TRACEABILITY POLICY

Revision 3

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1.0 SCOPE

1.1 This policy document is intended to explain the concept of measurement traceability, how it can be achieved, and how it can be demonstrated. AB requirements pertaining to measurement traceability are described. This document is intended for all AB-accredited and enrolled calibration and testing laboratories, inspection bodies, proficiency testing providers, and reference material producers.

1.2 Organizations are not permitted to claim a Calibration and Measurement Capability (CMC) on their scope of accreditation that is smaller than the CMC claimed by the National Metrology Institute (as stated in the key comparison database listed on the Bureau International des Poids et Mesures [BIPM] website, www.bipm.org) through which traceability is achieved unless allowance is made by AB. AB may accept uncertainties smaller than the NMI's "commercial" uncertainty that is provided to its own customers on a case-by-case basis.

2.0 GUIDANCE ON TRACEABILITY OF MEASUREMENT

2.1 UNCERTAINTY AND TRACEABILITY

2.1.1 Traceability is related to the concept of Uncertainty of Measurement. This diagram provides demonstration of their relation.

2.1.2 This diagram shows a series of results as the small white dots. They are not the same as the actual value one would get if we lived in a perfect world. This perfect or true value is represented by the centre of the target.

2.1.3 The black dot represents the average of all the results generated. It is not a result itself. It is also called the mean or average of the set of generated results. If a laboratory has produced a set of results from one large sample, then they may report this average as representative of the whole set.

2.1.4 Whether a laboratory reports a single result or the mean (average) of a set of results, the considerations for reporting uncertainty are the same in all cases. See the Definitions in Section 3 below.

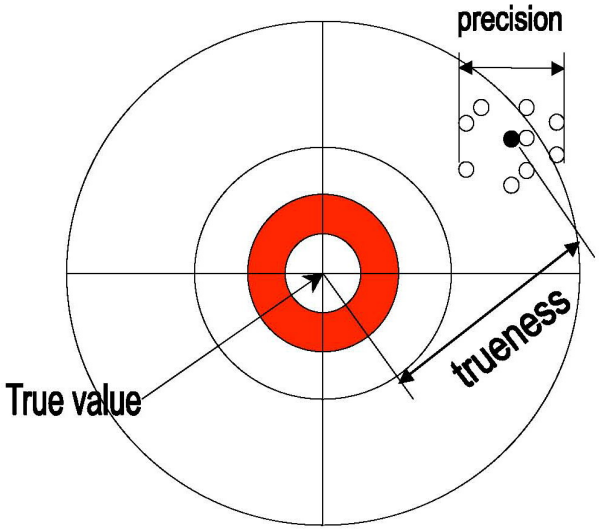

Figure 1. Relationships between traceability components

2.2 NEED FOR TRACEABILITY

2.2.1 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.

2.2.2 Traceability involves the competent propagation of uncertainties all along the chain of measurement to the test result produced by a testing laboratory. See the diagram on the following page. If uncertainties have not been propagated to the actual test result, the result is not traceable. If it is not traceable, then its precision and uncertainties may appear OK, but its trueness will always be suspect.

2.2.3 At the same time, uncertainties established along the traceability chain are the basis for the establishment of traceability of the measurement. The only property of a measuring instrument that counts, in considering traceability, is uncertainty. Test results, in order to be traceable, must be conducted using traceable instruments only.

2.2.4 Only those instruments that have been competently compared to others of known uncertainty (calibrated) can have their contribution to the overall uncertainty of the measurement objectively examined. When this condition is met, the measurement is considered traceable. If the instruments are not traceable, then the test result is not traceable.

2.3 TRACEABILITY CHAIN

2.3.1 At the top of this diagram are all of the National Metrology Institutes (NMIs) that are responsible in each nation for quantifying specific parameters for use within their nation. Most NMI's have signed a multilateral recognition agreement based on the demonstration of competence (e.g., accreditation against ISO/IEC 17025).

2.3.2 The first job of an NMI is to characterize a parameter, such as mass or temperature, to a specific level of uncertainty. They propagate this uncertainty in support of competent measurements. This affects legal measurements (butcher weigh scales and gas pumps) as well as other fields of science requiring competent measurement.

2.3.3 Each NMI has the ability to conduct measurements with very small uncertainties. They are also able to calibrate the instruments from calibration laboratories seeking to establish traceability to the NMI. This is the start of the traceability chain for a testing laboratory.

