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TRACEABILITY POLICY

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1.0 SCOPE

This policy document is intended to explain how measurement traceability can be achieved and demonstrated. BAB requirements pertaining to measurement traceability are described. This document is intended for all BAB-accredited and enrolled calibration and testing laboratories, inspection bodies and other conformity assessment activities where testing and/or calibration is involved (e.g., proficiency testing providers, and reference material producers).

2.0 TERMS AND DEFINITIONS

2.1 Accuracy: Accuracy is defined in the VIM as a qualitative term only. It refers only to the concept of closeness to a true value. If one considers only the numbers, then one might examine the quantitative equivalent considerations. 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.

2.2 Bias: Bias is defined (VIM) as the difference between the measurement result and its unknown 'true value'. It can often be estimated and/or eliminated by calibration to a reference standard.

2.3 Calibration: Calibration is a comparison of measurements between two standards or measurement devices. It involves the competent propagation of uncertainties from the instrument or standard whose measurement characteristics are known and traceable to the SI, to an instrument or standard whose measurement characteristics are to be quantified through this comparison.

2.4 Calibration and Measurement Capability (CMC): CMC is defined as "the smallest uncertainty of measurement that a laboratory can achieve within scope of accreditation when performing more or less routine calibrations of nearly ideal measurement standards intended to define, realize, conserve of reproduce a unit or that quality of one or more of its values, or when performing more or less routine calibration of nearly ideal measuring instruments designed for the measurement of that quality".
In relation with the accreditation of calibration laboratories, CMC is stated as expanded uncertainty at 95% confidence level. The important thing in the definition of CMC is that the CMC assigned to accredited calibration laboratory shall reflect the capability of the laboratory to carry out routine calibration of nearly ideal unit under test (UUT), which can be calibrated by the respective laboratory.
Based on the definition, CMC consists of the components which depend on many factors required for demonstrating the competence of a calibration laboratory, such as;

- Personnel education, training, technical knowledge and skill
- Environmental conditions of calibration laboratory
- Maintenance of equipment, including calibration and verification intervals

CMC can be evaluated by assessing a budget contributing uncertainty components, and/or by means of measurement standards that can be calibrated by the respective laboratory.
Detail discussions and examples on the evaluation of CMC are given in the JCGM 100 – *Guide to the Evaluation and Expression of Uncertainty in Measurement.*

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2.5 Control Standard: A standard used as a basis for comparison with calibration standards, prepared independently from the calibration standards, and which undergoes sample processing identical to that carried out for the calibration standards.

2.6 Precision: closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. In other words, how close the replicate measurements are to each other, without regard to how close any of them are to an accepted reference value.

2.7 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. (ISO/IEC 17034)

2.8 SI (Système International d'Unités): The name (International System of Units) adopted by the 11th General Conference on Weights and Measures (1960) for the recommended practical system of units of measurement. The base units are a choice of seven well-defined units: the metre, the kilogram, the second, the ampere, the Kelvin, the mole, and the candela.

2.9 Traceability: A property of the result of a measurement or the value of a standard whereby it can be related, with a stated uncertainty, to stated references, usually national or international standards, through an unbroken chain of comparisons. (ISO Guide 30).

2.10 Trueness: The closeness of agreement between the average value obtained from a large series of test results and an accepted reference value. (ISO 3534-1, 3.12). See Figure 1 above. Note how far the group of white dots is from the true value. Think of it as the distance from the true value to the black dot (mean) Note: It is important to understand that trueness and precision are Independent of each other. One has nothing to do with the other.

2.11 Uncertainty of Measurement: Parameter that characterizes the dispersion of the quantity values that are being attributed to a measurand, based on the information used. (VIM)

2.12 Verification: Confirmation through examination of a given item and provision of objective evidence that it fulfils specified requirements. [modified from ISO 9000] A procedure normally associated with the acquisition of data regarding an instrument to provide some indication as to whether it is operating within expected tolerances. For example, calibrated weights may be placed on a balance and the reading can provide some indication as to whether the balance is operating within expected tolerances. This operation should not be confused with calibration.

Verification does not establish traceability. Verification seeks only to determine whether or not the instrument is operating within its expected tolerances. It is not a method of propagating uncertainties, which is the core issue in a calibration.

Note that manufacturer's tolerances, as provided in data sheets and instrument manuals, may use the same method of expression as an uncertainty, such as ±3% or ±4 grams. These are still only tolerances and should not be confused with uncertainties associated with each range of measurement for the instrument as established through calibration.

