PL 003 - 03

POLICY ON TRACEABILITY OF MEASUREMENT RESULTS

Prepared by:	Okechukwu Ejiofor, Quality Manager
Reviewed by:	Lawrena Okoro, Director of Accreditation
Approved by:	Celestine Okanya, DG/CEO
Date of Approval	01/04/2023
Date of Implementation	01/04/2023

PL 003 – Traceability of Measurement Results Issue 3

Table of Contents

1. Purpose and Scope

1.1 The purpose of this NiNAS policy on calibration and measurement traceability is:

a) To identify and provide means to identify acceptable calibration and measurement providers for critical equipment for applicant and accredited laboratories seeking or maintaining accreditation in accordance with ISO/IEC 17025, General requirements for the competence testing and calibration laboratories.

b) To provide requirements where a recognised calibration provider does not exist.
c) To specify how laboratories shall document and demonstrate the competence of calibration and measurement capabilities.
d) To provide laboratories, Team Leaders and Technical Assessors with guidance to assess the selection of calibration providers for critical equipment and to highlight the documentation requirements.

1.2 This policy applies to both testing and calibration laboratories accredited by NiNAS to ISO/IEC 17025 and medical laboratories accredited by NiNAS to ISO 15189. It is also applied where testing and /or calibration is involved e.g. inspection and product certification in which case NiNAS has adopted the ILAC policy stated in sections 5 and 6 respectively of ILAC P10:07/2020.

1.3 This policy document establishes acceptable means of demonstrating the competence of calibration providers;

1.4 This policy applies to initial calibration and recalibration of all critical equipment;

1.5 Due to the nature of some tests, it is not possible, realistic or relevant to expect traceability of measurement results to be demonstrated.

2.0 References

a) ILAC-P10: ILAC Policy on the Traceability of Measurement Results.
b) ISO/IEC 17011: Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.
c) CAN-P-1626: Policy on Calibration and Measurement Traceability, Laboratory Accreditation Programme, Standards Council of Canada.
d) TN 2.0: GAC Technical Note 2: Policy on Metrological Traceability.
e) ISO/IEC 17025: General requirements for the competence of calibration and testing laboratories
f) ISO 15189: Medical laboratories – Requirements for quality and competence
g) ILAC P14_: ILAC policy for uncertainty in calibration
h) INAB Policy on Traceability of Measurements
i) JCGM 200, International vocabulary of metrology – Basic and general concepts and associated terms (VIM).
j) ISO/IEC 17000: Conformity assessment – Vocabulary and general principles.

3.0 Terms and Definitions

3.1) Terms

In this policy all terms in ISO/IEC 17000 and VIM 3rd edition shall apply.

3.1.1 Critical Equipment: As defined in ILAC-P10 / ILAC Policy on Traceability of Measurement Results, NiNAS has adopted the following definition for critical equipment:

> "Equipment used by testing and calibration laboratories, and inspection bodies that is necessary to perform a test, calibration or inspection from the scope of accreditation and which has a significant effect on the uncertainty of measurement of test, calibration or inspection results."

N.B: 'Significant' is defined as changing the value of the expanded uncertainty by 5% or more.

3.1.2 Calibration providers:

a) Recognised Calibration Provider

A laboratory that is ISO/IEC 17025 accredited by an Accreditation Body signatory to the ILAC/AFRAC Mutual Recognition Arrangements (MRA) or a National Metrology Institute (NMI) signatory to the CIPM MRA.

b) Non-Recognised Calibration Provider:

All providers other than those identified above.

3.1.3 In-house Calibration: The calibration of accredited CAB's own reference standards or measuring and test equipment by the laboratory's own staff for which the calibration measurement parameters are not included on their scope of accreditation. In-house calibration of critical equipment is conducted by a laboratory:

- For its own use within the laboratory itself; or
- For other accredited elements within its own organisation.

Note 1: In-house calibration can be performed by testing and/or calibration laboratories.

Note 2: For these measurements to be traceable, the requirements on in-house calibration stated below shall apply.

3.1.4 Internal Calibration: The calibration of an accredited CAB's own reference standards or measuring and test equipment by the laboratory's own staff for which the calibration measurement parameters ARE included on their scope of accreditation.

3.1.5 Measurement 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.

3.1.6 Reference Material (RM):- Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to the materials.

3.1.7 Certified Reference Material (CRM):- A Reference Material accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and trace abilities using valid procedures.

