



SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

**RULES & PROCEDURES for
ACCREDITATION of**

- 1. TESTING LABORATORIES**
- 2. CALIBRATION LABORATORIES**
- 3. MEDICAL TESTING LABORATORIES**
- 4. INSPECTION BODIES**
- 5. PROFICIENCY TESTING PROVIDERS**
- 6. REFERENCE MATERIAL PRODUCERS**
- 7. GOOD LABORATORY PRACTICE**



**ACCREDITATION SCHEME FOR TESTING LABORATORIES/
CALIBRATION LABORATORIES/ MEDICAL TESTING LABORATORIES/ INSPECTION BODIES/
PROFICIENCY TESTING PROVIDERS/ REFERENCE MATERIAL PRODUCERS/
GOOD LABORATORY PRACTICE**

Rules & Procedures for Accreditation

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, Biobanking, Certification Bodies for Management Systems, Products, Processes, Services and Persons, Inspection Bodies, Validation & Verification Bodies, recognition of Good Laboratory Practice, Proficiency Testing Provider and Reference Material Producers.

The work procedures of the SLAB for Conformity Assessment Bodies (CABs), are based on ISO/IEC 17011: 2017 – Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies and the applicable version of the relevant Accreditation standards. Reference will be given to subject specific documents published by International Laboratory Accreditation Corporation (ILAC) and Asia Pacific Accreditation Corporation (APAC), wherever applicable. 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 are available.

1. General

1.1 Scope

This document outlines the rules and procedures to be adopted when CABs seek accreditation for their conformity assessment activities from SLAB. Accreditation will be granted against the applicable International/Regional or National Standards or which contain requirements.

1.2 References

- Sri Lanka Accreditation Board for Conformity Assessment Act No 32 of 2005
- ISO/IEC 17011: 2017 - Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories
- ISO 15189 - Medical laboratories - Requirements for quality and competence
- ISO/IEC 17020 - Requirements for the operation of various types of bodies performing Inspection

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- ISO/IEC 17043 - General requirements for the competence of proficiency testing provider
- ISO 17034 - General requirements for the competence of for reference material producers
- ISO 20387 – Biotechnology-Biobanking- General requirements for biobanking
- OECD guidelines for Good Laboratory Practice
- AC-RG(P)-01 - Policy for governing the use of SLAB accreditation symbols
- AC-RG(P)-02 - Policy for participation in External Quality Assurance activities
- AC-RG(P)-04 - Policy on the traceability of measurement results
- AC-RG(P)-05 - Policy on in-house calibration
- AC-RG(P)-07 - Policy on cross frontier accreditation
- AC-RG(P)-08 - Terms & conditions for maintaining accreditation of TL, CL, ML, IB, PTP, RMP, GLP
- AC-RG(P)-20 - SLAB Policy on management of extraordinary events or circumstances affecting SLAB accredited bodies and their customers
- AC-RG(P)-06 - Policy for determination of uncertainty of measurements
- XX-RG(P)-01 - Fee structures of the relevant accreditation scheme
- SLAB Transition Policy/ies of the relevant accreditation scheme, if any
- AC-GL(P)-10 - Guidelines for Workflow Management System (SLAB WFMS)
- CL-GL(P)-02 - Guideline for determination of uncertainty measurement for calibration
- SLAB Specific Criteria of relevant accreditation scheme, if any

NOTE: The code ‘XX’ in the reference documents denotes the code of relevant accreditation scheme, ‘NN’ denotes the respective document number within a field of ‘XX’ and ‘P’ denotes the publicly available document.

2. Accreditation requirements

2.1 Accreditation Criteria

The applicable standards and referred standards therein are used by the SLAB along with specific criteria developed subject-wise, as applicable and required for accreditation of CABs and accreditation body’s Rules and Procedures explained in this document, Terms and conditions for maintaining accreditation and other General policies identified as reference documents in this document.

All applicant and accredited CABs 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.

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 steps to obtain views of interested parties and public comments prior to publication. Therefore, applicant and accredited CABs are requested to forward any written views/suggestions directly to the SLAB.

As relevant to the Accreditation Schemes, the mandatory documents and resolutions published time to time by International and Regional Accreditation Organizations will be considered as accreditation criteria. Depending on each accreditation scheme/ scope(s), specific criteria, if any will be laid down by SLAB and those shall be read in conjunction with the relevant International Standard under which the accreditation will be granted.

