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**Supplementary Requirements for Accreditation
of Calibration Laboratories**

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Foreword

This Philippine Accreditation Bureau Laboratory Accreditation Supplementary Requirements for Accreditation of Calibration Laboratories was developed by the Laboratory Accreditation Technical Committee on Metrology to provide clear technical criteria for assessment of calibration laboratories.

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1 INTRODUCTION

All permanent and/or on-site calibration laboratories applying for accreditation are required to satisfy these supplementary requirements and specific requirements in addition to the general requirements specified in PNS ISO/IEC 17025: 2005. The numbering of these supplementary requirements follows the numbering of PNS ISO/IEC 17025:2005.

2 AUTHORSHIP

This document was developed by the PAB Laboratory Accreditation Technical Committee for Calibration after deliberation by experts on calibration and representatives from PAB accredited laboratories for calibration.

3 DEFINITIONS

3.1 Permanent Laboratory: A calibration laboratory constructed on a fixed location for a period expected to be greater than three years.

3.2 Organization: Company, consultancy, partnership, other body or individual who does not necessarily have a permanent laboratory but who calibrates the characteristics or performance of measuring instruments or calibration equipment.

3.3 On-site Calibration: Calibration (including sampling where it forms part of the documented calibration procedure) performed by staff of a laboratory or organization outside of the premises or grounds on which the permanent laboratory or the organization's permanent base of headquarters is located.

On-site Calibrations are normally performed under two categories:

- By staff sent out on-site by an accredited, permanent laboratory.
- By organizations that do not have a permanent laboratory.

3.4 Site: Any location where on-site calibration takes place as defined in 3.3 above.


3.5 On-site Laboratory: A calibration laboratory facility set up in a dedicated area on-site for the duration of the calibration activities but not for periods expected to exceed three years.

3.6 Mobile Laboratory: Fully-equipped, self-contained, transportable calibration laboratory capable of performing calibrations under controlled environmental conditions.

(Note: Mobile laboratories are subject to the same terms of accreditation as an on-site laboratory. Mobile laboratories left at one site for three years or more will be subject to the same terms of accreditation as a permanent laboratory.)

3.7 Calibration and Measurement Capability

A CMC is a calibration and measurement capability available to customers under normal conditions:

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- a) As described in the laboratory's scope of accreditation by a signatory to the ILAC Arrangements; or
- b) As published in the BIPM key comparison database (KCDB) of the CIPM MRA.

Note: the meaning of the terms Calibration and Measurement Capability, CMC (as used in the CIPM MRA), and Best Measurement Capability, BMC (as used historically in connection with the uncertainties stated in the scope of accredited laboratory) are identical.

The terms BMC and CMC should be interpreted similarly and consistently in the current areas of application.

4 MANAGEMENT REQUIREMENTS

4.2 Management System

4.2.1. The quality manual or related quality documentation of the permanent laboratory or organization shall contain a section covering the arrangements for the site operations. This shall include:

- a) An up-to-date record of site laboratory locations and the purpose for which they were used, including identification of any mobile laboratories (See NOTE below);
- b) Details of the specific calibration(s) undertaken at each on-site location (See NOTE below);


NOTE: The records required in 4.2.1.a) and 4.2.1.b) may be controlled and maintained as a separate quality system document, not necessarily part of the quality manual

- c) A separate listing of those calibrations that the organization is capable of performing on-site;
- d) Details of how the quality system is applied to and incorporates site calibration (e.g. an organizational chart for the permanent laboratory showing lines of responsibility and authority for site calibration, etc.) as well as arrangements for the supervision of site calibrations where the site is not controlled by the customer but rather by a third party.

4.2.2. Controlled copies of calibration procedure either hard or soft copy shall be made available for the personnel on-site.

4.13 Control of records

4.13.1. Procedures shall exist for recording and reporting all results obtained on-site and shall be coordinated with the system operating in the permanent laboratory (where appropriate). Records (whether hard or soft copy) of original observations, calculations, data transfers and checks shall be identifiable by person and date. Records shall be made in a permanent manner and maintained so that they are not obliterated by rain, humidity, spills, leaks or other environmental factors that may affect the immediate or future readability of the records.

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4.13.2. Procedures shall exist for ensuring the security and confidentiality of calibration data obtained and held on-site.

4.14 Internal audits

4.14.1. Internal audits of the site laboratory's quality system shall be conducted using similar procedures as those applied to a permanent laboratory.

4.14.2. The designated internal auditor shall visit site and mobile laboratories as part of the internal audit process. The audit process shall contain specific elements to assess whether on-site calibrations continue to comply with the requirements of the quality system.

4.15 Management reviews

4.15.1. Management review shall take account of on-site calibration activities.

5 TECHNICAL REQUIREMENTS

5.2 Personnel


5.2.1. The permanent laboratory or organization shall have procedures for ensuring that staff performing on-site calibrations are properly trained and competent. Evidence of the competence of staff performing the specific on-site calibrations shall be available. (This evidence should include training records, appropriate analysis of blind proficiency samples (where available) and other demonstrations of method proficiency.)

