



SRI LANKA ACCREDITATION BOARD
For CONFORMITY ASSESSMENT

SPECIFIC CRITERIA FOR
CALIBRATION LABORATORIES

ABBREVIATIONS

CRM	-	Certified Reference Materials
QC	-	Quality Control
RM	-	Reference Materials
SLAB	-	Sri Lanka Accreditation Board for Conformity Assessment
LIMS	-	Laboratory Information Management Systems
APAC	-	Asia Pacific Accreditation Cooperation
ILAC	-	International Laboratory Accreditation Cooperation
CMC	-	Calibration & Measurement Capability

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1. INTRODUCTION

- 1.1. The requirements for accreditation are laid down in the International Standard ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories. These requirements apply to all types of calibrations, but in certain instances additional guidance is needed to streamline the accreditation process and take account of the specific type of calibration and the technologies involved. These criteria are applicable to laboratories, which perform repetitive calibrations in various parameters and desire accreditation from SLAB.
- 1.2. This document has been prepared by the Technical Advisory Committee on Calibration laboratories and approved by the Council of Sri Lanka Accreditation Board (SLAB). It supplements ISO/ IEC 17025 standard and provides specific guidance on the accreditation of mechanical, Temperature and Humidity, Electrical, Acoustics, Optical, radiation, time and frequency, Colour temperature and Illuminance calibrations for the use of assessors and applicant and accredited laboratories.
- 1.3. This document covers the application of the ISO/ IEC 17025 for accreditation of calibration laboratories, applicable to products groups as given in Appendix A. This document should be read in conjunction with the ISO/IEC 17025:2017, Terms and conditions for calibration laboratories and Rules and Procedures of SLAB.
- 1.4. This document clarifies SLAB’s stand on the measurement capability levels. SLAB intends to uphold its policy of granting accreditation to laboratories as per their requirements of accuracy and measurement capability.
- 1.5. This document provides the laboratories with necessary information on the requirements for assessment/ surveillance and to assist them in carrying out internal audit of their system.

2. SCOPE

This guide sets out the general requirements in accordance with which a laboratory must demonstrate that it operates, if it is to be accredited to carry out specific calibrations and tests. The general requirements for demonstrating competence in testing and calibration are found in the ISO/ IEC 17025 “General Requirements for the Competence of Testing and Calibration Laboratories”.

This guide supplements the general requirements of the ISO/ IEC 17025 and refers to each section with interpretation of these general requirements to provide specific

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requirements for assessors and calibration laboratories preparing for accreditation and for the development of the quality system of calibration laboratories. It may also be used by accrediting bodies and stakeholders.

Annexures are given for informative purposes. They may also be used to interpret the activities of the Calibration laboratories.

3. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17000, Conformity assessment — Vocabulary and general principles
- International Vocabulary of Basic and General Terms in Metrology (VIM)
- ILAC P9, ILAC Policy for participation in proficiency testing activities.
- ILAC P10, ILAC Policy on the traceability of measurement results.
- ILAC P14, ILAC Policy for uncertainty in calibration.

4. TERMS AND DEFINITIONS

For the purpose of this document terms and definition given in ISO/IEC 17000, ISO/IEC 17025 and International Vocabulary of Basic and General Terms in Metrology (VIM) apply.

5. STANDARD REQUIREMENTS

5.1. Impartiality & Confidentiality

The requirements of ISO/IEC 17025 clause 4.1 & 4.2 apply. If some laboratory performed both calibration activities and equipment supply and maintenance, laboratory should evidence how they maintained the Impartiality in the laboratory activities.

5.2. Structural Requirements

The requirements of ISO/IEC 17025 clause 5 apply.

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5.3. Resource Requirements

5.3.1 Personnel

The requirements of ISO/IEC 17025 clause 6.2 apply.

The management shall define each role in the laboratory and specify minimum competency requirements of each role.

Competencies of the laboratory personnel to be proved during the assessment. Records for maintaining competencies shall be available. The assessment of competence may take a variety of forms, dependent on the task(s) performed e.g. written and / or oral examinations; practical exercises; or direct observation by a qualified person. In many cases, some combination of competency assessment will be the most appropriate approach.