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2.2 Eligibility

The applicant CAB and its location/sites, Sample Collection Centers (SCCs) and Point of Care Testing (POCT) of Medical laboratories, must comply with all the requirements of applicable standard. In addition, the applicant CAB and its location/sites, SCCs and POCTs must comply with the relevant regulations (if any) and applicable documents of International and Regional Accreditation Organizations (if any) for the scopes covered under the scope of accreditation.

All documents referred in section 1.2 of this document shall applicable as relevant.

The applicant CAB shall have conducted at least one internal audit and a management review before submission of application to the SLAB.

3. Preparation for accreditation

3.1 Preparing for Accreditation of CABs

The management of CAB should first decide to obtain accreditation for their conformity assessment activity from SLAB. It is important for a CAB to make a definite plan of action for obtaining accreditation and nominate an authorized representative to co-ordinate all activities related to the accreditation process and identify a company specific email for SLAB Work Flow Management System (SLAB WFMS) login. The person nominated should be familiar with the CAB's existing quality system. SLAB will coordinate matters related to accreditation process only with the authorized representative of the CAB through the above given login email only.

A request can be made to SLAB in person, by post, by telephone, by e-mail or through SLAB WFMS for relevant information on accreditation. Information regarding SLAB accreditation process, relevant documents and application form are freely downloadable from the SLAB website (www.slab.lk). The CAB should be acquainted with the SLAB assessment procedure & methodology before submitting the application in the prescribed format.

Management system documents shall be prepared in accordance with the requirements specified in the applicable standards/ schemes and regulations, if any and this should be supplemented by a set of other documents such as procedures, standards, regulations, work instructions etc.

The CAB needs to establish the status of its existing quality system and technical competence with regard to the requirements of SLAB for accreditation.

3.2 Scope of accreditation

The scope of accreditation, often referred to as the 'scope', is defined as those conformity assessment activities for which to be covered under SLAB accreditation. Applicant CAB shall include scope of accreditation in the relevant annex/ section of application or make reference to further document which contain same format in the application. The scope also specifies the locations/sites/branches/POCT where the CAB carries out its activities.

During the pre-assessment process, the scope of the accreditation is discussed with the CAB in detail, and the nature and extent of the assessment will be based on that.

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4. Accreditation process

The accreditation process consists registration of the application followed by a resource review, document review, pre-assessment, initial assessment, grant of accreditation, surveillance assessment and reassessment. In addition, follow up assessment, unannounced assessment and witness assessment may plan separately as required.

4.1. Application and Registration for accreditation

The CAB shall submit application documents to SLAB/SLAB WFMS.

The application shall be accompanied with the prescribed application fee stated in the fee structure of relevant accreditation scheme (XX-RG(P)-01). Application fee is nonrefundable. The CAB has to take special care in filling the scope of accreditation for which the CAB wishes to apply. In case, the CAB finds any clause of the standard (in part or full) not applicable to them, it shall furnish justifiable reasons.

Applications are not accepted and registered until the submission of required documents and application fee.

Applicant CAB may withdraw its application or discontinue accreditation process before granting accreditation. In such case, applicant CAB shall settle all due payments, if any.

Foreign applicants/ accredited CABs shall follow Policy on cross frontier accreditation (AC-RG(P)-07) and accreditation fees as stated in XX-RG(P)-01.

4.2. Special cases

- **Additional accreditation**

If a CAB is already accredited and wishes to expand its accreditation for a new field or scope extension to existing accreditation, the procedure is same as for a new registration. However, in such case, the assessment by the SLAB may be limited to cover the areas not covered by the existing accredited scope and certain specific areas as decided by SLAB.

- **Already accredited CAB activities**

In case an applicant CAB is already accredited for the applied scope by an ILAC MRA partner accreditation body, in compliance with the SLAB cross frontier accreditation policy explained in AC-RG(P)-07, SLAB will communicate with the particular accreditation body to collect necessary information and will seek possibilities to act in collaboration with the said accreditation body when processing the accreditation application. However, all decision will be taken at the sole discretion of SLAB.

- **CABs operating in a foreign country**

In case if an applicant CAB operating in a foreign country of which accreditation body has been a ILAC MRA partner is seeking accreditation, SLAB will initially communicate with that accreditation body inquiring its obligations or objections with regard to processing of such application and based on the response will proceed with the application following the SLAB cross frontier policy explained in AC-RG(P)-07.