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

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

3.2) Definitions

3.2.1 BIPM: International Bureau of Weights and Measures
3.2.2 BMC: Best Measurement Capability
3.2.3 CABs: Conformity Assessment Bodies
3.2.4 CIPM: International Committee for Weights and Measures
3.2.5 CMC: Calibration and Measurement Capability
3.2.6 CRM: Certified Reference Material
3.2.7 ILC: Inter-laboratory Comparison
3.2.8 KCDB: BIPM Key Comparison Data Base.
3.2.9 NMI: National Metrology Institute.

4.0 Policy

4.1 Traceability requirements when performing calibration

4.1.1 According to ISO/IEC 17025:2017 , clause 6.5.1 , a laboratory must maintain metrological traceability of its measurement results by an unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. The general traceability requirement is that all equipment used for tests and/or calibrations, including equipment for subsidiary measurements

(e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling (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 service. The laboratory shall have an established programme and procedure for the calibration of its equipment.

The laboratory has an obligation to justify the need for the calibration (or not) for its equipment.

4.1.2 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI).

In the case of reference standards, a further requirement applies, which states:

4.1.3 The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in clause 6.5.2 of ISO/IEC 17025:2017. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

4.1.4 It is the policy of the Nigeria National Accreditation System (NiNAS) in further reference to the ILAC P10 document that 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:

a) An NMI whose service is suitable for the intended calibration and is covered by the CIPM MRA. Services covered by CIPM MRA can be found and viewed in

Appendix C of the BIPM KCDB which includes the range and uncertainty for each listed service.

N.B: 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 logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

b) An accredited calibration laboratory whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate calibration range and CMC) and the accreditation body is covered by the ILAC Arrangement or by the Regional Arrangements recognised by ILAC.
c) An NMI, whose service is suitable for the intended need but not covered by the CIPM MRA. In this case the AB shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025.
d) A calibration laboratory, whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC. In this case the AB shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025.

4.1.5 Accredited organisations using calibration services offered according to 4.1.4 c) and 4.1.4 d) should only be applicable when a) or b) is not possible for a particular calibration. When traceability is established through either option c) or d), the facility shall be required to demonstrate that there is evidence of claimed traceability and measurement uncertainty of the calibration services selected. The evidence will be reviewed by NiNAS at the assessment of the facility (which will add to the duration of assessments with associated additional fees reflective of the effort required).

4.1.6 In addition, clause 6.5.3b of ISO/IEC 17025:2017 can only apply when the facility has demonstrated that options a), b), c) and 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 NiNAS at assessments of the facilities.

The evidence the facility must maintain of the competence and claimed metrological traceability is likely to include but not be limited to the following (the numbers in brackets refer the clause numbers of ISO/IEC 17025:2017):

- Audits of the calibration service provider (6.6.2b and 8.8.1);
- Documentation for the competence of staff (6.2.5f);
- Documentation for accommodation and environmental conditions (6.3);
- Records of calibration method validation (7.2.2.1)];
- Procedures for estimation of uncertainty (7.6.2);
- Documentation for traceability of measurements (6.5.2); and
- Documentation for assuring the quality of calibration results (7.7.1).
- Proficiency of inter laboratory comparison participation records to demonstrate assurance of calibration result(s) and uncertainty;

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: It is possible that a laboratory may use a calibration provider that is accredited, but not for the specific calibrations required for the laboratory. In those instances, the laboratory must evaluate and verify the provider's ability to perform the calibration, by the methods outlined above. Records must be maintained of this evaluation.

4.2 When calibration cannot be strictly made to SI units

ISO/IEC 17025:2017 clause 6.5.3 states:

When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

- *Certified values reference materials provided by a competent producer (to give a reliable physical or chemical characterization of a material);*
- *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.*

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

5.0 Requirements for Performing Non-recognised In-house Calibrations

5.1 Where a laboratory performs its own non-recognised in-house calibrations on its critical equipment, the laboratory shall demonstrate a level of competence equivalent to the competence of available recognised calibration providers for the calibration required.

5.1.1 The laboratory records shall support and demonstrate the full extent of the competence of the in-house non-recognised calibration provider and the assessment of that provider.

5.1.2 The laboratory shall be assessed and required to meet the applicable requirements of ISO/IEC 17025 for the calibrations conducted.

5.1.3 Abridged reporting of calibration results is acceptable as long as the conditions of clauses 7.8.1.2 and 7.5.1 are maintained.

