

Guidance Document for Accreditation of Calibration Laboratories

Foreword

This Philippine Accreditation Bureau Laboratory Accreditation Guidance Document 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.

The 2nd issuance of this document was made to reflect the following updates:

- ILAC-P14:09/2020: ILAC Policy for Measurement Uncertainty in Calibration was reflected in the following provisions:*
 - Section 7.8.4.1 Statement of Measurement Uncertainty on Calibration Certificate of this document; and*
 - Annex 1: Policy on the Statement of Calibration and Measurement Capability.*

- References were updated to include ILAC-P14:09/2020 and JCGM 100:2008.*

Introduction

This document provides guidance to all accredited and applicant laboratories in conforming to the requirements of PNS ISO/IEC 17025:2017. The numbering system of this Supplementary Requirements follows the numbering of ISO/IEC 17025.

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 Terms and Definitions

3.1 Calibration and Measurement Capability (CMC): a calibration and measurement capability available to customers under normal conditions such as:

- As described in the laboratory's scope of accreditation by a signatory to the ILAC Arrangements; or
- 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

3.2 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.

3.3 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 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.

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

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

6 Resource requirements

6.2 Personnel

6.2.5 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.

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 criteria for qualification of an approved signatory can be evaluated by the following system below:

Criteria	Point			
	10	8	5	2
Education	Bachelor of Science in Engineering	Technology, Diploma, Technical related to Calibration	Undergraduate Engineering, Science and Technology Courses	Degree/ Diploma/ Undergraduate not related to Calibration
Years of experience	5 years and above	2 to 4 years	1 year and 11 months	6 to 11 months
No. of related training hours	36 hours and above	24 to 35 hours	12 to 23 hours	6 to 11 hours

Those who can meet 27 points and above can be qualified as PAB approved signatory but subject still for the evaluation and recommendation of a technical assessor/expert.

6.4 Equipment

- 6.4.2 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.

A laboratory that performs calibrations on a customer's site shall make a full list of all the equipment that is transported.

7 Process requirements

7.4 Handling of calibration items

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

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

7.7 Ensuring the validity of test results

7.7.2 All measurement audit used for accreditation is subject for PAB's approval. See Annex 2 of LA/SR01 (Supplementary Requirements on Participation to Proficiency Testing) for the measurement audit procedure.

If the measurement audit results show 80% satisfactory, this can be conditionally accepted subject for the evaluation and recommendation of technical assessor/expert. Investigations and corrective actions shall be taken and this will be checked and verified during assessment.

7.8 Reporting of results

7.8.2 Common requirements for reports

Results obtained from site calibrations shall be identified as such on issued Certificates/Reports, whether they form part or all of the information presented.

7.8.4 Specific requirements for calibration

7.8.4.1 Statement of Measurement Uncertainty on Calibration Certificates ^[2]

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:

- 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.*

In addition, the coverage factor and the coverage probability shall also be stated on the calibration certificate and that the laboratory shall ensure that the stated measurement uncertainty in the report complies with the GUM.

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.

7.8.4.3 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.

8 Management system requirements

8.4 Control of records (Option A)

8.4.1 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.

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

8.8 Internal Audits (Option A)

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

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

8.9 Management reviews (Option A)

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

References

- [1] ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories
- [2] *ILAC-P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration*
- [3] *JCGM 100:2008, Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM)*

Annex 1: Policy on the Statement of Calibration and Measurement Capability^[2]

The Calibration and Measurement Capability (CMC) is expressed in terms of:

- a) measurand or reference material;*
- b) calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;*
- c) measurement range and additional parameters where applicable, e.g., frequency of applied voltage;*
- d) measurement uncertainty.*

The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a coverage probability of approximately 95 %.

Furthermore, there shall be no ambiguity in the expression of the CMC on the scopes of accreditation. The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand and the use of terms “PPM” and “PPB” are no longer acceptable.

The CMC quoted shall include the contribution from a best existing device to be calibrated such that the CMC claimed is demonstrably realizable.