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- **CABs with multi-locations**

Applicant CABs operating through main office and locations shall declare in the initial application or subsequent application on its certification activities in main office, locations and how common management system covers both main office and locations.

4.3 Acknowledgement and registration of application

SLAB on receipt of application documents, other relevant documents and the fees, will issue an acknowledgement to the CAB. After scrutiny of application for its completeness in all aspects, a unique accreditation number will be allocated to the particular application, which shall be used for correspondence with the CAB thereafter.

SLAB may request for additional information/ clarification(s), if necessary, from the applicant CAB. If, on the basis of documents and information provided by the CAB, SLAB is of the opinion that an assessment cannot result in accreditation, the applicant CAB will be informed in writing giving reasons.

The SLAB's policies, processes and procedures are non-discriminatory and applied in a non-discriminatory way. SLAB makes 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 is not conditional upon the size of the applicant CAB or membership of any association or group, nor accreditation be conditional upon the number of CABs already accredited.

4.4 Appointment of Authorized officer & resource review

Once the registration of application is completed with required documents, Technical Manager of relevant accreditation scheme appoints an Authorized Officer for the application and continuation of the accreditation process. Authorized officer is the contact person for the applicant CAB.

A resource review (Technical review) will be carried out by the Authorized officer in consultation with Technical Manager and collect additional information from the CAB, if required. Authorized officer may indicate in the application form the additional information to be collected if required, for the assessment.

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

Authorized officer will contact the CAB with respect to application and further information required, if any.

4.5 Document review

4.5.1 Appointment of Assessor/ Team Leader

The SLAB will appoint a competent Assessor/ Team Leader from the pool of assessors to carry out document review on the management system documentation adopted by the applicant CAB.

4.5.2 Adequacy of management system documentation

The Assessor/ Team Leader will commence the assessment process with review of management system documentation based on the application submitted within twenty days. The aim of the

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document review is to determine whether the CAB is sufficiently prepared for the accreditation process and to ascertain the compliance of the documents with the requirements specified in applicable standard. The document review is also meant to obtain a clear idea of the intended scope of accreditation.

The Assessor/ Team Leader, will inform SLAB regarding the adequacy of the management system documentation, indicating deficiencies (if any) in the documentation which in turn should be communicated to the applicant CAB. Based on this feedback the CAB shall submit corrective actions and submit objective documentary evidence not later than fourteen days. Maximum of two months will be given to CAB to complete the corrective actions subjected to justifiable reasons. Any failure to submit satisfactory documentary evidences within two months, application will be terminated.

If the CAB satisfies the relevant requirements at the document review stage or after the CAB has taken necessary corrective action based on the document review, the assessment process will move to the next step of the accreditation process.

If the outcome of the document review is not satisfactory, SLAB may decide not to proceed with the application. In such cases, results with justification will be reported in writing to the CAB.

4.6. Appointment of Assessment Team

Towards the task of assessments, the Team leader will 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 assessment teams. In addition, SLAB may appoint observers whenever possible to provide the learning opportunities for Trainee Assessors.

SLAB will notify the composition of assessment team with their work place, their capacity & assigned assessment activities and possible date/s for the assessment, and request objections, if any. Any objections received, Technical Manager will review to determine the validity of the objections to ensure the impartiality and the credibility of the accreditation process and take a suitable decision. 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 assessment will be postponed, or that a part of the scope will not be assessed until a suitable replacement is found.

If no representation of the assessment team from SLAB, SLAB may nominate one of its officers to participate in the assessment as staff officer during the assessment to coordinate with SLAB and assessment team whenever necessary.

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

4.7 Assessment plan

The SLAB will schedule the assessment with the agreement of CAB for date(s) and the assessment team and the assessment plan (XX-PL-01) will be prepared.

4.8 Assessment

The assessments will be carried out as two stages namely pre-assessment and initial assessment (initial assessment is the final assessment before the grant of accreditation). During those assessments,

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witnessing of relevant conformity assessment activities at the site of the CAB or client's or service provider's site may be required.

Assessments consist of an opening and a closing meeting with assessment team members and key personnel of the CAB. Therefore, CAB shall arrange required facilities to conduct meetings and the assessment.

The assessment team will commence the assessment with an opening meeting at which the purpose of the assessment and criteria are clearly defined and the assessment plan and the scope for the assessment will be confirmed. During the assessment, the assessment team will assess the documentation and implementation of the management system as well as the competence of the CAB for the scope applied in accordance with the applicable standard and other accreditation criteria. In doing so, the assessment team will select a representative sample in the areas within the scope of the accreditation.