2.3.4 Calibration, Traceability and Uncertainty are all required at any point in the traceability chain. None of these are deemed to be present unless ALL are present.

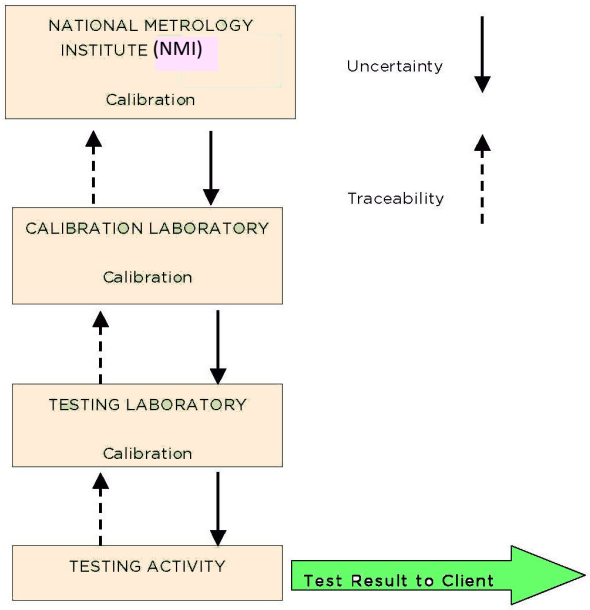

Figure 2. Traceability Chain in Myanmar

3.0 TERMS AND DEFINITIONS

3.1 **Accuracy**: See Figure 1 above. 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. These are trueness and precision: Accuracy is 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. These are trueness and precision.

3.2 **Bias**: See Figure 1 above. While the distance from the black dot to the centre of the target is a representation of how close the set of results came to the true value, the direction of the black dot from the true value can also be known as bias.

3.3 **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.

3.4 **Calibration Curve:** This applies to analytical laboratory instrumentation. The term defines the relation between analyte concentration and instrument response.

3.5 **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 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
- 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.*

3.6 **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.

3.7 **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.

See Figure 1 above. Precision is how dispersed the group of white dots are from each other and from the black dot (dispersion). Note: It is important to understand that trueness and precision are Independent of each other. One has nothing to do with the other.

3.8 **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 17043)

3.9 **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.

3.10 **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).

3.11 **Test Uncertainty Ratio (TUR):** It is often the case that a calibration certificate will contain the statement "in tolerance", or words to that effect, along with a statement to the effect that the measurement uncertainty does not exceed a certain fraction of the tolerance. Such fractions are often called "test uncertainty ratios", TURs for short. These do not meet the requirements of the AB Traceability Policy.

3.12 **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.

3.13 **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)

3.14 **Verification**: Confirmation through examination of a given item and provision of objective evidence that it fulfils specified requirements. [modified from ISO 9000:2005, item 3.8.4] 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.

4.0 REFERENCES

4.1 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

5.0 AB POLICY ON TRACEABILITY

5.1 POLICY STATEMENT

5.1.1 AB requires that:

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

- A calibration laboratory accredited to ISO/IEC 17025 by a internationally-recognized Accreditation Body; or,
- A recognized National Metrology Institute (NMI) including designated institutes. Recognition of the NMI is based on the Institute or designated institute being a signatory to the CIPM (Comité International des Poids et Mesures) MRA (Mutual Recognition Arrangement) and supporting the measurement comparison activities of the CIPM. A listing of these recognized Institutes can be found at http://www.bipm.org/en/cipm-mra/participation/signatories.html; or,
- A laboratory accredited by AB to ISO/IEC 17025 and found to meet the requirements of this document for their in-house calibrations.

(b) When possible, all reference materials shall be obtained from:

- A reference material producer accredited to ISO Guide 34 by a recognized International Laboratory Accreditation (ILAC) signatory recognized for accrediting reference material producers; or,
- A recognized National Metrology Institute (NMI) or designated institute.

(c) For those external calibrations and verifications, these must be recorded in a calibration certificate or report and must include:

- An endorsement by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body); and
- An indication of the type of entity that is accredited (e.g., via an accreditation certificate number, inclusion of "calibration laboratory" with the symbol, etc);

  Note: If newly purchased measurement equipment is not provided with an appropriate calibration certificate, which is still common for many pieces of dispensing equipment, then a calibration must be performed prior to use.

- Or contain an endorsement by the National Metrology Institute (NMI); and
- The measurement uncertainty.

(d) For internal calibrations and verifications, those requirements outlined in this document apply.