2.13 CABs: Conformity assessment bodies (calibration and testing laboratories, inspection bodies and other bodies performing conformity assessment activities where testing and/or calibration is involved (e.g., proficiency testing providers, and reference material producers)

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3.0 REFERENCES

The following documents govern in the interpretation and application of this policy:

- JCGM 100– Guide to the Evaluation and Expression of Uncertainty in Measurement (GUM).
- JCGM 200- Vocabulaire internationale de metrologie (VIM);
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories;
- ILAC P10- ILAC Policy on the Traceability of Measurement Results
- ILAC P14- ILAC Policy for Uncertainty in Calibration

4.0 INTRODUCING THE CONCEPT OF "TRACEABILITY"

Traceability is the 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. The purpose of requiring traceability is to ensure that measurements are accurate representations of the specific quantity subject to measurement, within the uncertainty of the measurement.

Traceability is characterized by six essential elements:

- An Unbroken Chain of Comparisons: going back to stated references acceptable to the parties, usually a national or international standard;
- Measurement Uncertainty: 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;
- Documentation: each step in the chain must be performed according to documented and generally acknowledged procedures; and the results must be recorded;
- Competence: the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence (e.g. by demonstrating that they are accredited);
- Reference To SI Units: the chain of comparisons must, where possible, end at primary standards for realization of the SI units;
- Calibration Intervals: calibrations must be repeated at appropriate intervals; the length in of these intervals will depend on a number of variables (e.g. uncertainty required, frequency of use, way of use, stability of equipment).
- 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.
- Performance check or Verification; provision of objective evidence that a given item fulfils specified requirements.

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5.0 NEED FOR TRACEABILITY

Traceability of the measurement is required to estimate the uncertainties associated with that measurement. Uncertainty of any measurement is required in order to establish the confidence that an interpreter of results can have in it. To ensure confidence in the results of accredited CABs, BAB implement ILAC policies and use guidance documents to assist in the uniform and harmonised approach of accreditation criteria. Metrological traceability of measurement results is a key topic for which a harmonised policy is needed if the market is to have confidence in calibrations, testing and inspections performed by accredited laboratories and inspection bodies covered by the ILAC Arrangement.

6.0 BAB POLICY ON TRACEABILITY

6.1 POLICY STATEMENT

Organizations accredited by BAB shall be able to demonstrate that calibration of measuring equipments, and hence the test, calibration and inspection result generated by that equipment, relevant to their scopes of accreditation, is traceable to the International System of Units (SI units).

Measuring Equipments used by testing, calibration laboratories and inspection bodies is considered by BAB to be those items of equipment necessary to perform a test, calibration or inspection from the scope of accreditation and which have a significant effect on the accuracy or validity of the test, calibration or inspection result.

NOTE: 'Significant' is defined as changing the value of the expanded uncertainty by 5% or more. (Ref: INAB)

BAB requires that:

a) All calibrations of measuring equipment and reference standards, be conducted by:

I. A calibration laboratory accredited to ISO/IEC 17025 by BAB or an internationally-recognized Accreditation Body that is signatory to the ILAC MRA for calibration activity; or,

II. A recognized National Metrology Institute (NMI) including designated institutes capable of providing traceable measurements suitable for the intended need but not covered by the CIPM (Comité International des Poids et Mesures) MRA (Mutual Recognition Arrangement) or,

III. A testing laboratory accredited by BAB to ISO/IEC 17025 and found to meet the requirements of this document for their in-house calibrations.

IV. When these above routes are not possible for a particular calibration, calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognised by ILAC is also accepted. The laboratory must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available. BAB will undertake an assessment of this evidence.

b) 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:

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i. the use of certified reference materials/ reference materials provided by a competent supplier when possible from reference material producer accredited to ISO/IEC 17034 to give a reliable physical or chemical characterization of a material;

ii. A recognized National Metrology Institute (NMI) or designated institute being a signatory to the CIPM MRA and supporting the measurement comparison activities of the CIPM;

[A listing of these recognized and designated Institutes can be found at http://www.bipm.org/en/cipm-mra/participation/signatories.html] or

iii. the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned;

Note: The situation iii can only be applied in the case in which the laboratory has demonstrated that the policy i and ii cannot reasonably be met. It is the responsibility of the laboratory to choose a way to satisfy iii and to provide the appropriate evidence. This evidence shall be documented and the documentation shall be assessed by BAB.

c) All BAB-Accredited and enrolled organizations must define their policy for achieving measurement traceability and also for achieving traceability for reference materials and participate in a suitable programme of inter laboratory comparisons is required where possible.. The policy shall ensure compliance with this policy document.

d) Shall have and apply procedures for evaluating measurement uncertainty for each calibration. However if a calibration is not a dominant factor in the 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.

e) All the CMCs are required to be expressed with ± sign inserted before in the scope which will be made publicly available.