With regard to the management system of the CAB, the assessment team will assess at least one complete cycle of the internal audit and management review.

In the assessment, in addition to visiting the main or head office, based on the scope of accreditation, visits will be made to all locations. Whenever a new location has applied, that location shall also be witnessed.

4.8.1 Remote and Hybrid Assessments

Remote/ hybrid (combination of remote and onsite) assessments may be conducted at SLAB's discretion based on the risk associated with the activities and extraordinary situations however, remote assessments are not encouraged by SLAB.

When remote / hybrid assessments are planned, the restrictions such as usage of cameras and video equipment, sites/locations, use of interpreters, no of man days, time differences etc., to be considered and Accreditation assessment process will be followed.

4.8.2 Pre assessment

Upon completion of document review, a pre assessment is conducted to gather information on following;

- a. assess the completeness of the documentation structure of the implemented system
- b. assess the degree of preparedness of the CAB for the initial assessment
- c. study the scope of accreditation so that the time frame, number of assessors required in various disciplines and visits to SCCs/POCTs/ sites/ locations, if applicable

Pre assessment is conducted by a Team Leader or Assessment team which consists of a Team Leader/Assessor/ Technical Assessor/Technical expert. At the end of pre assessment, assessment team will complete the pre assessment report and deficiencies identified during the pre-assessment and obtain the acknowledgement for recommendation and findings from the CABs.

CAB shall take necessary corrective actions for the deficiencies and submit the documentary evidences to SLAB within two months. If a CAB requests with a justifiable reason, Technical Manager may decide on an extension to submit corrective actions. However, this process to be completed within eight months after conducting the pre-assessment. Any failure to submit documentary evidences within eight months, the application will be terminated. The decision on termination of the application will be taken by the Technical Manager and communicated to the CAB.

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Upon the successful completion of pre-assessment, CAB will be notified and requested to prepare for initial assessment.

4.8.3 Initial assessment

Upon completion of pre-assessment, initial assessment is conducted to

- a. Conditions in the CAB to fulfill the competence requirements needed for accreditation
- b. Efficacy and suitability of the management system
- c. Technical execution and correctness of the methods for which accreditation has been applied
- d. Suitability and conditions of existing equipment, as applicable.
- e. Decide follow up actions required to verify the effectiveness of corrective actions taken for pre-assessment deficiencies if any.

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, nonconformities and other relevant assessment records. Assessment report will also provide a recommendation towards grant of accreditation or otherwise.

In case of a joint assessment conducted at a CAB with a foreign accreditation body, the recommendation will be given to the CAB based on both assessment reports.

The CAB shall submit objective documentary evidence for corrective actions within two months, however, depending on the severity of actions to be taken, CAB may take additional time up to six months from the date of Initial assessment, for taking suitable actions in agreement with SLAB. If the corrective actions cannot be submitted for all nonconformities within six months, Technical Manager may decide on the next step.

The assessment will not proceed into next stage unless all non - conformities are satisfactorily addressed and closed. However, initial assessment process to be completed within 10 months. If not, application will be terminated.

4.9 Assessment techniques

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

- **Document review:** assessing management system documentation etc. for compliance with the criteria; a document review can also involve records at the CAB's location, such as personnel files, quality control charts, audit reports, management review reports, etc.;
- **Office assessment:** an assessment of the premises of the CAB in order to assess the implementation of the system;
- **Interviews:** evaluating the expertise of the CAB's personnel via targeted interviews.
- **Witnessing:** Observing the conformity assessment activities carried out at the premises/ sites/ locations/ POCTs and visits to SCCs to ensure samples are properly collected, stored and transported to the main laboratory for testing.

Based on the risk and complexity associated with the matrices, fields, similarities in methods & techniques and technical judgments by the assessment team, scope will be witnessed initially during the assessment and within the accreditation cycle to ensure the competency for the scope applied.

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Inspections and examinations carried out by the inspection body will be witnessed as per the policy on assessment of inspection bodies with multi-sites and witness assessments (IB-RG(P)-07).

Witnessing of conformity assessment activities or part of the conformity assessment activities conducted at sites will be decided by the Authorized officer/Assessment team.

When planning and conducting assessments, any national/regulatory requirements will be considered, if relevant.

