



SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

RULES & PROCEDURES
for ACCREDITATION of
CALIBRATION LABORATORIES



ACCREDITATION SCHEME FOR CALIBRATION LABORATORIES

Rules & Procedures for Accreditation of Calibration laboratories

1. Introduction

The Sri Lanka Accreditation Board for Conformity Assessment (SLAB) is the National Accreditation Authority of Sri Lanka established under Act No. 32 of 2005. The SLAB offers accreditation services to bodies that provide Conformity Assessment Services such as Testing, Medical and Calibration Laboratories, Certification Bodies for Systems, Products and Persons, Inspection Bodies, GHG Validation/ Verification Bodies, Recognition of Good Laboratory Practice and Proficiency Testing Providers.

The work procedures of the SLAB for calibration laboratories are based on ISO/IEC 17011:2017 – Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies. Preference will be given to Subject Specific Documents published by International Laboratory Accreditation Corporation (ILAC) and Asia Pacific Accreditation Corporation (APAC), wherever applicable & provides guidelines on application of ISO/IEC 17025:2017 and it is intended to be used by SLAB for accreditation of calibration laboratories. It is recommended to consider requirements and interpretations of ILAC policy documents by calibration laboratories seeking to manage their operations and obtaining accreditation from the SLAB in order to ensure fulfilment of the requirements for accreditation. The Governing Council of SLAB or relevant advisory committees, if required, will develop specific guidelines and advice the SLAB management in the areas for which there are no ILAC, APAC or other acceptable interpretation documents available.

1.1 Scope

This document outlines the rules and procedures to be adopted when calibration laboratories seek accreditation for their calibration activities from SLAB. Accreditation will be granted against the applicable International/Regional or National Standards or widely accepted standards or guidelines that are auditable or verifiable. Conformity assessment schemes/criteria for calibration are reviewed by the SLAB and determine its suitability.

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1.2 References

- Sri Lanka Accreditation Board for Conformity Assessment Act No 32 of 2005
- ISO/IEC 17011- Conformity Assessment –Requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17025 – General requirements for the competence of Testing and calibration laboratories
- ILAC P8 -ILAC Mutual Recognition Arrangement: Supplementary requirements for the use of accreditation symbols and for claims of accreditation status by accredited conformity assessment bodies
- ILAC P9 - ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10 - ILAC Policy on Metrological Traceability of Measurement Results
- ILAC P14 - ILAC Policy for Uncertainty in Calibration
- ILAC G18 - Guideline for the Formulation of Scopes of Accreditation for Laboratories
- ILAC- G 24 /OIML D 10 – Guidelines for the determination of calibration intervals of measuring instruments
- AC-RG (P)-01 - Policy for Governing the use of SLAB accreditation symbols
- AC-RG(P)-02 - Policy for participation in proficiency testing activities
- AC-RG(P)-04 - Policy of traceability of measurement results
- AC-RG(P)-05 - Policy on in-house calibration
- AC-RG(P)-06 - Policy for determination of uncertainty of measurement
- AC-RG(P)-07 - Policy on cross frontier accreditation
- CL-RG(P)-03 - Terms & conditions for maintaining accreditation of Calibration laboratories
- AC-RG(P)-20 - SLAB Policy on management of extraordinary events or circumstances affecting SLAB accredited bodies and their customer
- AC-PR(P)-18 - Procedure for conducting remote assessment
- CL-GL(P)-01- Specific Criteria for Calibration Laboratories
- CL-GL(P)-02 - Guidelines for Determination of Uncertainty of Measurement in Calibration

2. Accreditation requirements

2.1 Accreditation Criteria

The international standard ISO/IEC 17025– General requirements for the competence of testing and calibration laboratories, is used by the SLAB along with specific criteria developed, as applicable and required for accreditation of Calibration laboratories and accreditation body’s rules and procedures explained in this document, Terms and conditions for maintaining accreditation of calibration laboratory and other General policies such as Metrological traceability, Participation in proficiency testing etc, identified as reference documents in this document.

All applicant and accredited calibration laboratories are advised to read this document and other related documents prior to apply for accreditation and contact SLAB for any clarification/ further information, if required.

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If this document or documents referred in this document are revised, the SLAB will announce in the official website (www.slab.lk) and automatically adopt those modifications in its criteria, but will give the parties concerned a realistic period of time for the transition.

Development of accreditation criteria involve a step to obtain views of interested parties and public comments prior to publication. Therefore, applicant and accredited Calibration laboratories are requested to forward any written views/suggestions directly to the SLAB.

2.2 Eligibility

The applicant calibration laboratory must comply with all the requirements of ISO/IEC 17025, standard or guideline specific to the scope/field of calibration, if available. In addition, the applicant calibration laboratory shall comply with the relevant regulations (if any), specific criteria (if any) of SLAB for the scopes covered in their calibration activities.

Based on objective evidences, SLAB accept and can be accredited any calibration activity undertaken by a calibration laboratory as a regular calibration activity/programme, developed under contractual, mutual, or regulatory arrangements for consumer protection, public safety, or any other mean.

The Applicant/ Accredited calibration laboratory must ensure that their personnel are competent, impartial, and involved in continual professional development activities gaining skills and competencies. Applicant/accredited calibration laboratories must update themselves to meet the demands and expectations of their clients/ stakeholders, and must maintained consistent application at all levels of calibration.

In the initial applications and the scope extension applications, all applicant/ accredited laboratories shall have following arrangements prior to apply for accreditation, and records shall be available and to be submitted along with the application and relevant annexures.