Records must be sufficiently detailed to show that staff who involve in Calibration/ any activity have been properly trained, that their subsequent ability to perform assigned task(s) has been fully assessed /training evaluated and that they have been authorized to perform work independently.

The calibration laboratory shall have adequate number of qualified competent and trained personnel with following minimum qualifications:

5.3.1.1 Technical Staff to perform calibrations

- Either National Vocational Qualification (NVQ) level 05 or above or equivalent in relevant field with one-year relevant experience
- **Or** three passes in GCE A/L examination with physics as a subject or equivalent and relevant work experience of two (02) years
- **Or** six passes in GCE O/L examination including Science & Mathematics or equivalent with five (05) years relevant work experience.

5.3.1.2 Laboratory staff to authorize calibration certificate and to perform specific laboratory activities

Bachelor degree from a recognized university in science stream with Physics as a subject or Engineering in relevant field or equivalent with 03 years of relevant experience

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5.3.2 Facilities and Environmental Conditions

The requirements of ISO/IEC 17025 clause 6.3 apply. Laboratories shall follow all applicable National and International legislations, guidelines and regulations relevant to the field of calibrations performed.

Laboratories shall provide documentary evidences to prove that they have maintained and monitored the Environmental Conditions Mentioned by the National or international requirements.

5.3.3 Equipment

The requirements of ISO/IEC 17025 clause 6.4 apply

Where a laboratory performs in-house calibrations, by means of comparisons between reference standards and working/measuring instruments, the calibration procedure shall be documented. Calibration records (e.g. calibration certificates, calibration data) shall be maintained.

If facilities are not available to carry out intermediate checks, method shall document and intermediate checks can be performed with NMI or any accredited calibration laboratory.

Initiation or review or revise calibration intervals should be according to the current ILAC/OIML Guideline. G 10, ILAC G 24 and international guidelines relevant to the field of Calibration.

5.3.4 Metrological traceability

The requirements of ISO/IEC 17025 clause 6.5 and ILAC: P10 shall be apply.

5.3.5 Externally provided products and services

The requirements of ISO/IEC 17025 clause 6.6 apply
All services obtained by the laboratory to be considered

5.4 Process Requirements

5.4.1 Review of Requests, Tenders and Contracts

The requirements of ISO/IEC 17025 clause 7.1 apply.

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5.4.2 Selection, Verification and Validation of method

The requirements of ISO/IEC 17025 clause 7.2 apply.

Method verification is the proof of the laboratory's capability carried out measurement/calibrations as per CMC values declared and records shall be maintained. If any laboratory has used inhouse calibration method developed by the laboratory based on one or more validated Calibration methods, all validation records shall be provided during the assessment.

5.4.3 Sampling

*The requirements of ISO/IEC 17025 clause 7.3 apply - **NOT RELEVANT***

5.4.4 Handling of test/calibration items

The requirements of ISO/IEC 17025 clause 7.4 apply

5.4.5 Technical records

The requirements of ISO/IEC 17025 clause 7.5 apply.

Laboratories should maintain the technical records soft and/or hard formats used.

5.4.6 Evaluation of measurement uncertainty

The requirements of ISO/IEC 17025 clause 7.6 and ILAC P 14 apply

5.4.7 Ensuring the validity of results

The requirements of ISO/IEC 17025 clause 7.7 apply

Policy for Participation in External Quality Assurance activities (AC-RG(P)-02) shall apply. Quality control procedures must be documented. Where appropriate, quality control data must be recorded in such a way that analyzed data can be readily evaluated.

5.4.8 Reporting of results

The requirements of ISO/IEC 17025 clause 7.8 apply.

5.4.9. Complaints

The requirements of ISO/IEC 17025 clause 7.9 apply.

5.4.10 Non-Conforming Work

The requirements of ISO/IEC 17025 clause 7.10 apply.

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5.4.11. Control of data and information management

The requirements of ISO/IEC 17025 clause 7.11 apply.

If the laboratory has implemented LIMS it should be validated and access control. User guides to be available.

5.5. Management System Requirements.

The requirements of ISO/IEC 17025 clause 8 apply.

If the laboratory follows Option B, Laboratory shall maintain management system as per ISO 9001 requirements. If the laboratory is certified as per ISO 9001 same system can be use. Internal audit of the laboratory to be covered both ISO 9001 requirements and ISO/IEC 17025 requirements.

