

SRI LANKA ACCREDITATION BOARD for CONFORMITY ASSESSMENT

TERMS & CONDITIONS FOR MAINTAINING ACCREDITATION OF

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



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

Terms & Conditions for Maintaining Accreditation

This document shall be applicable for applicant and accredited Conformity Assessment Body (CAB).

We the undersigned, on behalf the

(Name of CAB)

understand the Rules & Procedures and Requirements of the Accreditation Scheme for Testing laboratories/ Calibration laboratories/ Medical laboratories/ Inspection bodies/ Proficiency testing providers/ Reference material producers/ Good laboratory practice (*strikethrough as appropriate*) agree to fulfill and abide by the following terms and conditions adopted and implemented by the Sri Lanka Accreditation Board for Conformity Assessment (SLAB) for maintaining accreditation as given below.

(This document shall be signed by the Chief Executive or his Authorized Representative and submitted to SLAB in duplicate along with the application form. SLAB will return a copy after grant of accreditation by endorsing it. In case of changes to this document, SLAB will make sure that the current document is signed by the CAB, always.)

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Agreement

1. The CAB shall carry out its conformity assessment activities in such a way commit to fulfill continually the requirements of accreditation as of;

(indicate the version and select the standard as appropriate)

- ISO/IEC 17025: for Testing laboratories	
- ISO/IEC 17025: for Calibration laboratories	
- ISO 15189: for Medical laboratories	
- ISO/IEC 17020: for Inspection bodies	
- ISO/IEC 17043: for Proficiency testing provid	lers
- ISO/IEC 17034: for Reference Material produ	cers
- OECD guidelines for Good laboratory practice	

and specified requirements in relevant Rules & Procedures for Accreditation.

- 2. The accreditation shall be initially granted after a successful initial assessment, valid for a period of four years unless otherwise decided by SLAB and thereafter shall be subject to a surveillance assessment which shall be initiated at the 18th month from the date of grant of accreditation.
- 3. Before expiry of the validity period, the accreditation granted shall be renewed by a re-assessment, for which the CAB shall apply by submitting application documents six months before the date of expiry of accreditation. Thereafter SLAB shall conduct re-assessment in every four years and a surveillance assessment.
- 4. In addition to planned surveillance, depending on the performance/behavior of the CAB or in response to complaints with regard to violation of Rules and Procedures for accreditation, unannounced or other surveillance activities may be arranged. The CAB shall assist in the investigation and resolution of any accreditation related complaints about the CAB referred to it by the SLAB.
- 5. The 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, Sample Collection Centers (SCCs) in case of Medical laboratories, information including documents and records pertaining to accreditation that provide insight into the level of competency, independence and impartiality of the CAB to fulfill the relevant requirements for accreditation.
- 6. The CAB shall have a legally enforceable arrangement with their clients, relevant external providers and SCCs 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 sites or relevant external providers and SCCs.
- 7. When requested, the CAB shall afford accommodation and co-operation to enable the SLAB to verify fulfillment of requirements for accreditation. These facilities shall be available at all premises where the conformity assessment is supposed to take place. The CAB shall arrange witnessing of conformity assessment activities when requested by SLAB. The CAB shall provide Personnel Protective Equipment (PPE) for assessment team, when required.
- 8. On grant of accreditation, the CAB shall claim accreditation in only those locations/sites, fields, facility, disciplines and conformity assessment activities for which it has been accredited and as stated in the Certificate and Schedule of Accreditation.
- 9. In case of Medical laboratories, only those SCCs which are declared to the SLAB shall be claimed as to be covered by the Schedule of Accreditation. Neither the CAB nor the SCCs shall claim that any of the SCCs are accredited.

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- 10. For Calibration laboratories, calibrations shall be reported with allowed deviations, where possible and uncertainty of measurement. An accredited calibration laboratory shall not report a smaller uncertainty of measurement than the Calibration Measurement Capability (CMC) recommended on its endorsed documents.
- 11. The CAB shall abide by the Policy governing the use of SLAB Accreditation Symbols (AC-RG(P)-01). The mark shall be used for the purpose of identifying correctly and unambiguously its conformity assessment services are accredited by SLAB. If the policy of the CAB is to use the accreditation symbol for reports/certificates pertaining to accredited scopes, all reports/ certificates issued on accredited scopes shall carry the accreditation symbol.

In addition, the reports issued by the Calibration laboratories 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 and Measurement verification(s) are covered under the Schedule of Accreditation.