1. Participation in external quality assurance activities as per AC-RG(P)-02 and ILAC P:09
2. Laboratory must evaluate their Calibration Measurement Capabilities (CMC's) and it must express the CMC of all parameters on the scopes of accreditation applied as per AC-RG(P)- 06 and ILAC P:14
3. Laboratory must ensure the measurement traceability of its calibration measurements as per AC-RG(P)- 04 and ILAC P:10
4. The applicant laboratory must have conducted at least one internal audit and a management review before the submission of application, covering the applied scope of accreditation.
5. Where a Calibration Laboratory, who is seeking more than one accreditation, who has already accredited from another ILAC full member or those are seeking accreditation from SLAB, outside Sri Lanka, must comply with AC-RG(P)- 07.
6. Calibration laboratories who perform internal calibrations for their own reference standards or measuring and test equipment by the laboratory's own must comply with AC-RG(P)- 05.

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3. Preparation for accreditation

3.1 Preparing for Accreditation of Calibration laboratories

The management of calibration laboratory should first decide to obtain accreditation for their calibration activity from SLAB. It is important for a calibration laboratory to make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to the accreditation process. The person nominated should be familiar with the calibration laboratory's existing quality system. SLAB will coordinate matters related to accreditation process only through the authorized representative of the calibration laboratory.

The calibration laboratory's management should first determine whether they obtain SLAB accreditation for their calibration activities. A calibration laboratory must develop a specific plan of action to obtain accreditation and appoint a responsible person to coordinate all accreditation-related activities with SLAB and it should be clearly indicated in the SLAB application. The individual chosen should be conversant with the calibration laboratory's existing quality system and its activities. SLAB will coordinate matters related to the accreditation process only through the appointed authorized representative of the calibration laboratory.

For relevant accreditation information, contact SLAB in person, by post, by phone, or by e-mail. The SLAB accreditation procedure, related documents, and application documents are all free to download from the SLAB website (www.slab.lk). Before submitting the application in the prescribed formats, the calibration laboratory should be acquainted with the SLAB assessment procedure and methodology.

Management system documentation, such as calibration procedures, policies, standards, rules, guidelines, and work instructions, must meet ISO/IEC 17025 requirements, SLAB requirements, and, if applicable, ILAC requirements and regulations. Calibration laboratories must ensure that these documentations are implemented and that their quality system and technical competencies meet the accreditation requirement.

3.2 Scope of Accreditation

The scope of the accreditation, often referred to as the 'scope', shall define the activities that the calibration laboratory shall comply with according to the SLAB's requirements. The applicant calibration laboratory shall include the scope of accreditation in the appropriate annexure of the application, specifying that the field of calibration, type of instrument of calibration, range of calibration, calibration method/ Measurement procedure, Calibration Measurement Capabilities, and locations/branches/sampling where the calibration laboratory carries out its activities.

If a laboratory defines their scope for machine performance verification and measurement verifications of equipment, those verifications must cover all the calibration parameters relevant to the performance/Measurement verification of machine or equipment, and the calibration laboratory shall specify that the type of instrument/s of calibration, Calibrations performed, range of calibration, calibration method/ Measurement procedure, Calibration Measurement Capabilities, and locations/branches/sampling where the calibration laboratory carries out its activities

The scope of the accreditation is reviewed in detail with the calibration laboratory throughout the adequacy review process, and the nature and extent of the initial assessment are based on that.

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4. Accreditation process

The accreditation process consists of registration of application followed by a resource review, Adequacy review, initial assessment, grant of Accreditation, surveillance and re assessment. In addition, verification assessment, follow up assessment, witness assessment, unannounced assessment may plan separately as required.

4.1 Application and Registration for Accreditation

The calibration laboratory shall submit application documents, all Annexures and the supportive documents to SLAB. Every application shall be accompanied with a nonrefundable application fee as stated in the Fee structure for Calibration laboratories - CL-RG(P)-01. Calibration laboratory shall clearly define the scope of accreditation (CL-FM(P)-01(AA), Annexure 1) and provide justifiable reasons if any standard clauses are not applicable to the calibration laboratory. Applications are accepted only after all the required documents and fee are submitted.

Applicant calibration laboratory may withdraw its application or discontinue accreditation process before granting accreditation and in such case, applicant calibration laboratory shall settle outstanding payments.

Foreign applicant/accredited calibration laboratories shall adhere to the cross-frontier accreditation policy (AC-RG(P)-07) and apply accreditation fees as per CL-RG(P)-01 for applications from foreign countries.

4.2 Special cases

- **Additional accreditation**

An accredited calibration laboratory can expand its accreditation for a new field or a scope extension to the existing scope of accreditation, following the same procedure as a new application. However, in such situations, the SLAB may limit its assessment, to the areas not covered by the existing accredited system and any other specific areas decided by the SLAB.

- **Already accredited Calibration Laboratory activities**

If an applicant calibration laboratory is already accredited by another ILAC, APAC member or ILAC/APAC MRA accreditation body for the same scope applied, the SLAB will communicate the relevant accreditation body and seeking the possibilities to collaborate with that body to gather necessary information, when processing the accreditation application. In such situations, SLAB may grant accreditation with or without assessment, but such decision is at the sole discretion of SLAB.

- **Calibration laboratories with multi-locations/Temporary Locations**

Applicant calibration laboratories operating through main office and temporary locations shall declare in the initial application or subsequent application, of its calibration activities in main office, temporary locations clearly and they must also indicate how common management system covers both main office and temporary locations. If the management system controls by the head office/Main office and all other activities are perform at separate location, then those locations shall be clearly defined and to be applied

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separately.

