

Perry Johnson Laboratory Accreditation, Inc.

Measurement Traceability Policy

1.0 INTRODUCTION

1.1 A Conformity Assessment Body (CAB) seeking or maintaining accreditation shall maintain metrological traceability for its conformity assessment activity, whenever possible.

1.2 This document outlines the policy on how metrological traceability is achieved.

1.3 This document is written to meet the requirements outlined in ILAC-P10:07/2020.

2.0 METROLOGICAL TRACEABILITY

2.1 The CAB shall ensure that all testing and calibration results are traceable whenever possible through the US Department of Commerce, National Institute of Standards and Technology (NIST) or another National Metrology Institute (NMI) to the International System of Units (SI units). Acceptable sources of metrological traceability is as follows:

2.1.1 METROLOGICAL TRACEABILITY FROM AN NMI

2.1.1.1 Applicant and accredited CABs may submit appropriate physical standards and measurement and test equipment directly to a NMI or a Designated Institute (DI). A NMI or DI whose service is suitable for the intended use but not covered by the International Committee of Weight and Measures (CIPM) mutual recognition arrangement (MRA) shall be approved by PJLA as stated in section 2.2.

The current participants list for the CIPM MRA may be found on the International Bureau of Weights and Measures (BIPM) website.

Examples include, but are not limited to the following:

- In the US this is fulfilled by NIST, the National Institute of Standards and Technology, a non-regulatory agency of the U.S. Department of Commerce.
- In Japan, traceability is validated by the calibration of measuring instruments by “225 notifying manufacturing business operators for specified measuring instruments under Measurement Act" in addition to AIST (National Institute of Advanced Industrial Science and Technology), NMIJ (National Metrology Institute of Japan), and JCSS (Japan Calibration Service System).

2.1.2 METROLOGICAL TRACEABILITY FROM AN ISO/IEC 17025 ACCREDITED CAB

2.1.2.1 Applicant and accredited CABs may use ISO/IEC 17025 accredited calibration CAB services whenever available. Acceptable ISO/IEC 17025 accredited calibration laboratories are those accredited by PJLA or another

accreditation body that is a signatory of the International Laboratory Accreditation Cooperation (ILAC) MRA with the appropriate calibration services listed in the scope of accreditation.

A list of ISO/IEC 17025 laboratories accredited by PJLA is available on PJLA's website.

2.1.2.2 When using accredited calibration CAB services, the calibration certificates shall be an endorsed report (i.e. include the accreditation body symbol or claim of accreditation traceable to the certificate of accreditation) to be considered satisfactory for metrological traceability purposes.

2.1.2.2.1 Evidence of accreditation of the calibration provider with the applicable calibration in the scope of accreditation shall be available during the assessment.

2.1.3 METROLOGICAL TRACEABILITY FROM WEIGHTS AND MEASURES LABORATORY

2.1.3.1 CABs may use a national, state, or provincial weights and measures laboratory that is recognized and/or traceable to any recognized NMI.

2.1.3.1.1 Evidence of recognition and/or metrological traceability shall be available during the assessment.

2.1.4 METROLOGICAL TRACEABILITY FROM A NMI WHOSE SERVICE IS SUITABLE FOR THE INTENDED USE BUT NOT COVERED BY THE CIPM MRA

2.1.4.1 To ensure metrological traceability of measurement, an accredited CAB may have calibration performed by a NMI whose service is suitable for the intended use but not covered by the CIPM MRA, if the appropriate requirements of ISO/IEC 17025 and the following requirements are met:

2.1.4.1.1 The CAB shall maintain an appropriate environment for carrying out the calibration.

2.1.4.1.2 The CAB shall have appropriately trained personnel, with competence records to perform the calibrations it undertakes.

2.1.4.1.3 The CAB shall maintain metrologically traceable reference standards, certified reference materials, or reference measuring instruments are traceable with appropriate measurement uncertainties.

2.1.4.1.4 The CAB shall have documented procedure for each type of calibration.

2.1.4.1.5 The CAB shall maintain means of recording and reporting all data, results, and related measurement uncertainties according to the requirements of ISO/IEC 17025.

2.2 When an applicant or accredited CAB seeks to submit reference standards and equipment to a calibration provider not covered by the metrological traceability hierarchy above, the CAB shall complete the Traceability Acceptance Criteria Form (LF-123) and obtain approval of that non-accredited calibration provider by submitting the following evidence:

2.2.1 An unbroken chain of comparisons to a standard acceptable to the parties, usually a national or international standard.

2.2.2 Measurement uncertainty throughout the metrological traceability chain has been calculated according to accepted methods and stated so an overall uncertainty for the whole chain can be calculated.

2.2.3 Each step in the chain that has been performed according to documented and generally acknowledged procedures, with documented results.

2.2.4 Technical competence of the non-accredited provider.

2.2.5 Metrological traceability to SI units.

Note: PJLA reserves the right to reject a claim of traceability if all necessary requirements for establishing traceability have not been satisfied

2.3 The CAB shall maintain appropriate calibration intervals based on the variables and risks evaluated by the CAB.

3.0 METROLOGICAL TRACEABILITY USING REFERENCE MATERIALS

3.1 The CAB shall ensure that all testing and calibration results are traceable whenever possible through NIST or another NMI to the International System of Units (SI units).

When this is not feasible or possible, metrological traceability to reference materials, consensus standards, or defined methods shall be used.

3.2 Demonstrating Metrological Traceability Using Reference Materials

3.2.1 When the CAB obtains metrological traceability by using reference materials, it shall use one of the following:

a) Standard Reference Materials (SRM) from NIST or Certified Reference Materials (CRMs) produced from another NMI using a service that is included in the BIPM Key Comparison Database (KCDB). The current participants list for the CIPM MRA may be found on the International Bureau of Weights and Measures (BIPM) website.

b) CRMs from a reference material producer (RMP) accredited to ISO 17034 by PJLA or another accreditation body that is a signatory of the ILAC MRA for RMP.

Evidence of accreditation of the reference material producer with the applicable certified reference materials in the scope of accreditation shall be available during the assessment.

c) The certified values assigned to CRMs are covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database.

3.2.2 If metrological traceability per 3.2.1 is not possible, the CAB shall obtain metrological traceability from authoritative sources.

3.2.2.1 The CAB shall determine that reference materials obtained from authoritative sources are fit for intended uses in accordance with established and validated procedures.

3.2.3 If metrological traceability per 3.2.1 or 3.2.2 is not possible, or when no methods or reference materials are available, the CAB shall develop methods or materials and validate those methods or materials to demonstrate fitness for use.

3.3 The CAB shall maintain appropriate calibration intervals based on the variables and risks evaluated by the CAB.

4.0 IN-HOUSE CALIBRATIONS

4.1 To ensure metrological traceability of measurement, a CAB may calibrate its own reference standards or equipment that supports an accredited parameter in the scope of accreditation if the appropriate requirements of ISO/IEC 17025 and the following requirements are met:

4.1.1 The CAB shall maintain an appropriate environment for carrying out the calibration.

4.1.2 The CAB shall have appropriately trained personnel, with competence records to perform the calibrations it undertakes.

4.1.3 The CAB shall maintain metrologically traceable reference standards, certified reference materials, or reference measuring instruments are traceable with appropriate measurement uncertainties.

4.1.4 The CAB shall have documented procedure for each type of calibration.

4.1.5 The CAB shall maintain means of recording and reporting all data, results, and related measurement uncertainties according to the requirements of ISO/IEC 17025.

4.2 The CAB shall maintain appropriate calibration intervals based on the variables and risks evaluated by the CAB.