(e) For reference materials, these must be recorded in a certificate meeting the requirements of ISO Guide 31 and must also include:

- an endorsement by the recognized Accreditation Body's symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body); and
- an indication of the type of entity that is accredited or endorsed by the recognized NMI.

5.1.2 All AB-Accredited and enrolled organizations must define their policy for achieving measurement traceability and also for achieving traceability for reference materials if applicable. The policy shall ensure compliance with this policy document.

5.2 INTRODUCING THE CONCEPT OF "TRACEABILITY"

5.2.1 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.

5.2.2 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).

5.3 THE DISTINCTION BETWEEN CALIBRATION AND TESTING

5.3.1 Calibration is defined as the "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"4. A test is defined as a "determination of one or more characteristics of an object of conformity assessment, according to a procedure."

5.3.2 In short, "calibration" means determining and documenting the deviation of the indication of a traceable measuring instrument (or the stated value of a material measure) from the conventional "true" value of the measurand. The term "traceability" means a process whereby the indication of a measuring instrument (or a material measure) can be compared, in one or more stages, with a national or international standard for the measurand in question. Traceability is typically achieved through calibration services. However, in some instances, traceability can be achieved through test results. For example, since AB enforces the same requirements on dimensional testing laboratories (including traceability requirements and requirements pertaining to the calculation and reporting of measurement uncertainty) as it does for dimensional calibration laboratories, the distinction between calibration and testing can be lost.

5.4 CALIBRATIONS

5.4.1 Laboratories that calibrate their measurement equipment on an annual basis are deemed to be compliant with this policy. Decreasing the frequency of calibration will save the laboratory some calibration costs, but this can only be done if the laboratory has solid evidence in hand about how each instrument contributes to the overall uncertainties of all measurements made with it (see A.3.1 Significance Test in appendix A for an example). Conversely, it may be possible that the frequency of calibration needs to be increased (e.g., semi-annually, quarterly, or monthly). Calibration can be achieved by external calibration services or by internal calibration.

5.5 EXTERNAL CALIBRATIONS

5.5.1 When using an external calibration service to comply with this policy, the calibration laboratory used must be accredited to ISO/IEC 17025 and provide an appropriate calibration certificate. When looking at the calibration certificate the following things should appear on the certificate:

- A statement that that calibration laboratory is accredited to **ISO/IEC 17025**;
- An indication that the accreditation was done by a body signatory to the ILAC Mutual Recognition Arrangement;
- The serial number of the measuring equipment being used to calibrate your equipment and a statement that the measuring equipment is traceable to SI units through an NMI; and,
- The measurement range for which your equipment was calibrated and the specific uncertainty measurements for that range.

5.6 INTERNAL CALIBRATIONS

5.6.1 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 AB'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) and European cooperation for Accreditation (EA).

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

- 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;
- 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;
- The in-house laboratory shall have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be taken into account when statements of compliance with specifications are made;
- 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 of the reference standards.

5.7 OTHER POSSIBLE SOLUTIONS

5.7.1 Where traceability to National or International standards is not possible or applicable, the laboratory shall provide satisfactory evidence of co-relation of results, for example, by participating in P.T. programs.

5.8 VERIFICATIONS

5.8.1 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 no 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;

- 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).

5.9 ACCREDITED CALIBRATION AND TEST REPORTS

5.9.1 For the purpose of demonstrating measurement traceability, calibration certificates shall, wherever applicable, indicate the traceability to national or international standards of measurement and should provide the measurement result and associated uncertainty of measurement. Wherever applicable, and when suitable for customer requirements, a statement of compliance with an identified method or procedural specification can be accepted instead of measurement results and associated uncertainties.

5.9.2 Only calibration certificates or reports endorsed by a recognized accreditation body's symbol (or which otherwise makes reference to accredited status by a specific, recognized accreditation body) that is accompanied by an indication of the type of entity accredited (e.g., "calibration laboratory", "reference material producer") are considered to satisfy AB Traceability Policy requirements. By definition, such an endorsed certificate or report will contain an appropriate statement of measurement results accompanied by an appropriately defined uncertainty statement and a suitable statement of traceability.

5.10 ESTIMATION AND STATEMENT OF UNCERTAINTY

5.10.1 A crucial element of the concept of measurement traceability is measurement uncertainty.

"Where measurement uncertainty analysis is applicable, AB requires laboratories to calculate measurement uncertainty in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement." These uncertainties, when reported, shall be reported as the expanded uncertainty with a defined coverage factor, k (typically k = 2) and the confidence interval (typically to approximate the 95% confidence level)."

