

	<b>PNAC POLICY ON TRACEABILITY OF MEASUREMENT</b>	G-02/15 Issue Date: 11/01/13 Rev No: 02
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## PNAC POLICY ON TRACEABILITY OF MEASUREMENT

### 1. Purpose

This policy outlines the requirements of PNAC to meet requirement of ISO/IEC 17025 & ISO 15189 on traceability.

### 2. Scope

This policy is applicable to all testing and calibration labs seeking accreditation from PNAC.

### 3. Sources of traceability

- Measuring equipment used for calibration and testing, shall as a main rule be calibrated by accredited calibration laboratories.
- Reference standards of accredited calibration laboratories shall be calibrated by accredited calibration laboratories with a suitable best measurement capability.
- Certificate of quality management system in accordance with ISO 9001 do not present confirmation of a laboratory competence in making reliable calibration. PNAC in such a case do not recognize a laboratory as a competent body for assurance of traceability of measurement results.
- When accredited calibration laboratories within the country are not able to assure traceability in some calibration field (lack of appropriate reference standards), the source of traceability can be national metrology institute of other country being signatory of APLAC MLA or ILAC MLA or BIPM MLA accredited laboratory assuring reference to standards of this institute.

#### *Note :*

- If reference to national measurement standards is not technically possible or reasonable in special cases, the agreed reference material (or method), clearly described and approved by all parties concerned may be used.
- Certified reference materials shall be treated in the same way as other reference measurement standards and the requirements stated above shall be applied.

### 4. PNAC's policy on Traceability

4.1 In applying the criteria for measurement traceability, the following PNAC policies shall be noted:

- a. Specific recommendations for calibration and recalibration of selected items of equipment required by laboratories operating in the test categories for which PNAC accreditation is currently available have been set.

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- b. Laboratories shall note that any recommendation on calibration, including re-calibration intervals, is given for guidance only. For any individual instrument, it is the responsibility of the laboratory to determine the appropriate calibration regime based on its application, construction, drift history, etc. It is not advisable to adopt the recommendations indiscriminately in lieu of detailed investigation.
- c. Where traceability to the International System of Units (SI) is required, the calibration is to be performed by a “competent calibration body”. PNAC will, for the time being, accept as evidence of traceability to SI units, calibrations which have been performed by :
  - (i) The National Physical and Standards Laboratory;
  - (ii) Laboratories accredited under PNAC for the specific calibration services;
  - (iii) Laboratories with unbroken chain of traceability to international standard, accredited for calibration by MRA signatory accreditation body
- d. Some items of equipment may be able to be calibrated by accredited laboratories without the services of external calibration bodies, provided the laboratories have the necessary reference standards and materials and the calibration procedures do not demand specialist techniques which are outside the capabilities and experience of the laboratory staff. However, the uncertainty of calibration shall meet the requirements of the applications.
- e. Many items of equipment, and particularly for chemical analyses, are calibrated by comparative techniques using reference materials. The employment of reference materials to ensure demonstrated traceability to the SI units or the appropriate measurement standards is an essential condition for the accuracy of results.

#### 4.2 The metrological quality of such calibrations depends on:

- (i) the uncertainty of the reference materials used;
- (ii) the appropriateness of the reference materials with respect to the practical conditions of use, taking into account the analytical method to be employed and the characteristics of the test samples.

#### 4.3 Traceability confirmation

- a. Calibration of measuring equipment by competent organization is the base of traceability assurance.
- b. Confirmation of performed calibration is calibration certificate; contents of the calibration certificates shall meet the requirements of relevant standard e.g., ISO/IEC 17025 [5] clause 5.6.2.1.1, 5.10.2 and 5.10.4.
- c. PNAC doesn't accept verification certificates as traceability confirmation, but certificates of designated verification are accepted as their validity expired.
- d. Information on traceability in calibration certificates shall include identification of national or international standard to which measurements are referred; this statement may be formulated as follows: „Calibration results are referred to GUM national standard of length” or other similar.
- e. Calibration certificate shall also include identification of standard, which was used to perform the calibration.

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- f. PNAC doesn't accept only reference to the traceability for calibration but would ask for a prove of the copy of certificate wit traceability mentioned.

#### **4.4 Uncertainty of measurement**

The expression of uncertainty in measurement has been thoroughly described in ISO/IEC Guide 98-3:2008. Uncertainty of measurement in calibration of measuring equipment shall be estimated according to ILAC-G17 2002. Uncertainty budget shall be presented and overall uncertainty shall be given in the form of expanded uncertainty to a coverage probability of 95 %.

In calibration certificates the kind of uncertainty, coverage probability and coverage factor shall be determined i.e. "Presented uncertainty values are expanded uncertainty to a coverage probability of 95 % and coverage factor  $k=2$ ".

#### **4.5 In-house calibration**

##### **For calibration and testing labs**

In-house calibration system aim is to calibrate measuring equipment of the organization relatively to its own standards. The base of traceability of measurement results in such system is calibration of the own standards from accredited calibration laboratories with a suitable Calibration Measurement Capability (CMC) or through NPSL.

