

Laboratory Accreditation Programme  
Inspection Body Accreditation Programme  
Reference Material Producer Accreditation Programme  
Proficiency Testing Provider Accreditation Programme

## Technical Policy No.1: Traceability of Measurement

### 0 Preamble

IANZ has traditionally published its technical criteria for accreditation in the Specific or Supplementary Criteria for Accreditation publications relevant to each field of testing or calibration. To ensure consistency of application of generic policies, it has been decided to introduce generic technical policy publications that apply to all fields within the scope of the publication.

This technical policy document sets out the IANZ policy in regard to traceability of measurement to national or international standards of measurement. While this policy should not be substantially different to current policies stated in the Specific or Supplementary Criteria for Accreditation, it does supersede them. In the next revision of the Specific or Supplementary Criteria for Accreditation, the statements on traceability of measurement will be amended to refer back to this document and where relevant, provide programme or field specific guidance on how this policy is to be implemented.

### 1 Scope

This policy applies to all applicant and accredited testing, medical testing and calibration laboratories, inspection bodies, reference material producers and proficiency testing providers in the respective IANZ accreditation programmes.

### 2 Introduction

ISO/IEC 17025<sup>(1)</sup> requires calibration laboratories to have a programme for calibration of equipment that ensures that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*). <sup>(Note 1)</sup> The same requirements apply to test and measuring equipment used in testing laboratories, unless it can be established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. ISO Guide 34<sup>(2)</sup> requires compliance with ISO/IEC 17025 with regard to measuring equipment and, along with ISO/IEC 17043<sup>(3)</sup> both standards have their own metrological traceability requirements for the assigned values. Similarly, ISO 15189<sup>(4)</sup> requires the traceable calibration of items of equipment and ISO/IEC 17020<sup>(5)</sup> requires that, where applicable, measurements made by the inspection body are traceable to national or international standards of measurement, where available.

Measurement traceability is critical to the quality of measurements, testing and calibration. Traceability relates the range and uncertainty of measurements made by an accredited organisation to national and international standards, and this relationship is defined by a chain of comparisons with known uncertainty made by competent organisations. Traceability may also be established using accepted (certified) reference artefacts or reference materials.

The national metrology institute (NMI) of New Zealand is the Measurement Standards Laboratory (MSL; [www.msl.iirl.cri.nz](http://www.msl.iirl.cri.nz)), operating within the Crown Entity, Callaghan Innovation. MSL has responsibility to maintain New Zealand's national standards of measurements consistent with the SI, and to disseminate traceability of these national standards to New Zealand industry and commerce. IANZ has a Memorandum of Understanding on the accreditation of calibration laboratories with MSL in which both organisations agree to collaborate in all matter related to the dissemination of traceable measurements into the community through a network of accredited laboratories.

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### 3 IANZ Policy on Traceability of Measurement

This policy is consistent with the International Laboratory Accreditation Cooperation (ILAC) *Policy on the Traceability of Measurement Results* (ILAC-P10:01/2013)

**3.1** Measurement traceability must be established for all critical measurement <sup>(Note 2)</sup> and calibration equipment by:

- (a) Directly to the New Zealand NMI (MSL), or;
- (b) To another NMI or similar body that is a member of the CIPM MRA<sup>(6)</sup> and has relevant calibration and measurement capabilities (CMCs) on the BIPM<sup>(7)</sup> Key Comparison Database (KCDB), or;
- (c) From an IANZ-accredited calibration laboratory which is accredited for the particular measurement and/or calibration. The calibration certificate must be endorsed with the IANZ calibration laboratory accreditation symbol as this constitutes proof of traceability to national standards. Or;
- (d) From an accredited calibration laboratory which is accredited for the particular measurement and/or calibration by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for calibration, or a signatory to other regional arrangements recognised by ILAC e.g. the Asia Pacific Laboratory Accreditation Cooperation (APLAC) MRA. The calibration certificate must be endorsed with the accreditation symbol of the accreditation body as this constitutes proof of traceability to national standards. Or;
- (e) To an NMI whose service is suitable for the intended need but not covered by the CIPM MRA. In these cases IANZ shall, in consultation with MSL as appropriate, determine on a case-by-case basis the acceptability of the service to meet the relevant criteria for metrological traceability in ISO/IEC 17025, ISO 15189 or ISO/IEC 17020. Or;
- (f) From a calibration laboratory whose service is suitable for the intended need but is not accredited under the ILAC MRA or other ILAC-recognised regional MRAs. In these cases the IANZ applicant or accredited laboratory shall demonstrate that the service supplied meets the relevant criteria for metrological traceability in ISO/IEC 17025, ISO 15189 or ISO/IEC 17020.

