SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

RULES & PROCEDURES for MEDICAL LABORATORIES

ACCREDITATION SCHEME FOR MEDICAL LABORATORIES

RULES & PROCEDURES

1. Preparing for Laboratory Accreditation

Laboratory management should first decide to obtain accreditation for its laboratory from SLAB. It is important for a 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 laboratory's existing Laboratory management system.

A request can be made to SLAB in person, by post, by telephone or by e-mail for relevant information on Accreditation. A "General Information brochure" covering SLAB Accreditation process with relevant document will be made available to prospective clients (Ref. SLAB website; www.slab.lk). The laboratory should be acquainted with the SLAB assessment procedure & methodology and submit an application in the prescribed format.

Laboratory needs to establish the status of its existing management system and technical competence with regard to requirements of SLAB for accreditation. Is the system documented and effective, or does it need modification? Does it need to build the quality system of the laboratory from a very basic level?

The quality manual is a policy document, which has to be supplemented by a set of other documents such as procedure manuals, work instructions etc. to align the quality system in accordance with ISO 15189 and specific criteria of SLAB. Relevant requirements for SLAB accreditation should be discussed amongst concerned staff of the laboratory. This will enable them to understand their weaknesses and strengths. The laboratory must ensure that the procedures described in the Quality Manual and other documents are being implemented.

2. Eligibility for Applying for SLAB Accreditation

The applicant laboratory must comply with all requirements (clauses) of ISO 15189 "Medical Laboratories - Requirements for Quality and Competence"

The applicant laboratory should comply with the relevant specific criteria of SLAB for the Medical testing Laboratories.

In case of medical laboratories having sample collection centers at other locations the sample collection procedure should comply with the relevant requirements.

The applicant laboratory should have arrangements for participation in external quality assurance (EQA) programmes and SLAB's policy for participation in Proficiency Testing activities is available on AC-RG(P)-02.

Preferably the applicant laboratory must have conducted at least one internal audit and a management review before the submission of application.

3. Accreditation Procedure

3.1 Application for Accreditation

The laboratory shall apply to SLAB in the prescribed application form (ML-FM(P)-01) along with one copy of the quality manual of the laboratory that describes the Laboratory management system in accordance with ISO 15189:2012. The application shall be accompanied with the prescribed application fee. Laboratory has to take special care in filling the scope of accreditation for which the laboratory wishes to apply. In case, the laboratory finds any clause (in part or full) not applicable to the laboratory, it shall furnish the reasons and justify the situation.

3.2 Acknowledgement and Registration of Application

SLAB on receipt of application, the quality manual and the fees shall issue an acknowledgement to the laboratory. After scrutiny of application for its completeness in all respects, a unique customer reference number shall be allocated to the laboratory, which shall be used for correspondence with the laboratory. SLAB may request for additional information / clarification(s), if necessary. An Authorized Officer under the supervision of Technical Manager of the accreditation scheme, will be appointed on behalf of SLAB to deal with the application and handle the case file being maintained thereafter.

If, on the basis of documents and information provided by the laboratory, SLAB is of the opinion that an assessment cannot result in accreditation, the applicant laboratory shall be informed in writing giving reasons. All information of the laboratory shall be kept strictly confidential.

3.3 Appointment of Lead Assessor

The SLAB shall appoint a lead assessor from the pool of assessors to carry out assessments in respect of the applicant laboratory. The lead assessor shall have the overall responsibility of conducting the assessment and shall be responsible for evaluating the adequacy of the quality manual, documentation and records, pre-assessment of the laboratory and for conducting the on-site assessment of the concerned laboratory. Towards the task of on-site assessment, he/she shall be assisted by a team of assessors appropriate with the scope of accreditation.

The lead assessor for the applicant laboratory is appointed by SLAB ensuring that he / she is:

a. from the approved list of assessors.
b. acceptable to the applicant laboratory.
c. available for full assessment, including submission of report.

3.4 Review of Documents and Records

As stated in paragraph 3.2, the preliminary scrutiny of the application and quality manual is done by SLAB. If there are gross inadequacies, the quality manual will be returned to the laboratory for re-writing. It appears to be in order generally, a copy of the quality manual and associated documents along with a copy of the application of the laboratory shall be forwarded to the lead assessor to study in depth and verify the compliance in accordance with ISO 15189:2012 and relevant specific criteria.

