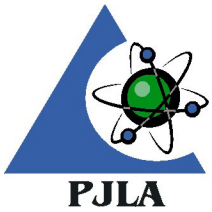


Perry Johnson Laboratory Accreditation, Inc.

Measurement Traceability Policy

1.0 INTRODUCTION

1.1 The following pages describe the responsibilities of organizations seeking accreditation by PJLA in reference to measurement traceability.

1.2 The policy detailed within this document applies only to calibrations or tests for which an accredited result is to be reported.

1.3 For the purpose of this procedure, the term 'traceability' is defined as the process by which the result of a measurement is compared to an international or national standard.

1.4 Traceability is characterized by a number of essential elements[1]:

1.4.1 **an unbroken chain of comparisons**, going back to a standard acceptable to the parties; usually a national or international standard;

1.4.2 **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 overall uncertainty for the whole chain may be calculated or estimated;

1.4.3 **documentation**, each step in the chain must be performed according to documented and generally acknowledged procedures; the results must be equally documented;

1.4.4 **competence**, the organizations or bodies performing one or more steps in the chain must supply evidence for their technical competence;

1.4.4.1 e.g., by demonstrating that they are accredited

1.4.5 **reference to the SI units**, the chain of comparisons must, where possible, end at primary standards for the realization of the SI units, and;

1.4.6 **calibration intervals**, calibrations must be repeated at appropriate intervals; the length of these intervals depends on a number of variables.

1.4.6.1 e.g., uncertainty required, frequency of use, manner of use, stability of equipment

2.0 DEFINITIONS

2.1 **Metrological Traceability (VIM clause 2.41):** 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. Note 1, clause 2.41 states that 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.

2.2 **Metrological Traceability Chain (VIM clause 2.43):** Metrological traceability where the reference is the definition of a measurement unit through its practical realization. Note 1-The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

2.3 **National Metrology Institutes (NMI) and Designated Institutes (DI):** Organizations that maintain standards in countries (regions), all over the world. Throughout this document the term “NMI” is used to cover both National Metrology Institutes as well as Designated Institutes.

2.4 **Joint Committee for Traceability in Laboratory Medicine (JCTLM):** The CIPM, IFCC and the ILAC platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

2.5 **Bureau International des Poids & Measures (BIPM):** Ensures world-wide uniformity of measurements and their traceability to the International System of Units (SI). It does this with the authority of the Convention of the Metre, a diplomatic treaty between fifty-five nations, and it operates through a series of Consultative Committees, whose members are the national metrology laboratories of the signatory States, and through its own laboratory work. The BIPM carries out measurement-related research. It takes part in, and organizes, international comparisons of national measurement standards, and it carries out calibrations for Member States.

2.6 **Key Comparison Database (KCDB):** A public website containing all information relating to the CIPM MRA, an arrangement establishing the equivalence of measurements made by, and certificates issued by, all the participating institutes signatory to the National Metrology Institutes and other designated institutes.

2.7 **In-house Calibration:** A calibration performed by an organization of its own equipment for use in its accredited calibration or testing activities. By definition, an in-house calibration is a calibration the organization is not accredited to perform. An organization must establish traceability for the results of in-house calibrations with the same degree of rigor required of accredited calibrations. The following requirements must be meet for all in-house calibrations:

2.7.1 a clearly defined quantity that has been measured;

2.7.1.1 e.g., the actual size represented by a micrometer when indicating 1.0000 inches

2.7.2 a complete description of the measurement system or working standard used to perform the measurement;

2.7.2.1 e.g., a grade 00 ceramic gage block with a stated size of 1.000001 in and an uncertainty of +/- 2 µin

2.7.3 a stated measurement result or value, with a documented uncertainty;

2.7.3.1 e.g., 1.0000 in with an uncertainty of +/- 57 µin

2.7.4 a complete specification of the stated reference at the time the measurement system or working standard was compared to it;

2.7.4.1 e.g., Mitutoyo 102-717 0-1 in micrometer with 0.0001 in resolution S/N 017189

2.7.5 an "internal measurement assurance" program for establishing the status of the measurement system or working standard at all times pertinent to the claim of traceability, and;

2.7.5.1 e.g., control chart based on the last 11 years of calibration results for the 00-gage block set with defined limits of variation and specified actions to be taken should these limits be exceeded

2.7.6 an "internal measurement assurance" program for establishing the status of the stated reference at the time that the measurement system or working standard was compared to it.