NOTE: It is emphasized 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.

6.2 INTERNAL CALIBRATIONS

6.2.1 The task for in-house calibration laboratories is to calibrate regularly the measuring and test equipment used in the calibration and testing carried out in the laboratories. The in-house calibration shall be carried out, against its reference standards that are traceable to the SI unit through calibration by BAB's accredited calibration laboratories or by a recognized national metrology institute or by calibration laboratories accredited by accreditation bodies that have signed Multilateral Recognition Agreements or Arrangements (MRAs) in the international organization, i.e. International Laboratory Accreditation Cooperation (ILAC) or in the regional organization, such as Asia Pacific Laboratory Accreditation Cooperation (APLAC), European cooperation for Accreditation (EA) etc.

6.2.2 Accreditation of in-house calibration laboratories is not always necessary to carry out separately from the accreditation of its parent organization. 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. However, to ensure the traceability of measurement, all in-house calibrations shall be supported by the following minimal set of elements and shall be assessed by the assessors who

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have sufficient knowledge in the field of metrology and calibration which will include document review and on-site witnessing:

- The in-house laboratory shall maintain documented procedures for the in-house calibrations and the in-house calibrations shall be evidenced by a calibration report, certificate, or sticker, or other suitable method, and calibration records shall e retained for an appropriate, prescribed time;
- A suitable environment in which to conduct the calibration;
- The in-house laboratory shall maintain training records for calibration personnel and these records shall demonstrate the technical competence of the personnel performing the calibrations;
- The in-house laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from accredited calibration labs or a national metrology institute;
- A means of recording and reporting the data and results of any calculations;
- A suitable level of quality control activities;
- Trained and authorised staff to perform the calibrations;
- The in-house laboratory shall have and apply procedures for evaluating measurement uncertainty for each calibration. Measurement uncertainty shall be taken into account when statements of compliance with specifications are made. However if a calibration is not a dominant factor in the 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;
- Reference standards shall be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals shall be based on the historical behavior and scientific justification of the reference standards;
- The ability to perform internal calibrations will not be included in the published scope of accreditation;
- An organisation will be required to participate in an external ILC programme for all the internal calibration activities performed within the 03 year accreditation cycle where possible.

NOTE: Organisations carrying out in-house calibrations in support of their accredited activities are required to provide details of these calibrations to BAB at least one month before the scheduled visit. Thereafter they must include the details of their in house calibrations which shall include information regarding the methodology involved, the traceability arrangements and the uncertainty budgets. Furthermore, is important that BAB is notified of any changes to these details as soon as they occur. BAB will use this information to ensure that the appropriate expertise is included in the assessment team to assess these activities.

6.3 VERIFICATIONS

6.3.1 Instruments that drift, or are prone to sudden changes in precision or measurement capability, require periodic verification. Affected equipment will include, but may not be limited to, balances, mechanical pipettes and portable thermocouples. For these types of sensitive instruments, the laboratory must have verification procedures that detail:

- The frequency of verifications. If a frequency less than daily (when in use) is used, the selected frequency must be such that there is minimal risk of suspect data being released to customers. There may be instances, such as use under adverse conditions, when a frequency greater than daily may be required;

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- The acceptance criteria and if the acceptance criteria are not met, the incident is treated as a non-conformance, investigated and a corrective action implemented (e.g., re-calibration or replacement).

6.3.2 However if a calibration is not a dominant factor in the 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.

7.0 IMPLEMENTATION OF THIS POLICY IN CABS

This policy means three things to CABs.

Firstly, it requires CABs to make use of measurement instruments, whose measurement traceability goes all the way back to an international standard (the SI) through a national measurement laboratory.

Secondly, it means that CABs must know how to spot the signs that a measurement is traceable or not.

Thirdly, it means that BAB CABs must understand the following simple relationship. All three of these components must exist at every level in the traceability chain in order for the final test result to be traceable.

NO CALIBRATION = NO UNCERTAINTY = NO TRACEABILITY