"If a calibration certificate or test report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement must be accompanied by an explanation of the meaning of the uncertainty statement."

5.10.2 An example of such an explanation might be the statement "Reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of k = 2". Statements of uncertainty which do not specify at least the coverage factor and the confidence level are incomplete and they are inadequate for the purpose of demonstrating that measurement traceability has been achieved.

5.11 STATEMENTS OF TRACEABILITY

5.11.1 This statement will affirm that the calibration reported was conducted using standards whose values are traceable to an appropriate national, international, intrinsic, or mutual consent standard. For example, if the traceability chain for a given laboratory originates at a National Metrology Institute (NMI) such as the National Metrology Laboratory – NMI (NML-NMI), then the statement will affirm that "This calibration was conducted using standards traceable to the SI through (name) NMI", or words to that effect. Calibration certificates and reports which do not contain equivalent statements of traceability are insufficient to demonstrate measurement traceability.

5.12 ACCEPTABLE ACCREDITORS OF CALIBRATION AND TESTING LABORATORIES

5.12.1 AB participates in multi-lateral recognition agreements or arrangements (MLAs or MRAs) with numerous accreditation bodies throughout the world. The import of these agreements is that the signatories promote the recognition and acceptance of certificates and reports issued by organizations accredited by accreditation bodies that have signed the arrangement. Through the vehicle of the arrangement, a uniform level of competence of the accredited bodies involved is assured and the need for multiple assessments is diminished or eliminated. This means that a supplier should only need one certificate or report to satisfy the markets and governments represented by other signatories. Currently, the primary arrangements amongst accrediting bodies is the International Laboratory Accreditation Cooperation (ILAC), of which the Asia-Pacific Laboratory Accreditation Cooperation (APLAC), is a recognised regional body. As signatories to arrangements, AB is committed to promoting the recognition and acceptance of accreditations granted by its fellow signatories.

5.12.2 Accredited test and calibration results, reported by laboratories that are accredited by the accreditation bodies recognized by any of these arrangements, and reported in a test or calibration report endorsed by the accrediting body's symbol (or which otherwise makes reference to accredited status by a specific, recognized accreditation body, for example through use of a statement that the organization is accredited by XYZ) that is accompanied by an indication of the type of entity accredited (e.g., through inclusion of an accreditation certificate number, words such as "calibration laboratory", etc.), are recognized by AB as satisfying the requirements pertaining to measurement traceability.

5.12.3 AB recognizes reference material certificates that are issued by reference material producers that are accredited by the accreditation bodies recognized by the APLAC mutual recognition arrangement for reference material producer accreditation, and reported in a certificate meeting ISO Guide 34 and endorsed by the accreditation body's symbol (or which otherwise makes reference to accredited status by a specific, recognized accreditation body) and an indication of the type of entity accredited.

5.13 STATEMENTS OF COMPLIANCE WITH SPECIFICATION

5.13.1 Clause 7.8.3.1 c) of ISO/IEC-17025 states: "… where necessary for the interpretation of the test results, include the following: … b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications".

5.13.2 Clause 7.8.6 of ISO/IEC-17025 states: "… When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule."

5.13.3 In harmony with those clauses, when a test and/or calibration is carried out to a stated specification require a statement of compliance; the report must contain a statement indicating whether the test and/or calibration results show compliance with the specification.

5.13.4 AB requires that, if certificates or reports include the statement of compliance with specification, it shall calculated using expanded uncertainty of measurement. In addition, the coverage factor and confidence level must be stated.

5.14 IMPLEMENTATION OF THIS POLICY IN ACCREDITED LABORATORIES

5.14.1 This policy means three things to accredited laboratories. First, it requires AB laboratories 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 (e.g., NMI).

5.14.2 Second, it means that AB laboratories must know how to spot the signs that an instrument is traceable or not.

5.14.3 Third, it means that AB laboratories 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

5.15 THE SIGNIFICANCE TEST

5.15.1 Clause 7.6.1 of ISO/IEC 17025 states: *"Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are **of significance**, including those arising from sampling, shall be taken into account using appropriate methods of analysis."*

5.15.2 Significance can be established using an approach that compares results from a simple statistical expression.

5.15.3 Any number, x, that is one third or less than another, y, will tend to have no significant effect on the outcome of the square root of the sum of their squares:

$$z = x^2 + y^2$$

5.15.4 If, x = 1.0 and y = 3.0, then z = 3.16 if x is included in the expression and 3.0 if it is not. The difference is approximately 5%, an insignificant difference when considering uncertainties.