2.7.6.1 e.g., a system of intermediate checks performed per a documented procedure and schedule

3.0 TRACEABILITY REQUIREMENTS: CALIBRATION &TESTING ORGANIZATIONS INCLUDING CLINICAL TESTING LABORATORIES (ISO 15189)

3.1 In order to achieve accreditation, the applicant organization must have documented policies and procedures for the calibration of all equipment having a significant effect on the accuracy or validity of results (*ISO/IEC 17025:2017, Section 6.5.1 and ISO 15189:2012 Section 5.3.1.4).* Knowledge of the organizations in-house calibrations should be utilized by PJLA in scheduling assessments and determining assessor assignments. In addition, knowledge of in-house calibrations shall be utilized by the assessor in preparing the assessment plan. Assessors are required to obtain evidence that the results of in-house calibrations are traceable to the SI where such traceability is possible and appropriate. Such evidence of traceability is to be included in the assessment package submitted.

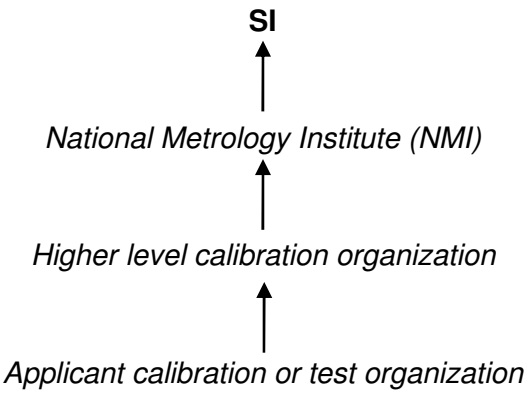
3.2 This significance shall be determined using the method specified in the Estimation of Measurement Uncertainty procedure of the applicant organization.

3.3 The process defined in the aforementioned procedure shall ensure that the results of calibrations and measurements made by the organization are traceable to the International System of Units (SI) through an unbroken chain of comparisons (ISO/IEC 17025:2017 Section 6.5.1, ISO 15189:2012 Section 5.3.1.4).

3.4 Calibration certificates issued by the accredited organization for calibrations performed must provide evidence that measurement results are traceable when this is necessary for the interpretation of results *ISO/IEC 17025:2017 Section 6.5.2, 7.8.4.1 c), Annex A.2.1, A.3.1).* If the organization chooses to reference this traceability on calibration certificates, it must reference traceability to the SI when possible. If it is not possible, then the appropriate measurement standards as listed (*ISO/IEC 17025:2017 Section 6.5.3)* must be identified.

3.5 This can be accomplished through inclusion of a statement similar to the following on the certificate or report. *"The calibration results published in this certificate were obtained using equipment capable of producing results that are traceable through NIST to the International System of Units (SI)"* This statement is intended only as an example and other statements which express the same intent would be acceptable. (ISO/IEC 17025:2017 Section 7.8.4.1 c).

3.6 A simple example for an unbroken chain of comparisons is as follows:



3.7 *Note:* Estimations of measurement uncertainty must be calculated, or provided, for each part of the chain so that the overall uncertainty of measurement can be calculated. For testing organizations, a rigorous, mathematically, and statistically valid estimate of the measurement uncertainty may not be possible, so the requirements (in *ISO/IEC 17025:2017 7.6.3, ISO 15189:2012 Section 5.5.1.4)* would apply. In such cases the organization must identify all the components of uncertainty and make a "reasonable estimation". The "reasonable estimation" is to be based on knowledge of the performance of the method and on the measurement scope. It also shall make use of previous experience and validation data. It can also be based on consensus standards such as ASTM E2554-13, where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results. In these cases, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (*ISO/IEC 17025:2017 7.6.3 incl. Note 1.)*