4.3 Acknowledgement and registration of application

Upon the receipt of application documents and other relevant documents and the fees, SLAB shall issue an acknowledgement to the calibration laboratory. After scrutiny of application for its completeness in all aspects, a unique accreditation number shall be assigned to the particular application, which shall be used for subsequent correspondence with the calibration laboratory.

In case of any calibration laboratory with multiple laboratories /sites/temporary sites controlled by a main organization, same number for the organization shall be continued unless requested by the calibration laboratory /decided by the technical manager.

SLAB may request for additional information/ clarification(s), if necessary, from the applicant calibration laboratory.

If, based on documents and information provided by the calibration laboratory, if SLAB in the view of that an assessment cannot result in accreditation, the applicant calibration laboratory shall be informed in writing, with reasons.

The SLAB's policies, processes /and procedures are non-discriminatory and applied in a non-discriminatory way. SLAB provides its services accessible to all applicants whose application for accreditation falls within the scope of its accreditation activities as defined within its policies and rules.

Access shall not be conditional upon the size of the applicant calibration laboratory or membership of any association or group, nor shall accreditation be conditional upon the number of calibration laboratories already accredited.

4.4 Appointment of authorized officer & resource review

Once the registration of application is completed with required documents, technical manager of accreditation scheme for calibration laboratories appoints one of competent Assistant Director/Deputy Director (Accreditation), Development Officer as Authorized officer for the application and continuation of accreditation process.

A resource review (technical review) will be carried out by the Authorized officer in consultation with technical manager and collect additional information from the calibration laboratory, if required. Authorized officer may indicate in the application form the additional information to be collected if required.

If relevant resources are not locally available steps will be taken to obtain resources through another accreditation body with the consent of the calibration laboratory. If the initial assessment cannot be conducted in a timely manner, this shall be communicated to the calibration laboratory.

Authorized Officer will contact the calibration laboratory with respect to application and further information required, if any. Authorized officer is the contact person of SLAB for the applicant calibration laboratory.

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4.5 Adequacy Review

Adequacy review consist with two steps as Offsite document and record review followed by the onsite verification for the Adequacy (hereinafter called onsite-adequacy review) of the application documents and its implementation. The SLAB will appoint a competent Team Leader/ Assessor/ Assessment team from the pool of assessors to carry out adequacy review on the management system documentation and other documents adopted by the applicant calibration laboratory with the assistance of SLAB.

4.5.1 Appointment of Assessment Team for the adequacy review

Towards the task of adequacy review, the Team leader shall be assisted by a team of Assessors/technical experts who will be appointed by SLAB as appropriate with the scope of accreditation and in accordance with the criteria adopted for the selection of adequacy review team.

The SLAB will propose the composition of adequacy review team. The calibration laboratory may lodge an objection in writing against specific team members with justifiable valid reason to do so. Such an objection shall be reviewed by the technical manager to determine the validity of the objection to ensure the impartiality and credibility of accreditation process. If the objection is found to be valid a new team or a new member is nominated in place of the member(s) in question. If no replacement is available, it is possible that the visit will be postponed, or that a part of the scope will not be assessed until a suitable replacement is found.

SLAB may also nominate one of its officers to participate in the adequacy review, unless an officer is appointed as an assessor/observer/staff officer during the adequacy review to convey his/her opinions to the Team leader and to provide clarification on the international standard and SLAB specific criteria (if any) to the adequacy review team and keep coordination with SLAB whenever necessary.

4.5.2 Offsite document and record review

Offsite Document and record review will be conducted by Team Leader/ Team member/ Team in relation to their scope allocated, based on the application submitted within one month. The aim of the Offsite document and record review is to determine whether the calibration laboratory is sufficiently prepared for a next step of the adequacy review, onsite-adequacy review.

In the offsite document and records review, that is determined that the Calibration laboratory is sufficiently prepare for the accreditation process and to ascertain the compliance of the documents with the criteria specified in ISO/IEC 17025. The adequacy review is also meant to obtain a clear idea of the intended scope of the accreditation.

Each team member including Team Leader/ team member, shall inform SLAB regarding the adequacy of the submitted documentation, indicating deficiencies in Annexure 07 (if any) relevant their scope allocated. Authorized officer shall communicate the applicant calibration laboratory, with a report indicating deficiencies; if any.

Based on report sent by SLAB, the calibration laboratory may take corrective actions before the onsite-adequacy review. Objective documentary evidence for corrective actions taken for the offsite document and record review deficiencies shall be verified during the onsite-adequacy review along with the other

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requirements to be fulfilled by the calibration laboratory, based on the policies and procedure of SLAB.

Onsite-adequacy review shall be conducted not later than one month from the date of offsite document and record review completed.

Based on the report of deficiencies the Offsite document and record review process, calibration laboratory can request an extension to conduct onsite-adequacy review with justifiable reasons, but the onsite-adequacy review shall be conducted not be more than six months from the date of offsite document and record review completed. In such situation, any failure to conduct onsite-adequacy review within given time, a fresh application documents including application fee shall be submitted (Proceed to 4.2). The decision shall be communicated in writing to the CAB.

4.5.3 Onsite-adequacy review

Upon completion of Offsite document and record review, onsite-adequacy review is conducted to gather information on following;

- a) Assess the completeness of the documentation structure of the implemented system
- b) Assess the establishment of Metrological traceability and Calibration Measurement Capabilities (CMC's), Participation of Internal and External Quality assurance activities
- c) Assess the degree of preparedness of the calibration laboratory for the initial assessment
- d) Study the scope of accreditation so that the time frame, number of assessors required in various disciplines and visits to sites, if applicable.

