Policy on measurement traceability PS5

1. Purpose

This Statement outlines INAB policy on traceability of measurement for laboratories accredited to ISO 17025 & ISO 15189, inspection bodies accredited to ISO 17020, biobanks accredited to ISO 20387 and reference material producers accredited to ISO 17034.

2. Definition of Traceability

The formal definition of traceability is given in the International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM 3 clause 2.41):

"*Property of measurement results whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.*"

Note 1 to clause 2.41 states that "*a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.*"

Traceability is further characterised as:

2.1) **An unbroken chain of comparison** going back to a stated reference acceptable to the parties, usually a national or international standard.

2.2) **Uncertainty of measurement**; the uncertainty of measurement for each step in the traceability chain must be calculated or estimated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated or estimated.

2.3) **Documentation**; each step in the chain must be performed according to documented and generally acknowledged procedures the results must be recorded.

2.4) **Competence**; CABs performing one or more steps in the chain must supply evidence for their technical competence, e.g. by demonstrating that they are accredited.

2.5) **Reference to SI units**; the chain of comparisons must, where possible, end at primary standards for the realisation of the SI units. The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

2.6) **Calibration interval**; calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables, e.g. uncertainty required, frequency of use, way of use, stability of the equipment.

2.7) **Calibration**; operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

2.8) **Performance check or Verification**; provision of objective evidence that a given item fulfils specified requirements.

3. Introduction

Because measurement results form the basis for many critical decisions in testing and inspection, it is crucial that all measurements are made with the appropriate assurance of accuracy and traceability.

Proper calibration of instrumentation traceable to international measurement standards is an essential first step to ensuring the required accuracy.

Accuracy is defined as the closeness of the agreement between the result of a measurement and the (conventional) true value of the measured quantity. The quantitative expression of this concept should be in terms of uncertainty. The accuracy of measurement achieved is influenced by a number of factors, including:

- The nature of the measuring instrument used;
- The calibration status of the measuring instrument;
- The environment in which the measurement is carried out;
- The procedure followed in performing the measurement.

The responsibility for determining the level of uncertainty to be achieved in tests lies with the CABs themselves. Therefore the organisation's operation (including supporting calibrations) have to be sufficient (and have to be shown to be sufficient) to achieve the level of uncertainty claimed. The verification that these arrangements are indeed adequate to ensure the level of uncertainty claimed will form a central part of the INAB assessment procedure. INAB will also wish to establish that the claimed uncertainty is compatible with limits stated or implied in technical specifications for the tests/inspections for which the laboratory holds or seeks accreditation, and that it is consistent with generally accepted technical considerations in the relevant area.

Traceability of measurement is essential if the results of various measurements are to be mutually comparable, and if uncertainty of measurement is to be meaningfully assigned. INAB requires that all measurements necessary for the proper performance of a method are traceable to international units of measurement, where the concept is applicable. This applies not only to the principal measurements involved, but also to any subsidiary measurements that may significantly affect the results or their validity.

If traceability is to be achieved, not only must an unbroken chain of calibrations exist, but every calibration in the traceability chain must be carried out in a technically sound manner: the staff, equipment, environment and procedures involved in the calibration must be adequate for the task involved. The precise technical requirements that are appropriate, for any given calibration, depend on a number of features, including the accuracy sought in the calibration, the nature of the equipment involved, and the use to which the calibrated equipment is to be put.

In most cases, it is necessary for the calibrations to be carried out in accordance with quite stringent technical requirements, at all stages of the calibration chain.

For more straightforward types of test measurement on the other hand (or for subsidiary measurements whose accuracy does not significantly affect the test result or its validity), the technical requirements at the lower end of the traceability chain may be less stringent. Such determinations will consider the impact of the overall uncertainty of the measurement on the final result.

Intervals between calibrations of measuring standards and measuring equipment shall be established by the accredited organisation on the basis of stability, purpose and usage. Intervals shall be established so that recalibration occurs prior to any probable change in accuracy that is of significance to the use of the equipment. Depending on the results of preceding calibrations, intervals of calibration shall be shortened, if necessary, to ensure continued accuracy.

The selection of a conservatively short initial calibration interval and documented reviews of these intervals in the light of calibration results are features of a good calibration system which will be sought by the INAB assessors.

4. INAB Policy on Traceability of Measurement Results

4.1. Organisations accredited by INAB shall be able to demonstrate that calibration of critical equipment, and hence the calibration, or result generated by that equipment, relevant to their scopes of accreditation, is traceable to the International System of Units (SI units).

"**Critical**" equipment includes those items of equipment necessary to perform an operation or activity from the scope of accreditation and which have a significant effect on the uncertainty of measurement of test, calibration or inspection result.

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

INAB recognises that, due to the nature of some tests, it is not possible, realistic or relevant to expect traceability of every measurement result.

4.2. For equipment and reference standards where calibration is required, the following are acceptable sources of traceability:

i. Directly from an appropriate national metrology institute whose service is suitable for the intended need and is covered by the CIPM MRA. or

ii. From a calibration laboratory that can demonstrate competence, measurement capability and traceability with appropriate measurement uncertainty, e.g. an accredited calibration laboratory whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate calibration) and the Accreditation Body is covered by the ILAC Arrangement or by regional arrangements recognised by ILAC. or

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

iv. 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.