N.B: A full report shall be produced if the calibration results are to be used in another laboratory, such as in another site (e.g. calibration laboratory/laboratories which perform calibrations within the organisation).

5.1.4 A laboratory conducting in-house calibrations shall retain the following additional records for proof of:

a) In-house capability;
b) Measurand(s), range(s) and associated uncertainty values;
c) Copies of certificates and reports to demonstrate traceability to the SI system of units, to CRMs or RMs as per option c or d above;
d) Documented requirement for environmental conditions of calibration and records where applicable;
e) Demonstrated technical competence of laboratory personnel conducting the calibration;
f) Demonstrated metrological traceability of all standards, all reference standards and measuring instruments shall be calibrated at appropriate intervals, the facility shall have

and apply a documented procedure for establishing these calibration intervals;

g) Demonstrated metrological traceability for measurand(s), range(s) and reported uncertainties;
h) Calibration procedures used by the laboratory: published methods or non-standard/modified procedure;
i) Procedures for evaluating measurement uncertainty;
j) Validation of uncertainty provided;
k) Validation document for non-standard/modified calibration procedures or method where published methods exist;
l) Proficiency testing or inter laboratory comparison participation records to demonstrate assurance of calibration result(s) and uncertainty;
m) evidence of internal audits of all activities that could influence the quality of calibration result

5.1.5 NiNAS shall assess the competence of the laboratory to conduct in-house calibrations including, but not limited to:

a) Competence of personnel conducting the calibrations;
b) Traceability of standards;
c) Records of measurements and environmental conditions;
d) Procedures for evaluating measurement uncertainty.

5.1.6 NiNAS may include as needed, additional team member(s) to verify competence of the laboratory to conduct in-house calibrations. This can include both on-site and offsite assessments or a combination thereof. Additional costs may apply. Specialist calibration assessors will only be used when either calibration is outside the area of expertise of the technical assessors who would normally conduct the assessment or reassessment or if it will be more time or cost effective.

6.0 Traceability Requirements When Performing Tests and Measurements

In accordance with ILAC P10:07/2020, section 3, the NiNAS Policy for measuring and test equipment shall be:

a) If the calibration of instruments used in testing laboratories under ISO/IEC 17025 or medical laboratories under ISO 15189:2012 contributes significantly (>5%) to the overall uncertainty, the same policy for traceability applies (as detailed under 5a to d).

b) If the calibration of instruments is not a dominant factor in the test or measurement result, the (facility) laboratory shall have quantitative evidence to demonstrate that the associated contribution of a calibration contributed little (insignificantly - <5%) to the measurement result and the measurement uncertainty of the test and therefore traceability does not need to be demonstrated.

7.0 When traceability to S.I. units is not possible

Where traceability of measurements to SI units is not technically possible, ISO/IEC 17025:2017 clause 6.5.3a and ISO 15189:2012, clause 5.3.1.4 shall respectively apply. See section 4.2 above.

ISO 15189:2012, clause 5.3.1.4 states that:

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

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; and
- Mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

Accordingly, where traceability to SI units cannot be achieved, the same criteria as covered in 6.2 shall apply.

8.0 Policy for traceability provided through Reference Materials (RMs) and Certified Reference Materials (CRMs)

In reference to clause 6.5...2b of ISO/IEC 17025:2017:

Reference materials shall, where possible, be traceable to SI units of measurement, or certified reference materials.

For ISO 15189:2012, clause 5.3.1.4

as stated above applies to traceability through RMs and CRMs.

8.1 The values assigned to CRMs by NMIs that are included in the BIPM KCDB or produced by an accredited Reference Material Producer (RMP) under its accredited scope of accreditation to ISO 17034 are considered to have valid traceability.

8.2 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.

8.3 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 in ISO/IEC 17025 or ISO 15189.

Note 1: Values associated with RMs may not be metrologically traceable. Values associated with CRMs are, by definition, metrologically traceable.

9. REVISION HISTORY

Revision Level	Revision Date	Description
Original Release	19/09/2018	Initial release of the NiNAS Policy on Traceability of Measurement Results
1	28/09/2018	Alignment of the objectives with the purpose and scope; reformulation of paragraph 1.1; and change of 'definitions' to 'terms and abbreviations'.
2	30/07/2020	Updated to reflect NiNAS new corporate structure and identity; and the requirements of ISO/IEC 17025:2017
3.	01/04/2023	Minor revision in the header and footer