4.10 Accreditation decision

After satisfactory closure of all non-conformities, the SLAB prepares a summary of all relevant information gathered during the processing of the application, the assessment reports prepared by the assessment team, additional information received from the CAB and the consequent verification activities, if applicable.

The summary report is placed before the accreditation committee which is appointed by the Governing Council as the provision of SLAB Act. The accreditation committee studies the assessment reports, nonconformities and corrective actions, scope of accreditation, other relevant annexures and the recommendation given by the assessment team and then makes the decision on grant of accreditation.

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

The SLAB informs the CAB in writing of the decision taken.

All decisions taken by SLAB regarding grant of accreditation will be open to appeal by the CAB consistent with the Procedures for dealing with appeals (GN-PR(P)-09), within 30 days.

4.11 Issue of certificate and schedule of accreditation

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.
- For a testing laboratory, a schedule of accreditation will define field of test, items or materials tested, specific tests performed, specification/ standard method or technique used, range of testing / limit of detection, wherever applicable.
- For a Calibration laboratory, a schedule of accreditation will define type of instrument/ Gauge, Calibration performed/ Measured quantity, Calibration method/ Measurement procedure, range of calibration, readability/ resolution as applicable, CMC, location.
- For a Medical laboratory including POCT, if applicable, a schedule of accreditation will define field of test, specification/ standard method or technique used, instruments, items or materials tested, specific tests performed, range of testing/ limit of detection, wherever applicable. Sample collection facilities at other locations and mobile testing services will be clearly identified in the scope of accreditation accompanying the certificate.
- For an Inspection body, schedule of accreditation referring to the scope of accreditation with type of inspection, inspection category, field of inspection, inspection method, reference

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standard/ regulation, range of inspection, stages of inspection, locations/sites covered under accreditation.

- For a Proficiency Testing Provider, a schedule of accreditation referring to field of PT schemes, specific area or product or material, determinant, reference method or procedure, range or limit, frequency and site/ location.
- For a Reference Material Producer, a schedule of accreditation referring specification/ standard method or technique used type of material, matrix or artifact, property/ies characterized, approach used to assign value.
- For a Good Laboratory Practise Facility, a schedule of accreditation referring field of study, group of study or material covers during study.
- For a Biobank, a schedule of accreditation referring material, Activities, Methods, Storage conditions
- Terms and condition for maintaining accreditation (AC-RG(P)-08) is considered as the agreement between SLAB and CAB. This contains the rights and obligations of both parties.
- In addition, to use ILAC MRA mark, separate agreement to be signed by the both parties. The applicant CAB must fulfil all the financial obligations payable to SLAB, before receiving the Certificate(s).

4.12 Post accreditation assessments

The SLAB accreditation certificate will be valid for a period of four years unless specified by the SLAB. During the validity of accreditation, the CAB must continuously comply with the requirements of the applicable standard and “Terms and conditions for maintaining accreditation” (AC-RG (P)-08).

In this regard SLAB will periodically review the validity of accreditation. Thereafter SLAB carries out a surveillance assessment which will be initiated at the 18th month from the date of grant of accreditation and a re-assessment in every four years which will be initiated at 3 ½ years.

During the accreditation period, the scope of the accreditation can be changed.

4.12.1 Surveillance assessment

Surveillance assessment will be initiated at the 18th month of the date of granting/renewing accreditation. The surveillance assessment will be informed to the CAB at the 12th month from the date of granting/renewing the accreditation by the Authorized officer. Following surveillance activities may be decided by the Technical Manager based on the risks associated with the activities;

- Special on-site assessment/remote assessment
- Review of changes to CAB’s management system
- Review of performance in PT and/or other Inter-laboratory comparisons
- Conduct advanced surveillance assessment

The CAB during the validity of accreditation may request to extend the scope of accreditation for which they shall preferably apply before the conduct of assessment.

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,

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however depending on the severity of actions to be taken, CAB may take additional time up to six months from the date of surveillance assessment, for taking suitable actions in agreement with SLAB. If the corrective actions cannot be submitted for all nonconformities within six months, Technical Manager may decide on the next step. If the CAB failures to complete the surveillance process, the suspension process will be followed.

If the nonconformities cleared within two months with the recommendation of Technical Manager a letter of continuation of accreditation will be sent to the CAB by the Director/ CEO.

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 CAB with conditions or suspend accreditation relevant to the particular nonconformity.

When a follow-up 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.