5.15.5 Any number, x, that is one tenth or less than another, y, will tend to have negligible effect on the outcome of the square root of the sum of their squares.

5.15.6 If, x = 1.0 and y = 10.0, then z = 10.05 if x is included in the expression and 10.0 if it is not. The difference is approximately 0.5%, a negligible difference when considering uncertainties.

5.15.7 The following three examples may be used by laboratories to determine which of their instruments meet the requirement for significant effect in their calibration program.

- **Example 1**: If the uncertainty of an instrument is smaller than one-tenth of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory has evidence to increase the period of calibration from one to two years or more, decreasing its frequency of calibration.
- **Example 2**: If the uncertainty of an instrument is between one tenth and one-third of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory must maintain the period of calibration at one year.
- **Example 3**: If the uncertainty of an instrument is larger than one-third of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory has evidence to decrease the period of calibration to less than one year; for example every six months.

5.15.8 The choices to a laboratory are the following, and they depend on the significance of the contribution of the instrument to the overall uncertainty of the desired test result as described by the examples above:

- When instrument performance is very much better than the requirement, the laboratory can reduce the calibration frequency (extend the cycle time). See example 1 above;
- When performance is at the same level as requirement, the calibration frequency must be increased. See example 3 above; or,
- When the laboratory does not know, they must calibrate that equipment once per year. See example 2 above.

5.15.9 In general, the only instruments in a typical analytical laboratory that require traceability through contracts with an external calibration laboratory are analytical balance calibration and thermometer calibration. Volume (e.g., pipettes) must also be traceable but their traceability is usually linked to mass (1.0 mL of water weighs 1.0 g at standard temperature and pressure).

5.15.10 Chemicals and standards purchased for the purpose of instrument calibration must also be traceable but their traceability is ensured through proper analytical methods and proper procurement procedures. A good description of chemical traceability can be found in Traceability in Chemical Measurements (Eurachem 2003).

5.16 MASS

5.16.1 Using a minimum of two weights that are within the weights typically measured on the balance allows the laboratory to demonstrate stability of operation of the balance over the whole range normally used.

5.16.2 The documented procedure for the verification process should include the use of appropriate weights (e.g., stainless steel), the storage and handling of the verification weights, and the acceptance criteria.

5.16.3 If the verification weight (mass) is to be subsequently used to calibrate balances, it must be calibrated and have an uncertainty associated with it.

5.16.4 Historical daily or as-used verification data can be used to develop standard deviations for calibration provided all the requirements for calibration are met for each verification reading. This includes, but is not limited to, ensuring:

- that the laboratory documents their verification procedure to include all of the same requirements for the performance of a calibration but with as few as one reading on each day of verification;
- that a statistically valid number of readings are used in the determination of the standard deviations for the calibration;
- that the person conducting the verification has been properly trained on the procedure used;

- that they can competently propagate uncertainties from the reference standard (calibrated weights) to the working instrument; and,
- that they use calibrated weights that meets the requirements of ISO/IEC 17025 for this purpose.

5.16.5 There must be an unbroken chain of uncertainty and traceability between the NMI and the working balance.

5.17 TEMPERATURE

5.17.1 As with the balances, a laboratory can demonstrate traceability of their temperature measurements in a couple of ways.

- A laboratory may opt to send all working thermometers to an accredited laboratory for calibration at an established frequency (e.g., annually). This is by far the easiest way to ensure traceability of all critical thermometers but can be costly and requires the purchase of more thermometers than are used on a daily basis in order to ensure the availability of calibrated thermometers when others are being calibrated.
- A laboratory may decide to maintain a limited number of thermometers that are sent to an accredited calibration laboratory on a scheduled basis (e.g., annually). The lab may then use these reference thermometers to calibrate working thermometers. The internal calibration must use an accepted protocol, such as NMI Special Publication 1088 – Maintenance, Validation and Recalibration of Liquid-in-Glass Thermometers. The internal calibration procedure involves replicate measurements and the propagation of uncertainty. The frequency of calibration of liquid-in-glass thermometers may be decreased provided a set of conditions are met; for details on the conditions and procedures, see NMI Special Publication 1088.

5.18 VOLUME

5.18.1 As with balances, dispensing devices must be calibrated upon receipt and at an established frequency (e.g., annually) and verified on a daily or as-used basis.