The lead assessor, within in a month shall inform SLAB regarding the adequacy of the quality manual with a report, indicating inadequacies (if any) in the quality manual which should be communicated to the client Laboratory. The laboratory shall amend the manual and also implement the management system accordingly.

3.5 Pre-assessment

In case there are no inadequacies in the quality manual or after satisfactory corrective action by the laboratory, a pre-assessment visit of the laboratory shall be organized by SLAB. Laboratories must ensure their preparedness by carrying out its internal audit and a management review before the pre-assessment.

The pre-assessment of the laboratory is conducted to:

a. evaluate deficiencies (if any) in the implementation of the management system.
b. assess the degree of preparedness of the laboratory for the assessment
c. study the scope of accreditation so that the time frame, number of assessors required in various disciplines and visits to sample collection facilities, if applicable, for the assessment can be determined.

The lead assessor shall submit a pre-assessment report to SLAB with a copy to the laboratory at the completion of pre-assessment. The laboratory shall comply with the inadequacies of the documented management system and its implementation and submit a corrective action report to SLAB.

3.6 Initial Assessment

After the laboratory confirms the elimination of inadequacies, SLAB shall propose composition of an assessment team. The team shall include the lead assessor, the assessor(s)/ technical expert(s) in order to cover various disciplines within the scope of accreditation sought. In case of certain specific or types of test, it may be necessary to obtain the services of an expert, who may not be a trained assessor under SLAB scheme.

As per the SLAB procedure for qualifying assessors, the potential assessor who has successfully completed the prescribed training course shall be given an opportunity, to be an observer / assessor in trainee the assessment team. On completion of five (05) man days, unless changed otherwise as a trainee assessor he / she can be considered for independent assessment provided his / her performance has been found satisfactory by the lead assessor.

Thereafter SLAB shall fix up dates for on-site assessment of the laboratory in consultation with the laboratory, the lead assessor and assessor(s). SLAB may also nominate one of its officers to participate in the assessment as an observer during the on-site assessment to convey his / her observations to the lead

assessor and provide clarification on ISO 15189:2012 and SLAB specific criteria to the assessment team, whenever necessary.

The laboratory is informed about the assessment team. A copy of this communication is sent to the members of assessment team, along with the requisite documents. The assessors are required to reach the place of assessment, well in advance of the scheduled time of the assessment.

The assessment team reviews the laboratory's documented management system and verifies its compliance with the requirements of ISO 15189:2012 and specific criteria of SLAB. The documented management system, SOPs, work instructions, test methods etc. are assessed for its implementation and effectiveness. The laboratory's technical competence to perform specific tests is also adjudged. The non-compliances, if identified are reported in the assessment report.

The assessment report shall contain the evaluation of technical manpower, all relevant material examined, test witnessed including those of replicate testing/ measurement, compliance to ISO 15189:2012 and relevant specific criteria and the non-conformances, if any. It shall also provide a recommendation towards grant of accreditation or otherwise. The assessment report is prepared by the lead assessor, in the formats prescribed by SLAB (ML-FM-17). The details of the non-conformances observed during the assessment are handed over to the laboratory by the Lead Assessor.

3.7 Scrutiny of Assessment Report

The assessment report shall be examined by SLAB, who shall communicate the outcome of the assessment to the laboratory and shall ensure that the non-conformances raised by the assessment team and not closed during the assessment, are available with the laboratory and are well understood by the laboratory.

Laboratory shall take necessary corrective actions on the remaining non-conformance(s)/ other concerns and shall submit a report to SLAB within a maximum period of 02 months unless otherwise extended with the agreement of SLAB, which is not exceeding 06 months. SLAB shall monitor the progress of closing of non-conformances. If the corrective actions are not submitted to the SLAB for enabling it to complete the accreditation process by 06 months or delayed until one year, a follow up assessment shall be conducted. If the laboratory takes more than one year to submit corrective actions, the laboratory shall re-apply for accreditation by filling a new application form.

When there are significant non-conformance(s) identified during the on-site assessment, the progress is monitored closely and SLAB may arrange for a verification visit for the closure of the non-conformance(s).

3.8 Accreditation Committee

After satisfactory corrective actions by the laboratory, the Authorized Officer in SLAB prepares a summary of all relevant information gathered during the processing of the application, the assessment report, additional information received from the laboratory and the consequent verifications. The summary report with recommendations of the Technical Manager of SLAB/ Deputy Director / Additional Director is placed before the Accreditation Committee for the approval for grant of accreditation.

