TN 2.0: GAC Technical Note 2

Policy on Metrological Traceability

Terms and definitions

The following definitions apply throughout this document:

Metrological traceability (VIM 3 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.

In ISO/IEC 17025 and ISO 15189 the term "traceability" is equivalent to the VIM's "Metrological traceability" and the term "traceability" is used throughout this document.

BIPM (International Bureau of Weights and Measures)

The BIPM is an intergovernmental organisation established by the Metre Convention, through which Member States act together on matters related to measurement science and measurement standards.

The key task of the Bureau is to ensure world-wide uniformity of measurements and their traceability to the International System of Units (SI).

CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement)

Signatories to the MRA include BIPM Member States, Associates of the BIPM General Conference on Weights and Measures, and other international organisations. The MRA provides a means of comparability of national metrology services including national measurement standards and calibration / measurement certificates issued by NMIs.

JCTLM (Joint Committee for Traceability in Laboratory Medicine)

The joint committee includes the CIPM, IFCC (International Federation of Clinical Chemistry) and ILAC.

KCDB (BIPM Key Comparison Database)

The KCDB is 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 signatories.

The KCDB comprises two main sections, one containing information about the internationally recognised Calibration and Measurement Capabilities (CMCs) of the participating signatories and the other containing information about the comparisons supporting these CMCs.

NMI (National Metrology Institute)

NMIs and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes as well as Designated Institutes. Australia's national metrology institute is called the National Measurement Institute and is often referred by the same NMI acronym.

Policy on Metrological Traceability

1. Purpose

This document covers GAC's policy on metrological traceability concerning testing and/or calibration activities, this policy applies to:

- All GAC applicant and accredited facilities;
- All measurements, whether physical, chemical or biological;
  Note: It is acknowledged that the concept of metrological traceability of measurement results in fields such as the chemical, medical, and biological sciences is still under development.
- Calibrations performed by a facility for its own activities and which are not parts of its scope of accreditation (so called "in-house calibrations").

2. Policy for traceability when performing calibrations

For equipment and reference standards that have a significant effect on the reported result and associated uncertainty of measurement shall be calibrated by one of the following:

2.1 Services which are subject to peer review

a) An NMI whose service is suitable for the intended need and is covered by the CIPM MRA. Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty for each listed service.

Notes: Some NMIs may also indicate that their service is covered by the CIPM MRA by including the CIPM MRA logo on their calibration certificates, however, the fixing of the logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

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.

b) An accredited calibration laboratory whose service is suitable for the intended need (i.e. the scope of accreditation specifically identifies the appropriate calibration) and accredited an accrediting body covered by the ILAC MRA for calibration.

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 recognised regional MRA e.g. Asia Pacific Accreditation Cooperation (APAC), may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

2.2 Services which are not subject to peer review

The following two options should only be applicable when options a) and b) above are not possible for a particular calibration.

c) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA.

d) A non-accredited calibration laboratory whose service is suitable for the intended need.

It is unlikely that a decision to choose option c) and d) will be made purely on economic grounds and is more likely to be a last resort. It should be noted that choosing one of these options will require significant effort by the facility i.e. it shall be required to demonstrate that there is evidence of claimed traceability and measurement uncertainty of the calibration services selected. This evidence will be reviewed by GAC at assessments of the facility (which will add to the duration of assessments with associated additional fees reflective of the effort required).
The evidence the facility must maintain of the competence and claimed metrological traceability is likely to include but not be limited to the following (aspects as required in ISO/IEC 17025)

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

In practical terms, the facility would need to have evidence of an assessment of the calibration service provider similar to that which would be conducted by an accreditation body which is signatory to the ILAC MRA.

N.B: Accreditations granted by GAC are accepted as proof to ensure the competence of calibration laboratories and to rely on their services to establish an efficient metrological traceability.

2.3 When calibration cannot be made to SI units and when traceability to SI units is not possible

ISO/IEC 17025, cl 6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

When the facility has demonstrated that options a) to d) cannot reasonably be met. It is the responsibility of the facility to choose a way to satisfy the clause and to provide the appropriate evidence which shall be reviewed by GAC at assessments of the facility.

3. Policy for traceability when performing tests and measurements

For tests and measurements:

e) If the results of calibration of equipment used contributes significantly to the overall uncertainty, the same policy for traceability applies (as detailed above).

f) If the result of a calibration is not a dominant factor in the test or measurement result, the facility shall have quantitative evidence to demonstrate that the associated contribution of the calibration contributes little (insignificantly) to the test or measurement result and associated measurement uncertainty and therefore traceability does not need to be demonstrated.

ISO 15189: clause 5.3.1.4 states:

Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.

Note: *Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.*

Where this is not possible or relevant, other means for providing confidence in the results shall be applied including but not limited to the following:

- *use of certified reference materials*
- *mutual consent standards or methods which are clearly established, specified, characterised and mutually agreed upon by all parties concerned*

Accordingly, where traceability to SI units cannot be achieved, the same criteria as covered in 2.3 shall apply.

4. Policy for traceability obtained through a reference material (RM) and certified reference material (CRM)

ISO/IEC 17025: cl 6.5.2 states that the laboratory shall ensure that measurement results are traceable to the International System of Units (SI).

For ISO 15189, same above applies.

Values associated with RMs may not be metrologically traceable. Values associated with CRMs are, by definition, metrologically traceable.

Traceability is considered to have been established where:

g) The values assigned to CRMs are produced by NMIs and included in the BIPM KCDB or produced by an accredited Reference Material Producer (RMP) under its accredited scope of accreditation to ISO/IEC 17034.

Note: RMPs accredited by a signatory to a regional body e.g. Asia Pacific Cooperation (APAC), are considered to have established valid traceability.

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

i) The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the facility shall demonstrate that each RM or CRM is suitable for its intended use as required by ISO/IEC 17025 or in ISO 15189.