3.8 The relationship between the measurement result and the SI can also be demonstrated by reference to (listed in order of precedence):

3.8.1 **primary standards[2]:** measurement standard established using a primary reference measurement procedure, or created as an artifact, chosen by convention;

3.8.2 **secondary standards[2]:** measurement standard established through calibration with respect to a primary measurement standard for a quantity of the same kind, and;

3.8.3 **intrinsic measurement standard[2]:** measurement standard based on an inherent and reproducible property of a phenomenon or substance.

3.9 There are some calibrations and tests for which a direct link to the SI is not possible. If traceability to the SI cannot be realized, the applicant organization shall establish traceability to appropriate measurement standards such as: (listed in order of precedence):

3.9.1 the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material or condition;

3.9.2 the use of specified methods and/or consensus standards that are clearly described and agreed upon by all parties concerned (*ISO/IEC 17025:2017 and ISO 15189:2012)*;

3.9.3 values associated with reference materials (RMs) may not be traceable. By definition values associated with certified reference materials (CRMs) are metrologically traceable. Values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited reference material producer (RMP) and in its accredited scope are considered to have traceability. (*ILAC P10.07/20 Policy provisions 7a) and 7b) and ILAC General Assembly resolution ILAC 8.12*), and;

3.9.4 other reference materials and certified reference materials produced by RMPs that do not meet requirements of the previous paragraph can be considered critical “consumables” and their suitability for use shall be verified by the laboratory as required by (*ISO/IEC 17025:2017 6.6.1 and 6.6.2 and ISO 15189:2012, 4.6)*.

3.10 Reference materials or consensus standards maintained by the organization must be used for no purpose other than calibration, unless it can be shown that their performance as reference standards would not be invalidated. The organization shall have and shall employ a documented procedure for the calibration of these reference standards. This procedure must contain the interval at which calibration of the reference standards must be repeated.

3.11 In addition, the applicant organization shall have a procedure for the verification, transport, storage, labeling/indication for validity of reference materials and reference standards. (ISO/IEC 17025:2017 6.4.3 & 6.4.8)

3.12 ISO/IEC 17025:2017 6.5.1 states “The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contribution to the measurement uncertainty, linking them to an appropriate reference.”

Annex A of the same document in A.2.1 further states:

A.2.1 Metrological traceability is established by considering and ensuring the following:

a) The specification of the measurand (quantity to be measured);
b) A documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards;
c) Measurement uncertainty for each step in the traceability chain measurement uncertainty is evaluated according to agreed methods;
d) Each step of the chain is performed in accordance with appropriate methods, and the measurement results and associated, recorded measurement uncertainties;
e) The laboratories performing one or more steps in the chain supply evidence for their technical competence.

3.13 ILAC-P10:07/2020 states that measuring equipment shall be calibrated by:

1) An NMI whose calibration is covered by the CIPM MRA. Calibration services covered by the CIPM MRA can be found in Appendix C of the BIPM KCDB (www.kcdb.bipm.org) with the range and uncertainty listed.

Note 1: Some NMIs may also indicate that their calibration services are covered by the CIPM MRA by including the CIPM MRA logo on their calibration certificates. The fixing of the logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

Note 2: NMIs from Member States participating in the Metre Convention may take traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services (including the range and uncertainty). Individual calibration certificates issued by the BIPM are also listed.

or

2) An accredited provider for which the calibration is covered by the scope of accreditation and the accreditation body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC (ex: APAC, EA, IAAC etc.).

