A61-01 – CALA Traceability Policy
Revision 3.3 – November 21, 2018

CALA
Laboratory Accreditation

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CALA TRACEABILITY POLICY

1.0 SCOPE

This CALA Policy documents the requirements for accredited laboratories to maintain traceability of measurement. This policy applies to all laboratories accredited under the CALA Accreditation Program.

2.0 BACKGROUND

In order for users of laboratory data to have confidence in that data, they seek comfort that the values reported from one laboratory are the same as those reported from another laboratory. This is especially critical for testing performed to determine conformance to a specific criterion (e.g., lead in drinking water). This comparability is obtained through traceability.

Traceability is generally obtained by comparisons of the laboratory's measurement equipment to calibration standards traceable to national standards held in a national metrology institute (NMI) (e.g., NRC in Canada or NIST in the USA). These comparisons typically involve a series of comparisons, each one performed under tightly controlled conditions, and each one involving a full accounting of the uncertainty at each step.

Where traceability of measurements to SI units is not possible or not relevant, traceability can be established by means of certified reference materials produced by competent Reference Material Producers, specified methods, and/or consensus standards.

For most analytical testing laboratories, the three most common measurements that require traceability are mass (e.g., balances), temperature (e.g., thermometers), and volume (e.g., pipettes, dilutors and dispensers).

Clauses 6.5.1 and 6.5.2 of ISO/IEC 17025 require that all laboratories establish and maintain traceability of their measurement results to the SI units (e.g., kg, m and s).

3.0 DEFINITIONS

Reference Standard: The standard used to calibrate the working standard (e.g., reference thermometers, masses).

Working Standard: Routinely used to verify measuring equipment or measuring systems (e.g., working thermometers).

Reference Material (RM): Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (ISO 17034:2016).

Certified Reference Material: Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO Guide 17034:2016).

Verification: Verification seeks only to determine whether or not the equipment is operating within its expected tolerances. As tolerances are not the same as uncertainties, verification does not establish traceability.

CIPM Mutual Recognition Arrangement (MRA): The framework through which National Metrology Institutes demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they issue.

BIPM KCDB: Bureau International des Poids et Mesures Key Comparison Database; this database is a public website containing all information relating to the CIPM MRA.

JCTLM: Joint Committee for Traceability in Laboratory Medicine.

ILAC: International Laboratory Accreditation Cooperation.

4.0 POLICY

All equipment used for tests, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the test result (e.g., significant contributor to overall test uncertainty, etc…), or are critical for establishing traceability to the SI (e.g., balances used to prepare calibration standards), shall be calibrated before being put into use. These calibrations shall be traceable to the SI units held at a National Metrology Institute (NMI) via an unbroken chain of comparisons.

4.1 Calibrations

4.1.1 External Calibration Services

For equipment and reference standards that must be calibrated, and if the laboratory chooses to use an external calibration service, the equipment and reference standards must be calibrated by:

- A National Metrology Institute (NMI) whose service is suitable for the intended need and is covered by the CIPM Mutual Recognition Arrangement (MRA); or,
- An accredited calibration laboratory whose service is suitable for the intended need (i.e., the scope of accreditation specifically covers the appropriate calibration, with appropriate uncertainty levels) and who is accredited by an ILAC MRA signatory.

If either of these options is not possible for a particular calibration, an NMI whose service is suitable but not signatory to the CIPM MRA may be used. Likewise, a calibration laboratory whose service is suitable for the intended use but not accredited may be used. In both these cases, the CALA laboratory shall take steps to ensure that the NMI or calibration laboratory is competent. These steps may include performing an assessment of the calibration laboratory or NMI against ISO/IEC 17025 or by obtaining documents and records from the calibration laboratory, including but not limited to:

- Records of calibration method validation
- Procedures for estimation of uncertainty
- Documentation for traceability of measurements
- Documentation for assuring the quality of calibration results
- Documentation for competence of staff
- Documentation for accommodation and environmental conditions
- Audits of the calibration laboratory

In all the above scenarios, the laboratory shall evaluate the certificate from the external calibration provider to ensure that the equipment or standard that was calibrated is fit-for-purpose.

4.1.2 Internal Calibrations

Accredited laboratories may perform internal calibrations for their own working standards and/or equipment. If internal calibration is performed:

- The laboratory shall have documented procedures that are based on valid and appropriate reference methods. As well, these procedures must include a suitable means of propagating uncertainty;
- The laboratory reference standard from which traceability is derived, has been calibrated according to Section 4.1.1 above;
- A calibration certificate is produced that conforms to sections 7.8.2 and 7.8.4 of ISO/IEC 17025. Note: this certificate may be a physical certificate or in suitable electronic form (e.g., pdf, EXCEL, etc.);
- Records of the review and authorization of the calibration certificate indicate fitness-for-purpose; and,
- Training records shall be maintained for staff performing calibrations and shall demonstrate competence and understanding of uncertainty. Depending on the complexity of the internal calibration, more rigorous training may be required (e.g., calibration of a balance).

Depending on the complexity of the internal calibration, CALA may request further information from the laboratory or assign a metrology expert to the assessment team.

4.2 Reference Materials

Accredited laboratories shall demonstrate traceability by use of certified reference materials produced by a competent Reference Material Producer (RMP), where available, appropriate and practicable.

A competent RMP is one who has been accredited to ISO 17034:2016 for the production of reference materials listed under its accredited Scope of Accreditation.

Alternatively, valid traceability can be established by using CRMs produced by NMIs and included in the BIPM Key Comparison Database (KCDB) or JCTLM database.

5.0 CALIBRATION PROGRAM

It is the responsibility of the laboratory to justify the need for calibration. If a calibration is not a dominant factor in the testing result, the laboratory shall have quantitative evidence to demonstrate that the associated contribution of the calibration contributes little (insignificantly) to the measurement result and the measurement uncertainty of the test. If this can be demonstrated, then traceability does not need to be demonstrated.

For equipment and standards requiring calibration, the laboratory calibration program shall be documented and specify the frequency of re-calibration. The frequency of re-calibration is dependent on many factors (e.g., whether it is a reference standard, frequency of use, stability, etc…). Although the frequency of re-calibration may be extended, it cannot be eliminated. The laboratory shall have documented rationale for the selected re-calibration frequency.

If newly purchased measurement equipment is not provided with an appropriate calibration certificate as per 4.1.1 above, then a calibration must be performed prior to use. (Note: It is common for newly purchased mechanical pipettes include a calibration certificate, however, many of these to not conform to section 4.1.1).

6.0 VERIFICATION

Whether or not there is need for calibration, equipment and standards that drift, or are prone to sudden changes in precision or measurement capability, require periodic verification. The verifications shall be appropriate to the range of the use of the equipment.

For these types of equipment and standards that require verification, the laboratory must have verification procedures that detail:

- The frequency of verifications;
- The acceptance criteria; and,
- Actions taken when the acceptance criteria are not met (e.g., recall of data, etc…).

7.0 REFERENCES

The following documents govern in the interpretation and application of this policy:

- Guide to the Expression of Uncertainty of Measurement (GUM)
- Vocabulaire internationale de metrologie (VIM)
- ISO/IEC 17025: *General requirements for the competence of testing and calibration laboratories*
- ISO 17034:2016 – *General requirements for the competence of reference material producers*
- ILAC P10: 01/2013 ILAC *Policy on the Traceability of Measurement Results*
- CALA P19 – CALA *Measurement Uncertainty Policy*
- CALA P07:2017 – CALA *Application of Requirements in ISO/IEC 17025:2017*

The most current version of the above references applies unless indicated otherwise.