The staff performing the on-site calibrations shall be qualified for that work without supervision unless the appropriate supervisor joins the activity. Otherwise work must be done under on-site supervision.

5.2.2. On-site personnel not employed or sub-contracted by the permanent laboratory or organization shall not assist in the performance of accredited calibrations unless adequately supervised by trained staff employed or sub-contracted by the permanent laboratory or organization. On-site personnel not employed or sub-contracted by the permanent laboratory or organization shall not perform accredited calibrations, unassisted, under any circumstances.

The applicant for Approved Signatory will be evaluated following the point system below:

Criteria	Point			
	10	8	5	2
Education	Bachelor of Science in Engineering	Technology, Diploma, technical related to calibration	Undergraduate Engineering, Science technology courses	Degree/ Diploma/ Undergraduate not related to calibration
Experience working in the present lab. (during application)	5 years & above	2 to 4 years	1 year & 11 months	6 to 11 months
No. of Trainings related to	36 hours &	24 to 35	12 to 23 hours	6 to 11 hours

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Criteria	Point			
	10	8	5	2
applied scope of test *combination of all scopes and echo seminars; 1 day seminar = 6 hours, 1 day echo = 2 hours	above	hours		
Supervisory Function	With supervisory function	-	-	No supervisory function

Where:

- 27 points & above qualified as applicant for approved signatory
- 26 points & below not qualified as applicant for approved signatory

Criteria for assessing the suitability of staff as Approved Signatory are defined in LA/GD07-Guidelines for Laboratory Personnel and Approved Signatories.

5.3 Accommodation and environmental conditions

5.3.2. Where calibrations are undertaken in a hostile or unstable environment or in an environment that may affect the calibration results, the environmental conditions shall be monitored and recorded. These data shall be analyzed to determine whether the measurements may be invalid or come-up with correction factors to make the measurement accurate.

5.3.3 When necessary, the laboratory shall have at least two distinct work areas:

a.) A receiving and cleaning area where items to be calibrated can be cleaned and prepared to enter the laboratory without contaminating the calibration area with dirt, dust, solvents, or solvent fumes, etc.


b.) A dedicated calibration area where the items are calibrated.

5.3.4. There shall be provisions for restricting access to the site laboratory when unrestricted access could invalidate the calibration results (e.g. limiting people entering the production area while calibration is on-going).

5.4 Estimation of uncertainty of measurement

5.4.6.1 As the definition of CMC implies, accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

The numerical value of the expanded uncertainty shall be given to, at the most, two significant figures. Further the following applies:

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- a) The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.
- b) For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided in Section 7 of the GUM.

5.5 Equipment

- 5.5.1. Appropriate checks shall be made on-site to confirm the calibration status and fitness for use of equipment before calibration begins. Where such checks cannot be made on-site (for equipment whose performance is not sensitive to movement), calibration status and fitness for use shall be checked in permanent laboratory or at the organization's permanent base before and after on-site calibration. Equipment whose performance is sensitive to movement shall be checked on-site. If equipment is found to be unfit for use and/or out of calibration, it shall not be used and shall be immediately withdrawn from service. The laboratory shall examine the effects of such equipment on previous calibrations.
- 5.5.2. If equipment other than that owned by the permanent laboratory or organization is used, the provider of such equipment shall be considered as a supplier of outside services/supplies, subject to the requirements specified in Section 4.6 of PNS ISO/IEC 17025:2005. The laboratory shall document and archive calibration certificates (where appropriate) and other relevant details of the "borrowed" or rented equipment. Borrowed or rented equipment must be inspected for damage or malfunction before each use. It is the site laboratory's responsibility to ensure that borrowed or rented equipment receives the same checks/calibrations and other controls as laboratory-owned equipment, prior to and during use.
- 5.5.3. A laboratory that performs calibrations on a customer's site shall make a full list of all the equipment that is transported.

5.6 Measurement traceability

- 5.6.1. When it is necessary to utilize reference standards on-site, adequate measures shall be taken to ensure that the necessary calibration status is maintained during transportation and while on-site. The response of such reference standards to environmental changes or other relevant parameters shall be known and documented.
- 5.6.2. Reference standards shall be maintained in a suitable environment at all times, such that handling, transport and storage do not invalidate their calibration status.
- 5.6.3. Calibration laboratories shall maintain an up-to-date list of reference standards and the names of the calibration service providers that calibrate these standards. This list shall be distinct from an inventory of all laboratory equipment. At a minimum, the list shall show the name of the laboratory or service, its geographical location and an indication that the organization providing the service is either a National Metrology Institute (NMI), or else is accredited for this service by PAB or other acceptable accreditation body.