- 12. The CAB shall not use reports/certificates or any part thereof in a misleading manner and not use SLAB accreditation or its accreditation symbol to imply a product, process, system or person is approved by the SLAB or/and not state SLAB accreditation in a manner as to be considered misleading or unauthorized and bring disrepute to SLAB.
- 13. The CAB shall ensure that no part of its report/certificates is used by its clients, or be authorized by its clients for use, for promotional or publicity purposes in any way that SLAB may consider to be misleading.
- 14. The CAB shall pay fees for processing of application, fees for assessments, fees for extending scope of accreditation, expenses towards travel, board & lodging for assessments, and annual accreditation fees as determined by SLAB. In the event of suspension of accreditation, the CAB shall pay the due payments and the annual accreditation fee. In case of withdrawal of accreditation, the CAB shall settle the due payments, if any and annual accreditation fee until the withdrawal of accreditation. Any late payments as specified by the SLAB will subject to an additional late payment charge as decided by the SLAB.
- 15. 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, scope of accreditation and other such matters that may affect the ability of the CAB to fulfill requirements of applicable accreditation criteria as in indicated in Clause 01.
- 16. The CAB shall normally perform its conformity assessment activities which is covered under scope of accreditation by itself. Where a CAB obtains services of external providers, those shall be obtained only from accredited CABs. If there are no such CABs, services may be obtained from non-accredited CABs having demonstrated competency through evaluation done by the CAB as per relevant accreditation criteria. The CAB shall record and retain details of its evaluation of the competence and compliance of its external providers. The CAB shall advise its clients at the time of contract review about the intended outsource activities.
- 17. As relevant, the CAB shall regularly and satisfactorily participate in External Quality Assurance Programmes covering its scope of accreditation as per SLAB policy for participation in External Quality Assurance activities (AC-RG(P)-02).
- 18. The accredited CAB shall respond promptly to the changes initiated by SLAB in its accreditation criteria, policies and procedures and for necessary changes the CAB will be given sufficient notice and time on the opinion of SLAB, as is found to be reasonable, to carry out adjustments in its system.

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- 19. SLAB may at subsequent stage decide to suspend or reduce the scope of accreditation, granted initially, if significant deficiencies are observed during surveillance assessment/ activities or reassessment in the CAB management system or technical competence, which is likely to adversely influence the results of the conformity assessment activities or the CAB is unable to complete corrective actions within agreed/stipulated time of the surveillance assessment/ activities or reassessment.
- 20. SLAB may suspend or withdraw accreditation of an accredited CAB, on one or more of the following grounds informing in writing, with prior written notification.
 - a. After undergoing a surveillance or re-assessment, CAB has not taken any corrective actions after agreed/stipulated time and notice from SLAB
 - b. Non-payment of accreditation related expenses
 - c. Non-cooperation with SLAB.
 - d. Refusal to allow examination of documents and records by SLAB & its assessment team
 - e. Denial of access to SLAB, its assessment team or peer evaluators/ regional evaluators to its conformity assessment areas.
 - f. Wrong representation of scope of accreditation.
 - g. Misuse of SLAB accreditation symbol/ ILAC MRA Mark or its use during suspension or after expiry of accreditation
 - h. Activity bringing disrepute to SLAB.
 - i. Result of complaint analysis or any other information which indicates that the CAB no longer complies with requirements of SLAB.
 - j. In the event of compromising impartiality of CAB's operations or violation of Rules and Procedures for accreditation.
 - k. Evidence of fraudulent behavior, or intentionally provides false or conceals information and misleading reporting of facts.
 - 1. Non adherence to significant changes as mentioned in Sec. 15 of this document
- 21. The accredited CAB upon suspension, reduction or withdrawal of its accreditation (however determined), or expiry of validity of accreditation shall forthwith discontinue its use of all advertising matter, public domains and any material that contain any reference to the accreditation status and return the Certificate(s) and Schedule(s) of Accreditation to SLAB.
- 22. The CAB is required to inform the SLAB in writing with justification, if any of the proposed assessment team members happens to be their Consultant or associated with the CAB in any other capacity, and SLAB shall not appoint these Consultants as assessment team members.
- 23. SLAB absolves itself of any legal or financial liability arising out of any activities involving any accidental or consequential damages to personnel/ equipment/ products at any time. CAB shall have arrangements (e.g.: Insurance, reserves or other means) sufficient to cover liabilities arising from the activities and areas in which it operates.
- 24. The CAB has the right to complaint on any dissatisfaction with SLAB accreditation process and all personnel involved in the accreditation activities as per Procedure for handling complaints (GN-PR(P)-08) or appeal on any adverse decision taken by the SLAB on accreditation and associated activities as per Procedure for dealing with appeals (GN-PR(P)-09).

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- 25. 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.
- 26. The SLAB publishes the details of scope of accreditation & accreditation status of the accredited CABs along with their contact addresses and status of accreditation such as suspension of accreditation, withdrawal of accreditation, and expiry of accreditation status in SLAB web site.
- 27. The SLAB protects the confidential nature of the assessment findings unless legally obligated to do so otherwise indicated in the contractual arrangements between SLAB and the CAB. If the CAB provides third parties with access to the assessment report, it shall provide access only to the complete assessment report. Assessment team and all other persons who, work for the benefit of the accreditation by the SLAB, shall have access to the CAB's files/ information only after they sign and handover confidentiality statement to the particular CAB.

By signing this document, it is agreed that the CAB as an applicant and after accreditation agrees to comply at all times with all Terms and Conditions for Maintaining SLAB accreditation.

Signature of Chief Executive or his/her Authorized Representative, CAB:

Name & Designation:

Date & Place:

Seal of the CAB, if any

Signature of Director/CEO, SLAB:

Name:

Date & Place:

Seal of SLAB:

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