The Accreditation Committee's observations on the assessment report and its recommendations shall be the deciding factors for grant of accreditation or otherwise. All decisions taken by the Accreditation Committee shall be recorded. In case that the Accreditation Committee finds deficiencies in the assessment report to arrive at the decision, the Authorized Officer obtains clarification from the Lead assessor/ assessor/ laboratory concerned.

The approval of the Accreditation Committee shall be submitted to the Council through Director / CEO, SLAB for covering approval. Laboratories are free to appeal against the findings of assessment or decision on accreditation within 30 days.

3.9 Issue of Accreditation Certificate

When the recommendation results in the grant of accreditation, the Authorized Officer shall prepare the accreditation certificate.

The accreditation certificate shall define field of test, items or materials tested, specific tests performed, specification / standard method or technique used, range of testing / limit of detection and accuracy, wherever applicable.

Sample collection facilities at other locations and mobile testing services shall be clearly identified in the scope of accreditation accompanying the certificate.

A unique certificate number shall be allotted to each Medical Laboratory. Certificate duly signed by the Director / CEO, SLAB is issued to the laboratory.

The applicant laboratory must make all payments due to SLAB, before the certificate(s) is / are issued to the laboratory.

All decisions taken by SLAB regarding grant of accreditation shall be open to appeal by the laboratory consistent with the appeal procedures of SLAB (GN-PR(P)-09).

4. Maintaining Accreditation

4.1 Validity

The SLAB accreditation certificate shall be valid for a period of 3 years. On grant of accreditation, the laboratory is able to use SLAB mark on all its test reports covered within the scope of the accreditation granted. SLAB accreditation mark may also be used on letterheads, brochures and any other material issued to its clients.

SLAB shall conduct an annual surveillance and a re-assessment of the accredited laboratory before the expiry of the accreditation certificate. The re- assessment audit is conducted on the same basis as an initial assessment.

During the validity of accreditation, the laboratory must continuously comply with the requirements of ISO 15189:2012, relevant specific criteria of SLAB and "Terms and conditions for maintaining accreditation" (ML-RG(P)-03).

4.2 Extension / Reduction of Scope of Accreditation

The laboratory during the validity of accreditation may enhance or reduce the scope of accreditation. On submission of a written request, SLAB shall assess the laboratory for extension of scope during surveillance / reassessment visit or by organising a supplementary / special visit. This request shall be made in writing to the SLAB before two months from surveillance or reassessment.

4.3 Supplementary / Special Visit

SLAB may also conduct supplementary / special visit at any time during the validity of accreditation, if:

i. the accreditation ISO 15189:2012 or specific criteria has changed.
ii. changes have been reported to SLAB affecting the laboratory's operations.
iii. the accreditation certificate / logo has been misused.
iv. a complaint has been received and the facts have to be verified.

4.4 Changes in the Accreditation / Specific Criteria

If there is a change in the general accreditation criteria ISO 15189:2012 or specific criteria of SLAB, SLAB shall inform the laboratory of this in writing indicating the transition period, which shall be not more than 6 months. On receipt of the aforesaid information, the laboratory must confirm to SLAB, its willingness to modify its management system in accordance with the changes. On confirmation from the laboratory, SLAB may conduct a supplementary / special visit to assess the implementation of the same.

4.5 Changes Affecting the Laboratory Operations

In the event of the laboratory informing SLAB about any changes in the information affecting the laboratories activities and operations, such as changes in legal or commercial ownership or organizational status, organizational structure, main policies, resources and premises, equipment, accommodation, environment, scope of accreditation or other similar change, SLAB may organize a supplementary/ special visit for significant changes or review others at the next assessment. In case of changes in key managerial/ technical personnel such as Quality Manager/ Technical Manager, signatory for terms and conditions, authorized signatories for issue of test reports, unless a special visit is organized, SLAB shall call over responsible personnel to the SLAB, interview them and then communicate with them in writing regarding their acceptability for respective work. The Recommended Authorized signatories shall be reviewed at the next assessment and updated accordingly.

In the event of transfer of accreditation, when the legal status or the ownership of the accredited laboratory changes, the laboratory shall communicate this with relevant documentary evidence & amended Quality manual. The final decision is communicated to the laboratory along with an amended certificate.

4.6 Voluntary Withdrawal

The laboratory at any time during the validity of accreditation may discontinue their accreditation, voluntarily by making a written request to SLAB. If the laboratory decides to regain the accreditation

status, after it has sought voluntary withdrawal it is treated as a new application for accreditation and has to pay all fees for application & accreditation and assessment expenses, as applicable at the time.