Organisations that have demonstrated traceability of their measurements through the use of calibration services offered according to i) or ii) above have made use of services that have been subject to relevant peer review or accreditation. In the situation where iii) or iv) applies, this is not the case, so these routes should only be applicable when i) or ii) are not possible for a particular calibration. The organisation must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available. INAB will undertake an assessment of this evidence.

It is emphasised that calibration certificates issued by equipment manufacturers or agents are not acceptable evidence of external traceability, unless these are clearly identified as having been issued by an accredited calibration laboratory.

4.3. CABs shall ensure the traceability of their in-house calibrations and/or accredited results to an external calibration provider that is accredited for suitably small uncertainties or that can otherwise demonstrate its competence, or to a national metrology institute or national reference laboratory or to a certified reference material or mutual consent standard or agreed method.

If the calibration of instruments used contributes significantly to the overall uncertainty, the same policy for traceability applies as for calibration laboratories applies, 4.2 i) to iv) above.

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

4.4. Accredited CABs: If the calibration is not a dominant factor in the overall testing result, the organisation shall have documented quantitative evidence to demonstrate that the associated calibration contributes little (insignificant) to the measurement result and the measurement uncertainty and therefore traceability do not need to be demonstrated.

4.5. INAB policy for traceability provided through reference materials (RMs) and certified materials (CRMs):

The values assigned to CRMs by NMIs that are included in the BIPM key comparison database or produced by an accredited reference material producer (RMP) under its accredited scope of accreditation to ISO 17034, are considered to have valid traceability.

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. 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.

5. INAB Policy on Internal Calibrations

5.1. CABs may choose to carry out some calibration activities in house to support their measurement activities, rather than seeking the services of an external accredited laboratory.

5.2. Where a CAB chooses this option, it is essential that these calibration activities provide appropriate traceability of results.

5.3. It is reasonable to expect that in-house calibrations are subject to the same level of technical rigour that would be obtained if an external accredited laboratory or recognised NMI were used.

5.4. To this end, the following shall be in place:

a) A suitable environment in which to conduct the calibration;

b) Trained and authorised personnel to both conduct the calibrations and to carry out any necessary checks;

c) Reference standards, certified reference materials or reference measuring instruments that provide traceable results with suitable measurement uncertainties;

d) A controlled and documented procedure for each calibration method to include details on the calibration and measurement capability and the uncertainty budget for the calibration method;

e) A means of recording and reporting the data and results of any calculations;

f) Details of proficiency/inter-laboratory calibrations. This should also be supported by a suitable level of quality control activities.

5.5. Specialist calibration assessors shall be assigned annually to the INAB assessment teams where internal calibrations are performed. The assessment procedures used will include document review and on-site witnessing.

5.6. Organisations carrying out in-house calibrations in support of their accredited activities are required to provide details of these calibrations to INAB as soon as possible. They also must inform INAB at minimum six months in advance of beginning the process of completing internal calibrations. This is to allow INAB sufficient time to organise an assessment of this activity. Thereafter they must include the details of their in house calibrations in the PS10 documentation. These details shall include information regarding the methodology involved, the traceability arrangements and the uncertainty budgets.

5.7. Furthermore, is important that INAB is notified of any changes to these details as soon as they occur. INAB will use this information to ensure that the appropriate expertise is included in the assessment team to assess these activities. Again, sufficient notice of a minimum of six months is required to ensure the appropriate expertise is available on the on site assessment team.

5.8. The ability to perform internal calibrations will not be included in the published scope of accreditation.

5.9. An organisation will be required to participate in an external PT/ILC programme for all the internal calibration activities performed within the 5-year accreditation cycle.

6. Calibration of Temperature and/or Humidity Controlled Enclosures

Calibration of a temperature and/or humidity controlled enclosure involves determining the difference between the display values of the enclosure and the corresponding values measured within it. This calibration should be performed in conjunction with a distribution mapping across the enclosure's useful volume to ensure that all locations within the enclosure meet the user's performance requirements.

The useful volume of an enclosure is the portion of the enclosure's total volume that is spanned by the sensor measurement locations used for calibration. Depending on the sensor arrangement, the useful volume may significantly differ from the enclosure's total volume. Calibration is essentially valid only for this useful volume. If calibration is conducted only at individual isolated measurement locations, only those specific locations, rather than the entire enclosure and its useful volume, are considered calibrated.

It is highly recommended that an enclosure be calibrated or characterized both when empty and with a load, especially if it is being characterised for the first time or has been modified, in accordance with national or international standards (eg the IEC 60068-3 series or Euramet CG-20). The requirements for ongoing monitoring and recalibration intervals shall be set by the

laboratory following appropriate evaluation of associated risks. Metrological traceability requirements are as above.

7. References

7.1. ILAC G24:2022 Guidelines for the determination of recalibration intervals of measuring equipment ILAC P9:01/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

8. ILAC P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results

9. Implementation

From date of publication.

10. Contact

For further information about this statement please contact the Irish National Accreditation Board at the Metropolitan Building, James Joyce Street, Dublin 1.

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