5.18.2 Dispensing devices may be sent to an accredited calibration laboratory for calibration but this is often cost prohibitive. Alternately, the laboratory may perform an internal calibration following a generally accepted procedure such as those provided by Troemner, Mettler-Toledo, and Rainin. These procedures generally involve the repeated weighing of dispensed volumes of water, corrected for standard temperature and pressure. For adjustable dispensing devices, this procedure is performed at more than one volume. The procedure will generally include 10 measurements at the low end and 10 at the high end of the dispensing range. Acceptable performance (precision) is based on the precision required for the piece of dispensing equipment. Historical daily or as-used verification data can be used to develop standard deviations for calibration provided all the requirements for calibration are met for each verification reading. This includes, but is not limited to, ensuring:

- that the laboratory documents their verification procedure to include all of the same requirements for the performance of a calibration but with as few as one reading on each day of verification;
- that a statistically valid number of readings are used in the determination of the standard deviations for the calibration;
- that the person conducting the verification has been properly trained on the procedure used;
- that they can competently propagate uncertainties from the reference standard (device) to the working instrument; and
- that they use a calibrated balance that meets the requirements of **ISO/IEC 17025** for this purpose.

5.19 SELECTING A CALIBRATION LABORATORY

5.19.1 Traceability means that all of the comparisons back along the Calibration chain to the national measurement laboratory were done by competent organizations (calibration laboratories). The competence of a calibration laboratory is most easily established by ensuring that the calibration laboratory is accredited to ISO/IEC 17025 for the task. For example, the following table represents a sample Scope of Accreditation for an accredited calibration laboratory:

Measurement Parameter	Range of Measurement	Related Uncertainty
Temperature	0.01 - 140.01 degrees C	+/- 0.003 degrees C
Volume	0.05 - 200.00 Litres	+/- 0.005 ml
Mass, Length, etc		

5.20 HOW TO DETERMINE IF A CALIBRATION CERTIFICATE WAS PROVIDED BY A COMPETENT CALIBRATION LAB?

5.20.1 The easiest way is to look for the logo or name of one of the accreditation bodies cited above on the calibration certificate. If it is not there, then the calibration service provider is proly not accredited. Remember, a service provider that is only registered (or certified) to ISO 9000 (or other management system standard) is not considered a technically competent calibration service provider.

5.20.2 From the rules which govern the accreditation of ISO 9000 registrars, IAF, certification/registration bodies may be accredited to certify/register the quality management systems of test and calibration laboratories, but it should make it clear to the client that such certification/registration is not equivalent to accreditation of the testing or calibration laboratory. IAF specifies that a certification/registration body shall not permit its marks to be applied to laboratory test and calibration reports, as such reports are deemed to be products in this context.

5.20.3 The second way to spot a lab with questionable competence is by the absence of an uncertainty statement for each range of measurement within the specific measurement parameter of the instrument associated with the calibration certificate. Remember two things when dealing with calibration service providers:

- You went to the trouble to have your lab's technical competence recognised through accreditation, so why would you wish to deal with a laboratory that won't do the same as a calibration laboratory?
- Your laboratory provides test results. That is the principle product of a testing laboratory. The principle product of a calibration laboratory is uncertainty as it relates to measuring instruments (for a specific measurement parameter, within a specified range of measurement).

5.20.4 If these are not on the calibration certificate as a minimum, then the certificate will not meet the traceable calibration requirements.

5.20.5 Before purchasing a traceable thermometer or calibration certificate, you may be able to obtain from your potential supplier an example of their calibration certificates. This will allow you to review the calibration certificate and if you have any concerns about whether you are meeting the traceability and calibration requirements, you can get answers from your supplier before you purchase the item or service.

5.20.6 Note: The cost for traceability is usually higher than the non-traceable calibration, so if you are choosing between levels of service and are paying the lowest price for a calibration, it’s probably not traceable.

5.21 IF AN ACCREDITED CALIBRATION LABORATORY IS NOT AVAILABLE FOR SPECIFIC MEASUREMENTS

5.21.1 There are many gaps in the measurement capability of competent calibration infrastructure in Bangladesh. Your first step is to let AB know that there is an unmet calibration need for the specific measurement. AB will let the national metrology institute know. Over time, these unmet needs should be filled.

5.21.2 If you have any questions on this, or any other policy associated with the assessment of your laboratory to the requirements the AB Accreditation Program, please feel free to contact AB.