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5.6.4 Where an intrinsic standard or system is used as a standard, the following requirements apply:

- a) Direct intrinsic standard or system-to-intrinsic standard or system comparison with NMI or an accredited laboratory shall be conducted at appropriate intervals to ensure the correct realization of the measurand;
- b) The device used to measure differences between intrinsic standard or system and unknown values shall be calibrated. Calibration history shall be documented and maintained;
- c) The intrinsic standard or system components (e.g., the time base of the reference frequency counter in a Josephson voltage array system) shall be regularly calibrated and documented;
- d) The system precision and stability (e.g., leakage currents, ground loops thermal emf's, step integrity, trapped magnetic flux, noise, and microwave power impinging on a Josephson voltage array) shall be periodically checked and documented.


5.6.5 Calibration intervals for each measuring instrument or standard shall be established to control the probability of calibrations being out-of-tolerance within the calibration interval. Measuring instruments and measurement standards in a calibration system shall be calibrated at intervals established on the basis of their stability, purpose, environment and degree of usage. Calibration intervals should not exceed the maximum period specified by the accreditation body as indicated in Appendix A, Recommended Equipment Calibration Intervals. However, laboratories may choose to exceed the recommended maximum intervals provided that substantial past calibration records and evaluation have proven the calibration intervals could be extended without increasing risk of instruments being out of specification.

5.6.6 Calibration procedures shall contain the required range and tolerance or uncertainty of each item or unit parameter being calibrated or verified. In addition, the procedures shall contain the generic description of the measurement standards and equipment needed with the required parameter, range, tolerances or uncertainties, and specifications for performing the measurement of the calibration or verification, and/or representative types (manufacturer, model, option) that are capable of meeting the generic description for the measurement standards. The procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations/verifications concerned.

5.8 Handling of calibration items

5.8.1. Appropriate precautions shall be taken during handling and preparation of items calibrated on-site to prevent damage thereto.

5.8.2 Tamper-resistant seals shall be affixed to operator accessible controls or adjustment on measurement standards or measuring and calibration equipment which, if moved, will invalidate the calibration. The laboratory's calibration system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.


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5.10 Calibration certificates and reports

- 5.10.1 The uncertainty of reported measurements shall be stated as the actual uncertainty of the measurement, not as the accredited best uncertainty unless that best uncertainty actually applies. An indiscriminate use of the best measurement uncertainty listed on the PAB scope of accreditation as the uncertainty of an actual calibration is not justified. Calibration laboratories shall follow the procedure of Evaluation of measurement data — Guide to the Expression of Uncertainty in Measurement, September 2008. Refer to LA/GD19 Guidelines on the Evaluation and Expression of Measurement Uncertainty in the Field of Calibration.
- 5.10.2 If a recommended recalibration interval is included on a certificate, this recommendation shall be qualified with the statement to the effect that any number of factors may cause the calibration item to drift out of calibration before the recommended interval has expired.
- 5.10.3 Laboratories are permitted to issue certificates with a statement of compliance (i.e., conformance to a specification) relating to the metrological aspects of specifications. In such cases the laboratory shall ensure that:
- The specification is a national or international standard or that has been agreed to or defined by the customer.
 - The measurements needed to determine conformance are within the accredited scope of the laboratory.
 - When parameters are certified to be within specified tolerance, the associated uncertainty measurement result is properly taken into account with respect to the tolerance by a documented procedure or policy established and implemented by the laboratory that defines the decision rules used by the laboratory for declaring in or out of tolerance conditions.
 - The certificate relates only with metrological quantities and states which clauses of the specification are certified to have been met.
- 5.10.4. Results obtained from site calibrations shall be identified as such on issued Certificates/Reports, whether they form part or all of the information presented.
- 5.10.5. In addition to the information specified in PNS ISO/IEC 17025, Section 5.10, Certificates/ Reports shall contain any details relevant to the calibration such as location of item calibrated.

Calibration certificate should indicate the traceability to national or international standards of measurement. The traceability statement shall follow LA/SR10 Supplementary Requirements for Traceability of Measurement.

PAB Logo/Symbol for Calibration Certificates must be in accordance with the LA/SR11-Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbols.


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Sanctions for violation on the proper use of logo are as follows:

- 1st offense=written warning
- 2nd offense=6 months suspension
- 3rd offense= suspension of accreditation

6 References

- 6.1 PNS ISO/IEC 17025:2005
- 6.2 Requirements for the Use of PAB Laboratory and Inspection Body Accreditation Symbol, LA/SR11/Issue 1/January 2015
- 6.3 Supplementary Requirements on Traceability of Measurements, LA/SR10/Issue 1/ January 2015
- 6.4 Supplementary Requirements on Participation to Proficiency Testing Programs, LA/SR09/Issue 1/ January 2015
- 6.5 Guidelines for Laboratory Personnel and Approved Signatories, LA/GD07/Issue 1/ January 2015
- 6.6 PAB Guidelines on the Measurement Uncertainty-Calibration, LA/GD 19/Issue 1/ January 2015
- 6.7 Guide to the Expression of Uncertainty in Measurement (GUM), issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML
- 6.8 ILAC-P14:01/2013 ILAC Policy for Uncertainty in Calibration
- 6.9 ILAC-P10:01/2013 ILAC Policy on the Traceability of Measurement Results

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ISSUE AND AMENDMENT RECORD

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