Standards and Technology (NIST) offers the following definition of "internal measurement assurance program" in a *Glossary of Terms* found at:
http://www.nist.gov/traceability/suppl_matls_for_nist_policy_rev.cfm#internal_map

Internal measurement assurance program: A program of sufficient complexity, within an organization, to provide credibility to the measurement uncertainty and measurement result for which traceability is to be established. An internal measurement assurance program usually involves monitoring the performance (e.g., stability, reproducibility) of the instrument, standard, or measurement system, both before and after it is characterized, calibrated, or used to obtain the traceable measurement result.