4.12.2 Reassessment and renewal of accreditation

As planned in the assessment schedule, Re-assessment will be conducted in every four years and CAB shall apply for re-assessment to SLAB/ through SLAB WFMS and complete the submission of application documents before 06 months of the date of expiry of accreditation as per the terms and conditions for maintaining accreditation (AC-RG (P) -08). The re-assessment will be informed before 12 months of the date of the expiry of the accreditation by the Authorized officer.

Application for renewal of accreditation is similar as initial application described above [Section 4.1](#). re application will be accompanied with the application fee as described in the fee structure.

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

Processing of application for renewal of accreditation is similar to that of first application except that no pre-assessment is conducted and likewise, the process for the reassessment is similar to that of initial assessment. If the results of reassessment visit are satisfactory and all non-conformances are cleared before the expiry of the validity of accreditation certificate, then the validity of the certificate is extended by a further period of four years without any discontinuity unless specified by the SLAB. The decision on renewal of accreditation is taken by the accreditation committee. A new Certificate and Schedule of accreditation will be issued while the accreditation number is retained.

4.12.3 Follow Up assessment

A follow up assessment may be recommended;

- a. by the assessment team, based on the level of the establishment and implementation of the quality management system
- b. based on the corrective actions submitted by the CAB
- c. based on the recommendations of the accreditation committee
- d. based on the recommendation of Director/CEO or Technical Manager
- e. based on the recommendation of Committee appointed to handle appeals and complaints
- f. based on the major changes of the CAB (e.g.: location, top management, etc.)

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If follow up assessment is recommended, the Authorized officer will arrange the assessment in consultation with the CAB and it will be conducted within six months from the date of initial assessment/ reassessment/ surveillance assessment.

Corrective actions for nonconformities raised at the follow up assessment shall be submitted within one month. If the corrective actions cannot be submitted within four months from the date of follow up assessment, application will be terminated.

4.12.4. Unannounced assessments

Unannounced assessment may be conducted;

- a. with the recommendation of Accreditation Committee
- b. with the recommendation of Director/CEO or Technical Manager
- c. with the recommendation of Committee appointed to handle appeals and complaints
- d. with the recommendation of the Scheme Owner
- e. depending on the performance/behavior of the CAB
- f. regard to violation of Rules and Procedures for accreditation
- g. as planned surveillance activities
- h. in any other circumstances which poses risks to maintenance of accreditation status and the accreditation activities.

CAB will be notified prior to entering the location/site of the CAB. CAB shall provide relevant documents, records, reports/certificates as requested by the Assessment team. If required, copies of the requested documents, records, reports/certificates shall be provided to SLAB to maintain as evidence.

Once the unannounced assessment is completed, invoice of assessment fees, transport cost and lodging expenses will be sent to the CAB.

If required, SLAB will inform the outcome of the assessment to the CAB.

4.13 Changes in Accreditation Criteria

If there is a change in the applicable accreditation scheme or in the accreditation criteria, ILAC/APAC mandatory requirements, etc SLAB will inform the CAB in writing indicating the transition policy with specific period for complying with new criteria. Upon receiving such information, the CAB must confirm to SLAB's transition policy on implementation of changes. SLAB will assess the implementation of changes during surveillance and reassessments or conduct special assessment.

4.14 Changes affecting the CAB operations

The CAB shall inform SLAB within one month of significant changes which affect the activities/ operations of CAB relevant to accreditation such as in legal, commercial, ownership or organizational status, any suspension or cancellation of registration status by regulatory bodies, organizational structure, top management and key personnel, main policies, resources, locations/sites, POCT activities, scope of accreditation and other such matters that may affect the ability of the CAB to fulfill requirements of applicable accreditation criteria. The CAB shall communicate this with relevant documentary evidence.

In the event of the CAB informing SLAB about such changes affecting the CAB's activities and operations, SLAB may organize a special visit. The final decision is communicated to the CAB along

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with an amended certificate and schedule of accreditation. The costs associated with the issue of amended certificate and schedule of accreditation will be charged to the CAB.

4.15 Reduction of the Scope

During assessments by the SLAB, the accredited CAB 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 CAB is of the opinion that parts of the scope no longer conform to the accreditation criteria, it is expected that the CAB will withdraw the relevant part of the scope itself. During an assessment, if it becomes clear that it is necessary to reduce accreditation for parts of the scope, the SLAB will also review the validity of the remaining accredited scope.

