



# **NATA Policy on Calibration and Measurement Traceability**

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## This Session

1. VIM Definitions Calibration and Metrological Traceability
2. Previous Policy on Metrological Traceability
3. Policy on measurement traceability to be updated in the next few weeks based on ILAC Policy P10
4. Policy on accreditation of Calibration Service Suppliers based on ILAC Policy P14

## Calibration: What is it?

An operation that, under specified conditions,

1. Establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties, and
2. Uses this information to establish a relation for obtaining a measurement result from an indication

*(Refer to ISO/IEC Guide 99 (VIM), definition 2.39)*

## A process of comparison

**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.

*(Refer to ISO/IEC Guide 99 (VIM), definition 2.39)*

## Previous Policy on Measurement Traceability

Policy Circular 11, *Policy on Metrological Traceability*:

- Applies to all tests, measurements and calibrations together with assigned values of reference materials
- Equipment or instruments must be calibrated by one of:
  - A NATA accredited lab (with an endorsed report)
  - An ILAC MRA partner accredited lab (with an endorsed report)
  - Australia's National Measurement Institute or one of the CIPM MRA partner National Metrological Institutes

## Previous Policy on Measurement Traceability

Reference materials must have evidence of traceability through:

- A NATA accredited Reference Material Provider (with an endorsed report)
- A Reference Material Provider accredited (as an RMP) by one of NATA's (APLAC) MRA partners (with an endorsed report)
- Australia's National Measurement Institute or one of the CIPM MRA partner National Metrological Institutes
- A competent supplier who can demonstrate traceability of its reference material(s) using specified methods and/or consensus standards that are clearly described and agreed by all parties concerned

**Question: What is a competent supplier?**

## Policy on Measurement Traceability, Calibrations (includes in-house calibration)

For equipment and reference standards that must be calibrated (in order to demonstrate measurement traceability and/or 'is fit for use'), the ILAC policy is that they shall be calibrated by:

1. An NMI who is a member of the CIPM MRA (NMIA is one of these) and only then for services which are listed on the BIPM Key Comparison DataBase KCDB. The KCDB lists the range and uncertainty for which the NMI is acknowledged.
2. A calibration laboratory whose service is accredited by an ILAC MRA partner (in calibration) and acknowledged as a calibration with range and uncertainty listed in their scope of accreditation.

## Policy on Measurement Traceability, Calibrations (includes in-house calibration)

3. 3a & 3b - Either an NMI or calibration laboratory whose service is suitable for the intended need but not covered by either the CIPM MRA or ILAC/regional/APLAC MRAs. In these cases the accreditation body shall establish a policy to ensure that those services meet the relevant criteria for measurement traceability.

For case 3 above what will be NATA's policy?

Option 3 **should** only be used when options 1 & 2 are not possible for a particular calibration.



## Policy on Measurement Traceability, Calibrations (includes in-house calibration)

When using Option 3 the facility must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available. This would include a (testing) facility's assessment of their service providers,

- Records of calibration method validation
- Procedures for estimate of uncertainty
- Evidence of measurement traceability
- Proficiency testing results
- Competence of staff
- Accommodation and environmental conditions
- Audits of the calibration service provider

The Accreditation body must then assess this assessment conducted by the (testing) facility of their service provider. This may require additional Technical Assessors

## Policy on Measurement Traceability, Calibrations (includes in-house calibration)

Clause 5.6.2.1.2 of ISO/IEC 17025 states

*There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:*

- the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;*
- the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.*

*Participation in a suitable programme of inter laboratory comparisons is required where possible.*

4. Clause 5.6.2.1.2 can only be applied in the case in which the facility has demonstrated that options 1 to 3 cannot be reasonably met. It is the responsibility of the laboratory to choose a way to satisfy 5.6.2.1.2 and to provide the appropriate evidence. This evidence shall be documented and the documentation shall be assessed by the accreditation body.

## Policy on Measurement Traceability in Testing

5. If the calibration of instruments used in testing contributes significantly to the overall uncertainty, the same policy for traceability applies as per options 1 to 4 above.
6. 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 a calibration contributes little (insignificantly) to the measurement result and the measurement uncertainty of the test and therefore traceability does not need to be demonstrated.

## Policy on Measurement Traceability provided through Reference Materials

The ILAC policy in regard to traceability provided by RMPs is:

7. The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO Guide 34:2009 [5], are considered to have established valid traceability.
8. The values assigned to CRMs covered by entries in the Joint Committee for Traceability in Laboratory Medicine (JCTLM) database are considered to have established valid traceability.
9. 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 by clause 4.6.2 in ISO/IEC 17025:2005 or 5.3.2.3 in ISO 15189:2012.)

## Policy on Measurement Traceability provided through Reference Materials

Clause 4.6.2 of ISO/IEC 17025 states;

*The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.*

## ILAC Policy on Calibration (P14)

- ILAC P14 (*ILAC Policy for Uncertainty in Calibration*) sets forth ILAC policy regarding the requirements for the evaluation of the uncertainty of measurement in calibration and measurement, evaluation of the calibration and measurement capability (CMC) and listing of the CMC in scopes of accreditation. Introduced in December 2011.
- P14 is applicable to:
  - Calibration laboratories (Physical, Chemical, Biological metrology)
  - Reference measurement laboratories for laboratory medicine
  - Producers of certified reference materials that provide calibration and measurement services
  - P14 may also be applicable to testing laboratories that perform their own calibrations
- States a requirement to report the measurement /correction and the uncertainty of measurement on all calibration reports (with one exception)

## Summary

- ✓ **Calibration:** an activity that provides suitable traceability (usually involves a set of measurements together with a calculation of measurement uncertainty). Is technically assessed as a calibration activity (ILAC P14 requirements in NATA criteria).
- ✓ NATA Policy on Traceability Policy circular 11 is about to be revised to fall in line with ILAC Policy P10
- ✓ Accreditation is task specific. The laboratory must be identified as a calibration service provider with a Calibration and Measurement Capability listed in the scope of accreditation
- ✓ Calibration laboratories must now report both the measurement/correction and the uncertainty of measurement in calibration reports
- ✓ Calibration laboratories can only place the endorsement on reports that fall within the scope of accreditation (CMCs and location of the calibration service)

## Questions?