Onsite-adequacy review is conducted by a Team leader or an onsite-adequacy review team which consists Team leader/Assessor/ Technical assessor/Technical expert. If required, on site witnessing may also be arranged at the adequacy review stage.

At the end of onsite-adequacy review, team complete adequacy review report and deficiencies identified during the adequacy review and obtain the acknowledgement for recommendation and findings from the calibration laboratory. Onsite-adequacy review team verifies the man day requirement for the initial assessment and propose and report required changes and planning of initial assessment.

Calibration laboratory shall take necessary corrective action for the deficiencies and submit documentary evidences within two months. On request with justifiable reason, an extension of two months will be given. However, if the calibration laboratory submits corrective actions within four to eight months, technical manager may decide on continuation of application based on the justifiable reason. Any failure to submit corrective actions within eight months, application shall be discontinued and inform the decision to the applicant calibration laboratory.

Upon the successful completion of Adequacy review, calibration laboratory shall be notified and request to prepare for initial assessment.

If, based on documents and information provided by the calibration laboratory, SLAB is of the opinion that an initial assessment cannot result in accreditation, the applicant calibration laboratory shall be informed in writing and the documents concerned will be returned to the calibration laboratory for necessary improvement.

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If the outcome of the adequacy review is not satisfactory, SLAB may decide not to proceed with the application. In such cases, results with justification shall be reported in writing to the calibration laboratory.

4.5.4 Onsite-adequacy review plan

The SLAB contacts the calibration laboratory to agree on the date(s) and schedule for the onsite-adequacy review. Based on this SLAB prepares the Onsite-Adequacy review Plan using assessment Plan (TL-PL-01) and the composition of the team and send it across to the calibration laboratory well in advance. For calibration witnessing, Calibration laboratory shall include possibilities of witnessing of calibration by the accreditation body verification team into contractual agreements with calibration laboratory and its customers.

4.6 Onsite-adequacy review/ Assessment

The onsite activities will be carried out in Onsite-adequacy review and Initial Assessment (Initial Assessment is the Final Assessment for the grant of Accreditation). During the assessment, calibration/site witnessing of the applicant calibration laboratory's or client shall conduct. Although there are no strict demarcations for these two activities, the objectives of these activities may be expressed in the following manner. Onsite-adequacy review/ Assessments consist of an opening and a closing meeting with assessment team members and key personnel of the calibration laboratory. Therefore, calibration laboratory shall arrange required facilities to conduct meetings and the Onsite-adequacy review /assessment.

The team shall commence Onsite-adequacy review /assessment with an opening meeting at which the purpose of the assessment and criteria are clearly defined and the Onsite-adequacy review /assessment plan and the scope for the Onsite-adequacy review /assessment are confirmed.

During the Onsite-adequacy review /assessment, the team will assess the documentation and implementation of the management system as well as the competence of the calibration laboratory in accordance with the ISO/IEC 17025 and specific criteria (if any) of SLAB. In doing so, the team will select a representative sample in the areas within the scope of the accreditation.

The calibration laboratory shall demonstrate that it is competent in all the activities at all sites including temporary, mobile, or other for which accreditation has been requested. With regard to the management system of the calibration laboratory, the Onsite-adequacy review /assessment team shall be able to assess at least one complete cycle of the internal audit and management review.

As MRA partner of APAC and ILAC, SLAB may select assessment of calibration laboratories for peer evaluations and appoint peer evaluators as observer of assessment. In addition, assessment team may consist witnessing assessor from SLAB to evaluate the performance of SLAB assessors

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4.7 Initial assessment

Upon completion of Adequacy review, initial assessment is conducted to

- a. Assess the effectiveness of the implementation of the documented system
- b. Calibration laboratory's competence in performing calibration activities
- c. Finalize the scope of accreditation
- d. Take a decision on the recommendation for the grant of accreditation
- e. Decide follow up actions required to verify the effectiveness of corrective actions taken for previous nonconformities

At the end of each assessment, a closing meeting is conducted to disclose findings of the assessment. Initial assessment reports contain, assessment report, scope of accreditation, recommended authorized signatories, nonconformities, and other relevant assessment records. Initial assessment report shall also provide a recommendation towards grant of accreditation or otherwise. Assessment team is not allowed to take decisions on granting accreditation.

Calibration laboratory shall submit corrective actions within two months with satisfactory documentary evidence. However, depending on the severity of actions to be taken, calibration laboratory may take additional time up to one year from the date of Initial assessment, for taking suitable actions in agreement with SLAB.

If follow up assessment is recommended, it shall be conducted within ten months from the date of Initial assessment and corrective actions for non-conformities raised at the follow up assessment shall be submitted within one months.

If the corrective actions cannot be submitted within one year from the date of Initial assessment, another Initial assessment shall be arranged.

A verification assessment may be recommended for the effective implementation of corrective action and the Authorized Officer will arrange the assessment in consultation with the calibration laboratory

- Based on the recommendations of the assessment team
- Based on the corrective actions submitted by the CAB
- Based on the recommendations of the accreditation committee

In case of a verification assessment the Authorized Officer will arrange the assessment in consultation with the CAB as per Sec.4.4 of this document.

A follow up assessment may be recommended based on the following situations and the Authorized Officer will arrange the assessment in consultation with the calibration Laboratory.

- By the assessment team based on the level of the establishment and implementation of the quality management system
- Based on the corrective actions submitted by the CAB
- Based on the recommendations of the accreditation committee

In case of a follow up assessment the Authorized Officer will arrange the assessment in consultation with the CAB as per Sec.4.4 of this document.