Note: Some calibration laboratories indicate that their service is covered by the ILAC Arrangement by including the ILAC Laboratory Combined MRA mark on the calibration certificate. Alternatively, the accreditation symbol of the accreditation body that is a signatory to the ILAC Arrangement and/or a recognized regional MLA, may be included on the calibration certificate. Both of these options may be taken as evidence of traceability. The use of such logos or marks is not mandatory and the accredited scope remains the authoritative source or reference.

or

3) In the United States, pursuant to the Constitution Article 1 Section 8, and an act of the US Congress in 1901, the National Institute of Science and Technology (previously was called the National Bureau of Standards) was created to establish authoritative national standards. For this and mainly for measures used in legal metrology, NIST recognizes State laboratories as capable of providing traceability through its Weights and Measures program. Not all States have laboratories that are part of the program, and not all States have the same scopes of measurements or calibrations recognized under their Certificate of Metrological Traceability. Some of the recognized laboratories are also accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) an ILAC MRA signatory. However, for the published scopes NIST, the NMI, assesses the laboratories based on ISO/IEC 17025:2017, other criteria (National Conference on Weights and Measures (NCWM) and International Organization of Legal Metrology (OIML) and this is supplemented by an established inter-laboratory comparison proficiency program. Calibrations performed by the laboratories for items covered on their published scopes are accepted as being traceable. The Office of Weights and Measures within NIST maintains current Certificates of Metrological Traceability on their website at https://www.nist.gov/pml/weights-and-measures/resources/state-laboratories-c.

or

4) An NMI whose calibration is suitable for the intended need, but it is not covered by the CIPM MRA. In this case, PJLA has established a policy and process to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025:2017 as documented in this document section 4.0.

5) A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC. In these cases, the accreditation body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025:2017. PJLA has documented this process in section 4.0.

3.14. The ILAC-P10:07/2020 policy for the traceability for Reference Materials Providers (RMPs) through Certified Reference Materials (CRMs) is that certified values of the CRMs are considered to have valid metrological traceability when:

- CRMs are produced by NMIs employing services covered by the BIPM KCDB
- CRMS are produced by an accredited RMP under the scope of accreditation and the Accreditation Body is covered by the ILAC arrangement or a Regional Arrangement recognized by ILAC
- The certified values assign to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

When traceability to the SI is not technically possible, the Accredited Organization shall:

- choose a way to satisfy the traceability requirement using certified values for references materials provided by a competent provider.
- Determine suitable comparison to reference measurement procedures, specified measures, or consensus standards that are accept as providing results fit or intended use. Evidence of this comparison shall be assessed by PJLA.

Surplus test materials from proficiency tests or interlaboratory comparison studies from competent providers that demonstrate measurement or material traceability and within their period of stability (or a documented extended period as determined by the provider) might be used to be evidence of the validity of results.

4.0 TRACEABILITY REQUIREMENTS: NON-ACCREDITED EXTERNAL CALIBRATION PROVIDERS AND NMI(S) NOT COVERED BY CIPM MRA

4.1 Use of non-accredited external calibration providers and NMI's not recognized by the CIPM MRA will be approved on a case-by-case basis. If such situations arise, applicant or accredited organizations shall complete the LF-123 Traceability Form located on the PJLA website. Organizations shall make this document and relevant information available during assessments. Assessor approval will be required, and records of the approval and associated documentation will be provided with the assessment material filed at PJLA headquarters. When an approval is issued, the organization receiving the deviation will be solely responsible for verifying traceability of the conformity assessments performed by the non-accredited external calibration provider. Such verification shall be maintained on file by the organization and shall consist of any documentation provided by the external calibration provider and the basis for the organization's acceptance of the claim of traceability.

PJLA reserves the right to reject a claim of traceability if in the opinion of PJLA all necessary requirements for establishing traceability have not been satisfied. Should it be determined that a claim of traceability is not adequately established and therefore rejected, PJLA will initiate its policy for removal of the conformity assessment activity from the scope of accreditation. Organizations should consult NIST's or other appropriate NMI websites for information required to demonstrate and substantiate traceability.