In order to demonstrate that the CAB is complying with the criteria for the complete scope of accreditation, the CAB 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 for the affected time period.

The concerned part of the scope shall be reduced if records do not demonstrate this. If this means that the entire scope is reduced, then the entire accreditation is withdrawn.

4.16 Extension of Scope

At any given moment, the CAB can request an extension of the scope. A written application shall be submitted to SLAB or through SLAB WFMS.

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 CAB.

The Scope can be extended to any of the following aspects or any combination thereof.

Accreditation of Testing and Calibration laboratories:

- a) Same field- new test in same product matrix or same product group/new calibration in same field of calibration
- b) Same field- new test in different product matrix or different product group/new calibration in different equipment of calibration
- c) Different field/new locations/new sites

Accreditation of Medical testing laboratories:

- a) Same field- new test/test method
- b) Same field- new sites/locations
- c) Different field

Accreditation of Inspection Bodies:

- a) Same field- new inspection/ new inspection method/ new product groups
- b) Same field- new sites/locations
- c) Different field

Accreditation of Certification Bodies:

- a) Same scheme- new scopes representing new NACE/IAF Codes/Categories/different products, process, service
- b) Same scheme- new sites/locations
- c) Different scheme

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Accreditation of Validation/Verification Bodies:

- a) Different sector under existing Validation/Verification scheme/ program
- b) Different Validation/Verification scheme/ program

Accreditation of Good Laboratory Practice:

- a) Different field of study

Accreditation of Proficiency testing Provider

- a) Same field- new scheme/ new product matrix/new method or procedure
- b) Different field

Accreditation of Reference Material Producer

- a) Same field - new product matrix
- b) Different field

Accreditation of Biobanks

- a) Same field - new matrix
- b) Different field

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 CAB.

4.17 Transfer of Accreditation

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

- The CAB remains operating within the legal and regulatory framework of the country in which it operates;
- The policy and management system remains unchanged;
- The management and key personnel remain unchanged;
- 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;
- The general composition of the CAB's personnel remains the same;
- The basic infrastructure and other facilities are not compromised.

The CAB shall provide the SLAB with the necessary documents showing that the above conditions are met. The costs for reviewing the documents/ conducting onsite review may be charged to the CAB.

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

4.18 Management of Extraordinary Situations

It is important for SLAB and its accredited CABs to be able to demonstrate reasonable due diligence, mutual understanding, and trust to establish an appropriate course of action in response to extraordinary events.

In the event of an extraordinary situation, SLAB Policy on the management of extraordinary events or circumstances affecting SLAB accredited bodies and their customers (AC-RG(P)-20) will be followed.

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5. Obligations

5.1 CAB

5.1.1 General

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

5.1.2 Co-operation

The CABs 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 CAB's management system within the criteria;
- It shall be possible to gain insight into the relationship between the documented system and the applicable standard via an up-to-date review;
- It shall be possible to observe the activities at the CAB.
- The CAB shall provide the assessment team with the necessary safety instructions, safety equipment & personnel protective equipment;
- CAB shall offer SLAB assessment teams including observers, witnessing assessors and Peer Evaluators/ Regional Evaluators, access to its related bodies, all relevant personal, equipment, location/sites, SCC, POCT, information including documents and records pertaining to accreditation; whenever required.
- In case the assessment of SLAB requires the participation of clients or other related bodies of the CAB, the CAB shall take measures to assure this participation; in particular CAB shall have legally enforceable arrangements with their clients/ relevant external service providers, SCCs and POCTs that commit to provide, on request, access to SLAB assessment teams including observers, witnessing assessors and Peer Evaluators/ Regional Evaluators to assess the CAB's performance when carrying out conformity assessment activities at client's/ relevant external service provider's sites/ SCCs and POCTs.
- Assessors of SLAB will not be put in a position where their independence and objectivity could be compromised.

5.1.3 Accreditation Symbol

The CABs shall comply with the Policy on governing the use of accreditation symbol (AC-RG (P)-01). Misuse of the accreditation symbol by accredited CAB may lead to suspension or withdrawal of the accreditation. If non-accredited CAB use the accreditation symbol, the SLAB can resort to legal action.