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4.8 Assessment plan

The SLAB contacts the calibration laboratory to agree on the date(s) and schedule for the assessment. Based on this SLAB prepares the assessment Plan (TL-PL-01) and the composition of the team and send it across to the calibration laboratory well in advance. For witnessing, Calibration laboratory shall include possibilities of witnessing of calibration by the accreditation body assessors into contractual agreements with calibration laboratory and its customers.

4.9 Assessment techniques

The SLAB assessors use one or more combination of the following assessment techniques when conducting the assessment.

- **Document review:** assessing quality system documentation for compliance with the criteria; a document review can also involve records at the calibration laboratory's location, such as personnel files, quality control charts, audit reports, management review reports, etc.;
- **Office assessment:** an assessment of the premises of the calibration laboratory in order to assess the implementation of the system;
- **Interviews:** evaluating the expertise of the calibration laboratory's personnel via targeted interviews.
- **Calibration Witnessing:** observing calibrations and examination carried out by the calibration laboratory shall be witnessed on site. Based on the matrices, fields, similarities in methods & techniques and technical judgments by the assessment team, calibrations shall be witnessed during the onsite-adequacy review/ assessment to ensure the competency for the scope applied.

When planning and conducting onsite-adequacy review/assessments any national/regulatory requirements shall be considered, if relevant.

4.10 Participation in external quality assurance activities

If applicable, the calibration laboratory shall participate in external quality assurance activities as per SLAB policy for participation in external quality assurance activities (AC-RG(P)-02) and ILAC P 14.

4.11 Accreditation decision

After satisfactory closure of all nonconformities, the SLAB prepares a summary of all relevant information gathered during the processing of the application, the assessment report prepared by the assessment team, additional information received from the calibration laboratory and the consequent follow up and verification activities. The summary report is placed before the accreditation committee

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which is appointed by the Governing Council as per the provision of SLAB Act. The accreditation committee for testing and calibration laboratories, GLP and PTPs. studies the assessment reports, nonconformities and corrective actions, scope of accreditation, final report (CL-FM-46) and the recommendation given by the team and then makes its own decision on grant of accreditation.

The decision on the approval of grant of accreditation shall be submitted to the Council through Director/CEO, SLAB for information.

The SLAB informs the calibration laboratory in writing of the decision taken.

All decisions taken by SLAB regarding grant of accreditation shall be open to appeal by the calibration laboratory as per appeal procedure (GN-PR(P)-09) within 30 days.

4.12 Issue of accreditation certificate and schedule

As soon as a decision is taken to grant accreditation SLAB will prepare the following documents.

Accreditation certificate with a unique number for identification duly signed by the Director / CEO, SLAB. This certificate specifies the date on which the accreditation was granted, the standards based on which the accreditation was granted and the period of validity of the certificate.

A schedule of accreditation shall define Type of instrument, Calibration performed, Calibration methods / Measurement procedure, Range of calibration, CMC values and location, wherever applicable. The calibration parameters relevant to the performance/Measurement verification of machine/equipment indicate separately.

Terms and condition for maintaining accreditation of calibration laboratory (CL-RG(P)-03) is considered as the agreement between SLAB and calibration laboratory. This contains the rights and obligations of parties; the party providing the accreditation and the party being accredited and signed by both parties. In addition to use of ILAC MRA mark, separate agreement to be signed by the both parties. The applicant calibration laboratory must fulfil all the financial obligations payable to SLAB, before receiving the certificate(s).

4.13 Post accreditation assessments

The SLAB accreditation certificate shall be valid for a period of 3 years unless specified by the SLAB. During the validity of accreditation, the calibration laboratory must continuously comply with the requirements of the ISO/IEC 17025 and “Terms and condition for maintaining accreditation of calibration laboratory” (CL-RG (P)-03). In this regard SLAB will periodically review the validity of accreditation. To this end, the SLAB carries out surveillance assessments and a re-assessment within three years. During the accreditation period, the scope of the accreditation may be changed.

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4.14 Surveillance

Surveillance assessments will be planned by the Authorized Officer depending on the accreditation cycle. SLAB will conduct surveillance of all accredited calibration laboratories or following surveillance activities may be decided by the Technical manager based on the risks associated with the activities;

- 4.14.1.1 Special on-site/remote assessment
- 4.14.1.2 Review of changes to calibration laboratory's management system
- 4.14.1.3 Review of performance in proficiency testing and/or other inter-laboratory comparisons
- 4.14.1.4 Conduct advanced surveillance assessment

Surveillance is aimed at examining whether the accredited calibration laboratory is maintaining all the requirements of the ISO/IEC 17025 and SLAB specific criteria (if any).

As planned in the assessment schedule, Authorized officer of SLAB will in writing inform the accredited calibration laboratory of the surveillance assessment at the beginning of the year and agree on the dates of surveillance assessment before the due date of assessment.

The calibration laboratory during the validity of accreditation may request to extend the scope of accreditation for which they should preferably apply before the conduct of assessment/ surveillance. The mode of surveillance visit is similar to the initial assessment and it will cover only selected areas. The non-conformities, if any, shall be closed within two months of conduct of surveillance. The summary of the surveillance report along with other relevant information shall be submitted to the Director / CEO, SLAB to make a decision on the continuation of accreditation or otherwise. SLAB will inform the calibration laboratory, in writing, about the decision.

If there are remaining nonconformities with a justification by the Technical manager considering the associated risks, a letter of continuation of accreditation may be sent to the calibration laboratory with conditions or suspend accreditation relevant to the particular nonconformity.