**3.2** Laboratories and inspection bodies that have demonstrated traceability of their measurements through the use of calibration services offered according to 3.1 (a), (b), (c) or (d) above have made use of services that have been subject to relevant peer review or accreditation. In the situation where 3.1 (e) or (f) applies, this is not the case, so these traceability routes should only be applicable when 3.1 (a) – (d) are not possible for a particular calibration. Evidence for claimed traceability and measurement uncertainty must be available for IANZ to assess the acceptability of the service. Such evidence may be, but not be restricted to, the following:

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

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- Audit records of the calibration laboratory.

**3.3** For traceability provided through reference materials (RMs) and/or certified reference materials (CRMs) <sup>(Note 3)</sup>, the following policies apply:

- (a) The values assigned to CRMs produced by NMIs. Ideally, these should be included in the BIPM KCDB to be considered to have valid established traceability.
- (b) The values assigned to CRMs produced by accredited reference material producers (RMPs) under its scope of accreditation to ISO Guide 34 by an accreditation body that is a signatory to the ILAC MRA for testing, calibration and/or RMP, or a signatory to other regional arrangements recognised by ILAC e.g. the APLAC MRA, are considered to have valid established traceability.
- (c) The values assigned to CRMs covered by the entries in the JCTLM database<sup>(8)</sup> are considered to have established valid traceability.
- (d) The majority of other RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the laboratory or inspection body shall demonstrate that each RM or CRM is suitable for its intended use as required by clause 4.6 of ISO/IEC 17025, ISO 15189, and ISO Guide 34, clause 5.6 of ISO/IEC 17043, and clause 6.2 of ISO/IEC 17020.

**3.4** In New Zealand, legal metrology is regulated by Trading Standards, an operational unit in the Consumer Protection and Standards branch of the Ministry of Business, Innovation and Employment (MBIE). In general, measurement results from calibration laboratories approved under the Weights and Measures Act are only acceptable for demonstrating measurement traceability if they are also accredited by IANZ.

### Notes:

Note 1 “Traceability (of measurement)” is traceability to the SI *through* bodies such as NMIs and accredited calibration laboratories as set out in Section 3.1; it is not traceability to such bodies themselves.

Note 2 Critical measurements/calibrations are those which will affect the accuracy and proper performance of a test. For testing laboratories, if a calibration or measurement is not a dominant factor in the testing result, the laboratory or inspection body will need to 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.

Note 3 Values associated with RMs may not be metrologically traceable. Values associated with CRMs are, by definition, metrologically traceable.

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### 4 References

1. ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories
2. ISO Guide 34:2009 – General requirements for the competence of reference material producers
3. ISO/IEC 17043:2010 – Conformity assessment – General requirements for proficiency testing
4. ISO 15189:2012 – Medical laboratories – Requirements for quality and competence
5. ISO/IEC 17020:2012 – Conformity assessment – Requirements for the operation of various types of bodies performing inspection
6. CIPM MRA – Comité International des Poids et Mesures (International Committee for Weights and Measures) Mutual Recognition Arrangement (<http://www.bipm.org/en/committees/cipm/>)
7. BIPM – Bureau international des Poids et Mesures (<http://www.bipm.org/en/home/>; <http://kcdb.bipm.org/>)
8. JCTLM - CIPM, International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) & ILAC Joint Committee for Traceability in Laboratory Medicine (<http://www.bipm.org/en/committees/jc/jctlm/>)