5.0 TRACEABILITY REQUIREMENTS: TESTING ORGANIZATIONS (INCLUDING CLINICAL TESTING ORGANIZATIONS (15189)

5.1 For testing organizations, PJLA's policies regarding measurement traceability must be maintained (see above), unless it has been established that the uncertainty of the calibration is not a significant contributor to the total uncertainty of the test result(s). Where practicable, an unbroken link to the SI must be demonstrated through objective, verifiable evidence. In the event that traceability to the SI is not possible, the testing organization shall demonstrate traceability to

certified reference materials applicable and accepted reference standards, methods or consensus standards as described above *(ISO/IEC 17025:2017 and ISO 15189:2012*).

5.2 If calibration is not a dominant factor in the testing result(s) and the associated uncertainties the laboratory is to have evidence to substantiate or confirm the fact that traceability (of the equipment calibration results) does not need to be demonstrated (*ILAC P10.01/13 Policy provision 5*).

5.3 The applicant testing organization shall have documented procedures detailing the verification, transport and storage of reference standards. In addition, the applicant organization shall have documented policies and procedures regarding measurement traceability. If the organization chooses to reference this traceability on test reports/certificates, it must reference traceability to the SI when possible and relevant and if not possible and relevant, the appropriate measurement standards as listed in (*ISO/IEC 17025:2017 Section 6.5.2 and ISO 15189:2012, 5.3.1.4)* must be identified.

5.3.1 This can be accomplished through inclusion of a statement similar to the following on the certificate or report. “The test results published in this report were obtained using equipment capable of producing results that are traceable through NIST to the International System of Units (SI)” This statement is intended only as an example and other statements which express the same intent would be acceptable.

5.4 For reference material producers (RMP) the requirements follow those for testing organizations with specific outline in *ISO 17034:2016 General requirements for the competence of reference material producers.*

6.0 TRACEABILITY REQUIREMENTS: REFERENCE MATERIAL PRODUCERS (RMPS)/(CRMS)

6.1 The values assigned to CRMs produced by NMIs are included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to *ISO17024:2016,* are considered to have established valid traceability.

6.2 The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

6.3 The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the laboratory shall demonstrate that each RM or CRM is suitable for its intended use as required (*ISO/IEC 17025:2017 6.6.2 and ISO 15189:2012, 5.3.2).*

6.4 The metrological traceability shall be achieved through an unbroken chain of calibrations, all having stated uncertainties wherever practical and possible. For many reference materials metrological traceability is not achievable. When this cannot be defined for the reference material, the reference material producer shall provide satisfactory evidence of the correlation of results with other stated values, either by exhaustive evaluation of the measurement process or by comparison with known and accepted certified reference materials, which have certified values preferably with comparatively small uncertainty and which are higher in the metrological traceability hierarchy with few steps of comparison.

PJLA requires the traceability to be stated on the RMPs certificate (if a CRM) or for an RM defined between the RMP and client as part of the contract review.

7.0 TRACEABILITY REQUIREMENTS: ACCREDITED ORGANIZATIONS

7.1 Upon attainment of accreditation, organizations are required to maintain the traceability of calibration and test results in the same manner as detailed previously for applicant organizations.

REFERENCES

- ILAC-P10:07/ 2020 ILAC *Policy on Metrological Traceability of Measurement Results*
- *International Vocabulary of Basic and General Terms in Metrology (VIM), 3rd edition, JCGM 200:2012 (JCGM 100:2008 with minor corrections) available from the BIPM homepage www.bipm.org or ISO/IEC Guide 99:2007 available from ISO.*
- ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*
- ILAC-G24:2007 *Guidelines for the Determination of Calibration Intervals of Measurement Instruments*
- ISO 17034:2016 *General requirements for the competence of reference material producers*
- ILAC P14:09/2020 *ILAC Policy for Uncertainty in Calibration*
- ASTM E2554-13 *Standard Practice for Estimating and Monitoring the Uncertainty of Test Results of a Test Method Using Control Chart Techniques*
- Eurachem/CITAC guide*: Quantifying Uncertainty in Analytical Measurement, Third edition, (2012)*
- *ILAC General Assembly Resolution* ILAC 8.12.
- ISO 15189: 2012 *Medical Laboratories Requirements for Quality and Competence*