When a follow-up assessment/Verification assessment is recommended and conducted, documentary evidence for corrective actions for remaining nonconformities/ new nonconformities, if any shall be sent to the SLAB within a month unless there is any issue which may be compromised with reasonable justification.

On practical situations, faced by either party with reasonable justification, the maximum time that should be allowed for advancing or delaying the annual surveillance shall only be three months from the planned surveillance assessment.

The surveillance assessment process shall be completed within ten months from the date of surveillance assessment. If the CAB failed to complete the surveillance process the suspension procedure shall be followed.

4.15 Reassessment and renewal of accreditation

As planned in the assessment schedule, Authorized officer will in writing inform the accredited calibration laboratory of the re-assessment at the beginning of the year.

Accredited calibration laboratory shall apply four months before the expiry of accreditation for renewal of accreditation as per the Terms and conditions for maintaining accreditation of calibration laboratory (CL-RG (P) -03). Application for renewal of accreditation is similar as initial application described above 4.1. Re –application shall be accompanied with the application fee as described in the fee structure.

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The calibration laboratory may request for extension of scope of accreditation, which should be explicitly mentioned in the application form.

The procedure for processing of renewal of application is similar to that of first application except that no onsite-adequacy review is conducted and likewise, the procedure for the reassessment visit is similar to that of initial assessment. If the results of reassessment visit are positive and all non-conformances are closed before the expiry of the validity of accreditation certificate, then the validity of the certificate is extended by a further period of three years without any discontinuity unless specific by the SLAB. In case of renewal, a new certificate and schedule of accreditation is issued while the certificate number is retained. The decision on renewal of accreditation is also taken by the accreditation committee for testing and calibration laboratories, GLP and PTPs.

4.16 Special assessments

The SLAB may organize extraordinary assessments, unannounced or ad hoc or other activities supplementary/ special visits under the following circumstances:

- 4.16.1 Repeatedly find nonconformities or many nonconformities during the surveillance/ reassessment which directly affect to the credibility of accreditation.
- 4.16.2 Receiving complaints that are substantiated with facts or on instances where the calibration laboratory is found to be misusing the certificate/ accreditation symbol.
- 4.16.3 Based on public complaints, publications, or information from interested parties and the government.

The Director/CEO, SLAB with the recommendation of Technical manager may decide to carry out special assessments at any time during the period of validity of accreditation. The execution of special assessments may take place with no prior notification or with very short time between notification and execution.

Special assessment may also become necessary when changes occur in accreditation criteria, organizational structure and in management/ ownership/ location/authorized signatories. However, in these cases, the SLAB will give calibration laboratories sufficient time for preparation.

All costs associated with special assessments will be charged to the calibration laboratory.

4.17 Changes in the accreditation criteria

If there is a change in the ISO/IEC 17025 or in the accreditation criteria, SLAB will inform the calibration laboratory in writing indicating the transition policy with specific period for complying with new criteria. Upon receiving such information, the calibration laboratory must confirm to SLAB's transition policy on implementation of changes. SLAB may assess the implementation of changes during surveillance and re assessments or conduct special assessment.

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4.18 Changes affecting the calibration laboratory operations

In the event of the calibration laboratory informing SLAB about any changes affecting the calibration laboratory's activities and operations, SLAB may organize a special visit. Calibration laboratory shall communicate this with relevant documentary evidence. The final decision is communicated to the calibration laboratory along with an amended certificate and schedule of accreditation. The costs associated with the issue of amended certificate and schedule will be charged to the calibration laboratory.

4.19 Reduction of the scope

During assessments by the SLAB, the accredited calibration laboratory shall demonstrate that it complies with all accreditation criteria regarding the entire scope and that it has complied with these criteria from the date on which accreditation was granted. If a calibration laboratory is of the opinion that parts of the scope no longer conform to the accreditation criteria, it is expected that the calibration laboratory will terminate the relevant part of the scope itself. If during an assessment it becomes clear that it is necessary to reduced accreditation for parts of the scope, the SLAB will also review the validity of the remaining accredited scope.

In order to demonstrate that a calibration laboratory has complied with and is complying with the criteria for the complete scope of accreditation, the calibration laboratory shall be able to provide records of the activities carried out. During SLAB assessments, these records shall demonstrate that the procedures for carrying out specific activities have been applied correctly by competent personnel in the past year.

The concerned part of the scope shall be reduced if records do not demonstrate this. In this case that the entire scope is reduced, then the entire accreditation is withdrawn. However, the calibration laboratory concerned can again be granted accreditation for the standard and the scope involved, after submission of new application.

4.20 Extension of scope

At any given moment, the calibration laboratory can request an extension of the scope. To this end, a written application shall be sent to the SLAB. An assessment for extension of scope will not be initiated, if nonconformities are currently open in related parts of the scope or in the general management system of the calibration laboratory.

The SLAB distinguishes between extension within and extension outside the scope already accredited. Extensions of the scope that fall within the framework of the same accreditation standard will be considered extension within the scope and if not, it will be considered otherwise. Requests for accreditation involving a different accreditation standard shall be treated as a new application.

Depending on the size and nature of the extension requested, the extent of the assessment needed for the extension will be determined by SLAB on a case by case basis. All costs for extension of scope will be charged to the calibration laboratory.

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4.21 Transfer of accreditation

If the ownership or name of an accredited calibration laboratory changes, the accreditation may be transferred to the new owner or to the new name if the calibration laboratory involved make such requests in writing. For such a transfer the following pre-conditions apply:

- 4.21.1.1 The calibration laboratory remains operating within the legal and regulatory framework of the country in which it operates
- 4.21.1.2 The policy and management system remain unchanged
- 4.21.1.3 The management and key personnel remain unchanged
- 4.21.1.4 The former owner does not remain active in the same sphere of activity or a similar area under the old name or a related name
- 4.21.1.5 The general composition of the calibration laboratory's personnel remains the same
- 4.21.1.6 The basic infrastructure and other facilities are not compromised

The calibration laboratory shall provide the SLAB with the necessary documents showing that the above conditions are met. The costs for reviewing the documents/ conducting onsite or remote review will be charged to the calibration laboratory.