If the laboratory follows Option A, Laboratory shall maintain management system documentation as per ISO/IEC 17025 clauses.

5.5.1 Management system documentation

The requirements of ISO/IEC 17025 clause 8.2 apply

5.5.2 Control of management system documents

The requirements of ISO/IEC 17025 clause 8.3 apply

The requirements for the accessibility and control of documents apply to permanent facilities and also to all sites or locations where work is performed.

5.5.3 Control of records

The requirements of ISO/IEC 17025 clause 8.4 apply

Retention time of the records to be complied to national information security regulations

5.5.4 Actions to address risks and opportunities

The requirements of ISO/IEC 17025 clause 8.5 apply

5.5.5 Improvement

The requirements of ISO/IEC 17025 clause 8.6 apply.

Laboratory can initiate and implement improvements in conjunction with risk and opportunities identified in clause 8.5.

5.5.6 Corrective action

The requirements of ISO/IEC 17025 clause 8.7 apply.

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5.5.7 Internal audits

The requirements of ISO/IEC clause 8.8 apply.

The internal audit shall be conducted at least annually to cover all standard requirements. Witnessing of calibration activities/ any activity performed by the laboratory personnel to be witnessed during the internal audit.

Calibration activities which are infrequently encountered may require other means by which to confirm competence and other activities which take place for the purpose of confirming competence.

5.5.8 Management review

The requirements of ISO/IEC 17025 clause 8.9 apply.

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Annexure – I

Areas to be considered for calibration services

1. Acoustics Ultrasound and Vibrations (AUV)
2. Electricity and Magnetism (EM)
3. Length (L)
4. Mass and related quantities (M)
5. Photometry and Radiometry (PR)
6. Amount of Substance (QM)
7. Ionization Radiation (RI)
8. Thermometry (T)
9. Time and Frequency (TF)

Fields to be considered in accreditation

1. General physics

- **Acoustics, Ultrasound, Vibration**

This metrology area covers the fields of acoustics, ultrasound and vibration.

- **Electricity and Magnetism**

This metrology area covers the fields of DC and AC measurements, impedance, electric and magnetic fields, radiofrequencies and measurements on materials.

- **Length**

This metrology area covers the fields of laser frequencies and dimensional metrology.

- **Mass and related quantities**

This metrology area covers the fields of mass standards, force, pressure, density, hardness, torque, gravity and viscosity.

- **Photometry and Radiometry**

- **Thermometry**

- **Time and Frequency**

2. Chemistry and Biology

- **Chemistry and Biology**

This metrology area covers all fields relevant to chemistry and biology.

3. Ionizing radiation

- **Ionizing Radiation**

This metrology area covers the fields of dosimetry, radioactivity and neutron measurements

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Annexure – II

COMPOSITION OF THE TECHNICAL ADVISORY COMMITTEE

1	Mr. R G Perera Head of Calibration, Lanka Calibration Services (Pvt) Ltd , Colombo 07 and SLAB assessor in the calibration Scheme	Chairman
2	Ms.S Udakara Director- Metrology, Sri Lanka Standards Institution, Colombo- 05 and SLAB assessor in the calibration scheme	Member
3	Dr. W M S Wijesinghe Senior Deputy Director, Industrial Metrology Laboratory, Industrial Technology Institute, Colombo 07 and SLAB Accreditation Committee member	Member
4	Mr. R G S A Perera Deputy Director, Measurement Units Standards and Services Department, Pitipana, Homagama and SLAB assessor in the calibration Scheme	Member
5	Mr. H L I S Sampath Assistant Director, Measurement Units Standards and Services Department, Pitipana, Homagama	Member
6	Mr. L H D Bandusoma Deputy Director, Sri Lanka Accreditation Board for Conformity Assessment (SLAB)	Member
7	Ms. M H Wickremasinghe Deputy Director, Sri Lanka Accreditation Board for Conformity Assessment (SLAB) and Technical Manager Testing and Calibrations	Member
8	Ms. Punya U Liyanage Assistant Director, Sri Lanka Accreditation Board for Conformity Assessment (SLAB) and Deputy Technical Manager Testing and Calibrations	Secretary

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