5.1.4 Reporting Changes

The CAB 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 CAB's organizational status;
- Changes in the sphere of activities or economic activities of the CAB
- Change in management and its structure;

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- Policy changes;
- Changes in personnel that fill key positions, such as managers, authorized signatories and decision-makers and personnel with specific and unique expertise for the CAB;
- 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 CAB expects the changes to have a temporary negative effect on the accredited activities, then the CAB can request a voluntary suspension. In case of that the SLAB possesses the right to carry out extra assessments to ensure that the CAB 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 CAB 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 XX-RG(P)-01. A CAB shall always take actions to settle such payments within the defined period. If a CAB does not make payment on time, the SLAB sends a reminders and late payment charges may apply. If payment is still not made, then the suspension procedure will begin. If there are payments outstanding during the any 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 CAB complies with the applicable accreditation criteria. In doing so, Assessors will make use of the relevant criteria documents, scope-related documents (including standards, descriptions of methodology, diagrams etc.) and generally accepted interpretations. Assessors may not accept any gifts, presents etc. from CAB that may compromise their neutral role in assessments. Assessors will follow the health and safety instructions of the CAB being assessed.

5.2.2 Confidentiality

SLAB will treat all the information obtained or created during the accreditation process of CABs/sources other than the CABs 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 CAB will not be disclosed, outside the SLAB without written consent of that particular CAB, unless otherwise required by law. Any information about a CAB obtained from other sources is not shared with that CAB, unless agreed by the source.

6. Suspension, Withdrawal and Reduction

Suspension, Withdrawal and Reduction of scope of accreditation arises, in the event of a CAB persistently failing to meet the requirements of accreditation criteria, and/or violating the Rules and

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Procedures in this document and Terms and Conditions maintaining accreditation (AC-RG(P)-08) 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 will be withdrawn/reduced with immediate effect. The decision will be informed to the CAB and published in the web site. SLAB may issue a revised certificate/schedule of accreditation, if applicable.

6.1 Suspension

During the suspension period, the CAB shall 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 process. If the CAB take actions to reinstate accreditation within 4 months, another two months maximum will be given to complete or reinstate. Any failure to rectify the issue related to suspension within the given period accreditation will be withdrawn or reduced with immediate effect by the Director/ CEO, SLAB and decision will be informed to the accreditation committee. If the decision is to suspend or withdraw or reduce accreditation, Director/CEO, SLAB will inform the CAB of the decision in writing and may issue a revised Certificate or Schedule of accreditation.

A CAB may request a voluntary suspension from the SLAB if it is temporarily unable to comply with the accreditation criteria. It is not possible to submit a request for a voluntary suspension during the period that a SLAB assessment is being carried out.

In such circumstances, the CAB shall have to refrain from using the accreditation symbol or otherwise referring to the accredited status for the suspended full/ part of scope of accreditation. CABs shall also inform its affected clients of the suspension of its accreditation and the associated consequences without undue delay and make appropriate arrangements to stop the use of the accreditation symbol by the certificate holders.

6.2 Withdrawal and Reduction

The accredited CAB or the SLAB can withdraw/ reduce the scope of accreditation. From the moment of withdrawal/reduction, the CAB shall 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 reports/certificates issued under SLAB accreditation shall also have to be withdrawn/re-issued.

If CAB 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 CAB brings the accreditation into grave disrepute, the SLAB will impose the withdrawal/reduction. SLAB informs the CAB of the withdrawal/reduction in writing.

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After a voluntary withdrawal, the SLAB will not accept an application for accreditation from the same CAB within a period of three months, in case of a forced withdrawal due to fraudulent behavior, it will be six months.

7. Disputes, Complaints and Appeals

7.1 Disputes

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

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

The CAB can report the existence of such dispute to the Director/CEO, SLAB in writing. The Director/CEO, SLAB will consult with the parties involved and with the Committee appointed by the Director/CEO, SLAB whenever required and takes a decision.

The decision will be communicated to the parties in writing. All disputes, if any, arising out of SLAB decisions that remain unresolved through internal mechanism provided by SLAB are subject to the alternate dispute resolution (Arbitration). If fails can initiate litigation within the jurisdiction of the Courts in Sri Lanka and none other.

7.2 Complaints

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

7.3 Appeals

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

8. Publicity

SLAB will publish the Certificate and Schedule of accreditation & accreditation status of the accredited CABs 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 and Applications and supportive documents and subsequent changes in the SLAB official website. CABs 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 CAB 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 grant of accreditation or suspension/ withdrawal of the accreditation, and neither shall SLAB be held responsible for any damage whatsoever, caused to any party by the acts of CAB.

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

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