Nature and scope of in-house calibration may differ depending on needs and capability of the organization in order to assure enough precision and reliability of performed measurements. Accreditation of in-house calibrations not always is necessary, but taking into account traceability of measurement assurance the following conditions shall be fulfilled:

- a. calibration procedures shall be documented, calibration results shall be presented as certificates, reports etc. and measurement notes should be stored for the fixed period of time,
- b. competency of personnel involved in performing calibration should be documented; the documentation of trainings and evidence of competency (i.e. in the form of results of exams or results of audits in the scope of calibrations) shall be stored;
- c. traceability of calibration results to national or international standards shall be documented;
- d. uncertainty of measurement estimation procedures shall be consistent to ILAC-G17 2002 [7]; uncertainty of measurement shall be taking into consideration by reporting of compliance with specification;
- e. reference standards shall be calibrated at fixed intervals in order to assure their reliability; policy and procedures of establishing and changing these intervals shall be put on long-term observation of reference standards; the guidelines given in standard [4] should be taken into account.
- f. Participation in recognized proficiency testing/inter laboratory comparisons scheme

**All testing labs**, which wants to do in-house calibration has to satisfy para 4.5



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ISO Guide 32 gives guidelines on calibration in analytical chemistry and use of certified reference materials. Laboratories should follow these guidelines for equipment calibration. When using CRMs for assessment of a measurement process, the guidelines given in ISO Guide 33 should be followed.

**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 materials.

*NOTE : A reference material may be in the form of a pure or mixed gas, liquid or solid. Examples are water for the calibration of viscometers, sapphire as a heat capacity calibrant in calorimetry, and solutions used for calibration in chemical analysis*

**Certified reference material (CRM) :** Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

### NOTES :

1. A reference material certificate is defined as document accompanying a certified reference material stating one or more property values and their uncertainties, and confirming that the necessary procedures have been carried out to ensure their validity and traceability.
2. CRMs are generally prepared in batches for which the property values are determined within stated uncertainty limits by measurements on samples representative of the whole batch.
3. The certified properties of reference materials are sometimes conveniently and reliably realised when the material is incorporated into a specially fabricated device, e.g. a substance of known triple-point into a triple-point cell; a glass of known optical density into a transmission filter; spheres of uniform particle size mounted on a microscope slide. Such devices may also be considered as CRMs.
4. All CRMs lie within the definition of measurement standards or etalons given in the International vocabulary of basic and general terms in metrology (VIM).
5. Some RMs and CRMs have properties which, because they cannot be correlated with an established chemical structure or for other reasons, cannot be determined by exactly defined physical and chemical measurement methods. Such materials include certain biological materials such as vaccines to which an international unit has been assigned by the World Health Organisation.

Where laboratories are undertaking calibrations of equipment through the use of certified reference materials or reference materials, the onus will be on the laboratories to demonstrate to PNAC:

- i. that sufficient reference materials are held by the laboratory to calibrate the relevant items of equipment over their intended measurement ranges;

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- ii. that full records are kept of the identity and source of each certified reference material and/or reference material;
- iii. in cases where certified reference materials are used, that these materials are supplied by a recognised national institution. Full documentation of the certified values of these materials and the mode of validation of the certified values shall be held;
- iv. in cases where it is necessary to use commercially prepared chemical standards as reference materials, that the claimed values of each batch of these chemicals are verified before use and records of verification are held;
- v. that, where necessary, all precautions have been taken to match the matrices of the reference materials to those encountered in the laboratory's test samples or that the laboratory has determined and accounted for the effects of any non-matching of matrices.

Laboratories are asked to advise PNAC of any doubts about the assigned values of reference materials and laboratories are encouraged to refer all such doubts, together with supporting technical details, to the producers of the materials concerned.

- g. The requirement for measurement traceability is not applicable to laboratories when the calibration contributes little to the total uncertainty of the examination result. In such cases, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed. This may be achieved by internal calibrations or verifications, or by calibrations performed by a laboratory which need not satisfy the criteria but which should be competent.
- h. Designated officers of the laboratory shall be assigned the responsibility for the calibration of equipment and management of reference materials.
- i. Where an external calibration laboratory is used, the laboratory shall also be informed of the calibration requirements, including the ranges, the cardinal points, the required calibration uncertainties and the conditions under which calibrations are to be performed.

#### **4. BIBLIOGRAPHY**

1. ISO/IEC 17025:2005. General requirements for the competence of calibration and testing laboratories.
2. ISO 15189:2012 Medical laboratories - Requirements for quality and competence
3. ILAC-P10: 01/2013. ILAC Policy on Traceability of Measurement Results
4. International Vocabulary of Basic and General Terms in Metrology (VIM); polish edition translated in Central Office of Measures.
5. PN-ISO 10012 Quality assurance requirements for measuring equipment - Metrological confirmation system for measuring equipment;
6. ISO/IEC Guide 98-3:2008 Uncertainty of measurement -- Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)
7. ILAC-G17:2002. Introducing the concept of uncertainty of measurements in testing in association with the application of the standard ISO/IEC 17025.