If all requirements are met, the new calibration laboratory retains the registration/accreditation number and receives the new accreditation documents. The surveillance and re-assessment schedule will remain unchanged.

4.22 Management of extra ordinary situations

In the event an extraordinary situation, SLAB policy on the management of extraordinary event or circumstances effecting SLAB accreditation bodies and their clients AC –RG(P)-20 shall be applied.

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5 Obligations

5.1 Calibration laboratory

5.1.1 General

A calibration laboratory shall always comply with the relevant regulations and accreditation criteria. This not only applies to accredited Calibration laboratories but also to calibration laboratories whose accreditation has been suspended.

5.1.2 Co-operation

The calibration laboratory shall provide the SLAB assessment teams with all the necessary support in order to carry out their work efficiently, safely and honestly, whereby:

- It shall be possible to check the compliance of the calibration laboratory's management system within the criteria
- It shall be possible to gain insight into the relationship between the documented system and the Standard via an up-to-date review
- It shall be possible to observe the activities at the calibration laboratory
- The calibration laboratory shall provide the assessment team with the necessary safety instructions, safety equipment & personnel protective equipment
- If requested, the calibration laboratory shall provide access to all relevant locations, equipment, dossiers and documents
- In case the assessment of SLAB requires the participation of clients/ /external service provider or other related bodies of the calibration laboratory, the calibration laboratory shall take measures to assure this participation; in particular calibration laboratory shall have enforceable arrangements with its clients/external service provider holding an accredited certificate, to ensure SLAB access to witness the calibration laboratories' compliance at the calibration laboratory's client's/external service provider's site.
- Assessors of SLAB shall not be put in a position where their independence and objectivity could be compromised.

5.1.3 Accreditation Symbol

Accredited calibration laboratories have the right to use the applicable accreditation symbol. As such, on grant of accreditation, the calibration laboratory may use SLAB accreditation symbol on letterheads, brochures and any other material issued to its clients including the certificates. However, such usage shall be confined within the scope of Accreditation. The calibration laboratory shall comply with the "Policy on governing the use of the accreditation symbol" (AC- RG (P)-01). If the policy of the calibration laboratory is to use the accreditation symbol for calibration reports pertaining to accredited scopes, all reports issued on accredited scopes shall carry the accreditation symbol. The reports issued for machine performance verification and measurement verifications of equipment, the accreditation symbol can be used only if all the calibration parameters relevant to Machine/Equipment performance/Measurement verification/s, are covered under schedule of accreditation.

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Misuse of the accreditation symbol by accredited calibration laboratory may lead to suspension or withdrawal of the accreditation. If non-accredited calibration laboratory uses the accreditation symbol, the SLAB can resort to legal action.

5.1.4 Reporting Changes

The calibration laboratory shall inform the SLAB immediately of every change that can have considerable impact on the activities covered by the scope. Such changes may be of following nature:

- Changes in the legal, commercial or calibration laboratory’s organizational status
- Changes in the sphere of activities or economic activities of the calibration laboratory
- Change in management and in structure
- Policy changes
- Changes in personnel that fill key positions, such as managers and decision-makers and personnel with specific and unique expertise for the calibration laboratory
- Changes in location and other resources that can have a significant influence on the accredited activities carried out
- Significant changes in working procedures

If a calibration laboratory expects the changes to have a temporary negative effect on the accredited activities, then the calibration laboratory can request a voluntary suspension. In case of that the SLAB possesses the right to carry out extra assessments to ensure that the calibration laboratory again complies with the accreditation criteria before lifting the suspension. If during a surveillance activity of SLAB, it is found that SLAB was not informed about changes may decide to extend the assessment to review the changes and their impacts.

5.1.5 Financial Obligations

The calibration laboratory will receive an invoice for all the accreditation activities carried out by the SLAB. The amount invoiced will depend on the number of man-days worked; the applicable fee and other costs be found in CL-RG(P)-01. A calibration laboratory shall take prompt actions to settle the such payments. If a calibration laboratory does not make payment on time, the SLAB sends a reminder and late payments charges may apply. If payment still not made then, the suspension procedure will begin. If there are payments outstanding during the initial phase of the accreditation process, the SLAB has the right to halt the accreditation process until payment is done.

5.2 SLAB

5.2.1 Behavior of Assessment Teams

The assessment team will limit its assessment activities to an investigation of whether the calibration laboratory complies with the applicable criteria. In doing so, Assessors will make use of the relevant criteria documents, scope-related documents (including standards, descriptions of methodology, diagrams

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etc.) and generally accepted interpretations. Assessors may not accept any gifts, presents etc. from calibration laboratories that may compromise their neutral role in assessments. Assessors shall follow the health and safety instructions of the calibration laboratory being assessed.

5.2.2 Confidentiality

SLAB will treat all the information obtained or created during the accreditation process of calibration laboratories/sources other than the calibration laboratories as strictly confidential, unless otherwise required to be disclosed under a legal or regulatory framework and unless agreed by the source.

Legally enforceable agreements are made available to safeguard the confidentiality of the information obtained in the process of accreditation at all levels of SLAB including the staff of SLAB, committees, service providers, assessment team, or other bodies or individuals acting on behalf of the SLAB. Confidential information related to any calibration laboratory shall not be disclosed, outside the SLAB without written consent of that particular calibration laboratory, unless otherwise required by law. Any information about a calibration laboratory obtained from other sources is not shared with that calibration laboratory, unless agreed by the source.

6 Suspensions, Withdrawals and Reductions

Suspension, Withdrawal and Reduction of scope of accreditation arises, in the event of a calibration laboratory persistently failing to meet the requirements of accreditation criteria, and/or violating the Rules and procedures and Terms and Conditions agreed upon at the stage of granting accreditation. On CAB's request, the scope may also be suspended, withdrawn or reduced.

SLAB will take decision on suspension of accreditation for a maximum of four months or Withdrawal/Reduction of accreditation with immediate effect. Any failure to rectify the issues related Suspension within the given period, accreditation shall be withdrawn/reduced with immediate effect. The decision will be informed to the calibration laboratory and published in the web site. SLAB may issue a revised certificate/schedule of accreditation.

6.1 Suspensions

During the suspension period, the calibration laboratory may not make use of the accreditation symbol or in any other way actively refer to the accredited status.

A suspension is lifted if an additional assessment shows that the reason for the suspension no longer exists. If the suspension period ends without this being the case, the SLAB implements the withdrawal procedure. If the laboratory actions to reinstate accreditation within 4 months another two months maximum will be given to complete or instate. Any failure to rectify the issue related to suspension within the given period accreditation shall be withdrawn or reduced with immediate effect by the Director/CEO and decision will be informed to the accreditation committee. If the decision is to suspend or withdraw or reduce accreditation Director/CEO shall inform the laboratory of the decision in writing and may issue a revised certificate or schedule of accreditation.

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A calibration laboratory may request a voluntary suspension from the SLAB if it is temporarily unable to comply with the accreditation criteria. In such circumstances, the calibration laboratory is not permitted to make use of the logo or refer to the accredited status. It is not possible to submit a request for a voluntary suspension during the period that a SLAB assessment is being carried out.

6.2 Withdrawals and reduction

The accredited calibration laboratory and the SLAB can withdraw/reduce the scope of accreditation. From the moment of withdrawal/reduction, the calibration laboratory will have to refrain from using the accreditation symbol or otherwise referring to the accredited status for the full/part of scope of accreditation. In such situations the certificates issued under SLAB- accreditation shall also have to be withdrawn/re issued.

If calibration laboratory wishes, for whatever reason, to terminate its scope of accreditation in full/part, it shall submit a request to the SLAB for voluntary withdrawal/reduction in writing. Withdrawal shall apply to the entire scope and reduction shall apply for the part of the scope. The SLAB confirms the withdrawal/reduction in writing.

When SLAB determines that a suspension of full/part of the scope of accreditation, has not been lifted within the applicable period or if evidences are found to substantiate that the calibration laboratory brings the Accreditation into grave disrepute, the SLAB will impose the withdrawal/reduction. SLAB informs the calibration laboratory of the withdrawal/reduction in writing. After a withdrawal, the SLAB will not accept an application for accreditation from the same calibration laboratory within a period of six months.

7. Disputes, complaints and appeals

7.1 Disputes

The SLAB defines a dispute as difference of opinion between the accredited calibration laboratory or applicant Calibration laboratory and the SLAB with regard to:

- 7.1.1 The interpretation of a requirement of a standard;
- 7.1.2 The working procedure of the SLAB.

The calibration laboratory can report the existence of such dispute to the Director/CEO, SLAB in writing. The Director/CEO, SLAB will consult with the parties involved. The decision will be communicated to the parties in writing.

All disputes if any rising out of SLAB decisions, that remains unresolved through internal mechanism provided by SLAB are subjected to the alternate dispute resolution (arbitration). If fails, can initiate litigation within the jurisdiction of the courts in Sri Lanka exclusive jurisdiction of the courts in Sri Lanka.

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7.2 Complaints

The SLAB distinguishes two types of complaints:

- 7.2.1.1 Complaints about the SLAB and its personnel on behalf.
- 7.2.1.2 Complaints about registered or accredited calibration laboratories.

In both these cases Director/CEO, SLAB or the panel appointed by him/her will investigate the complaints.

The complaints will be handled in accordance with the Procedure for Complaint handling (GN- PR(P)-08), which is available on SLAB website.

7.3 Appeals

Calibration laboratories are free to make appeals against decisions taken by the SLAB such as appointment of assessors, grant of accreditation, reduction/ expansion of scopes, suspensions/ withdrawal etc. All such appeals will be dealt with in accordance with the SLAB procedure for dealing with Appeal (AC-PR(P)-09) which is available on SLAB website.

8. Publicity

SLAB will publish the details of scope of accreditation & accreditation status of the accredited Calibration laboratories along with their contact addresses and suspension/withdrawal of accreditation status in SLAB web site.

SLAB posts all Rules and Procedures, Terms and Conditions, Fee Structures, Specific Criteria's and Applications and supporting documents and subsequent changes in the SLABs official website. Calibration laboratories are required to implement such changes as per instructions given by the SLAB.

9. Liability

SLAB will not be responsible for any damages, which the calibration laboratory may suffer as a result of any action or negligence by those who are carrying out the tasks on behalf of SLAB and any failure to the grant of accreditation or abeyance/suspension/withdrawal of the accreditation, and neither shall SLAB be held responsible for any damage whatsoever, caused to any party by the acts of Calibration laboratory.

Calibration laboratory shall have adequate provisions (Insurance coverage or reserve) to cover liabilities arisen from its operation.

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