5. Surveillance

5.1 SLAB shall conduct annual surveillance of all accredited laboratories.

5.2 Surveillance is aimed at examining whether the accredited laboratory is maintaining all the requirements of ISO 15189:2012 and SLAB specific criteria.

5.3 SLAB shall inform the accredited laboratory at least three months before the due date of accreditation for conducting the surveillance visit and the laboratory shall confirm its readiness within 15 days.

5.4 The laboratory during the validity of accreditation may request to enhance the scope of accreditation for which they should apply two months before the conduct of assessment/ surveillance. Scope extension request at the time of assessment/ surveillance would be considered only if the assessment team has the necessary expertise and extra time available. If a laboratory requests scope extension independent of surveillance visit, SLAB will arrange separate assessment visit

5.5 The formalities involved with the surveillance assessment are similar to the first assessment visit. The non-conformances, if any, shall have to 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 for continuation of accreditation or otherwise. SLAB shall inform the laboratory, in writing, about such decision.

6. Re-assessment and Renewal of Accreditation

The Laboratory may apply for renewal of accreditation by submitting an application in the prescribed Application form (ML-FM(P)-01). A copy of the current Quality Manual of the laboratory which describes the quality system in accordance with ISO 15189:2012 should be made available.

The application shall be accompanied with the prescribed re-assessment charges. The laboratory may request for extension of scope of accreditation, which should explicitly be mentioned in the application form.

The request for renewal should be submitted at least 3 months before the expiry of the validity of accreditation. If the laboratory does not apply for renewal of accreditation, one month before the expiry of accreditation, it shall be presumed that the laboratory is no longer interested in accreditation and the accreditation status of the laboratory shall expire on the validity date mentioned in the certificate. In such a case the laboratory shall have to apply afresh and the continuity of the certificate shall be disturbed.

The procedure for processing of renewal application is similar to that of initial application except that no pre-assessment is conducted.

The procedure for the on-site reassessment visit is similar to that of initial assessment visit.

If the results of reassessment visit are positive and all non-conformances are closed before the expiry of the certificate, then the validity of the certificate is extended by another three years without any discontinuity.

The maximum duration that should be allowed for the laboratory to take corrective action shall be two months, unless otherwise agreed upon, whichever should be before the expiry of accreditation.

A new certificate of accreditation is issued on renewal and the certificate number remains the same.

7. Adverse Decisions

7.1 SLAB may take an adverse decision on accreditation of a laboratory, if the laboratory at any time during the validity of accreditation does not fulfill the requirements of ISO 15189:2012 and relevant specific criteria of SLAB, and /or violates the "Terms and condition of maintaining accreditation" (ML-RG(P)-03) or does not fulfill the obligations otherwise. The conditions of taking adverse decisions, like a reduction in scope of accreditation, abeyance, suspension and forced withdrawal are described in respective Procedures of SLAB.

In case of adverse decisions like abeyance, suspension and forced withdrawal, the laboratory shall discontinue the use SLAB accreditation mark, in any form. The suspension and forced withdrawal status shall also be publicized.

7.2 In case the laboratory's accreditation has been withdrawn by SLAB, it is disqualified to participate in the accreditation programme for a period of at least one year. The laboratory may apply afresh by giving valid justification for earlier withdrawal and paying all fees & expenses, as applicable at that time.

8. Appeal

All decisions taken by SLAB regarding grant / continuation / renewal of accreditation shall be open to appeal by the laboratory, to the Chairman SLAB. All such appeals will be considered under the SLAB appeal procedure (GN-PR(P)-09) and the decision taken on such issue by the Council of SLAB will be the final.

9. Complaints

The complaints with regard to accreditation process, decisions taken thereof or any activity related to the operations of SLAB or executed by any staff member or assessor on behalf of SLAB are entertained by the SLAB. Complaints if any, shall be sent to the Director/CEO of SLAB in writing with proper authenticity of the informant. All such complaints are handled as per the procedure (GN-PR(P)-08) adopted by the SLAB.

10. Publicity

The information with regard to accreditation process and concurrent changes in the process as well as in the operations of SLAB, accredited laboratories and their contact addresses and scope of accreditation are published in the SLAB web site. In addition, withdrawal of accreditation, suspension of accreditation and termination of accreditation status are also posted in the SLAB website and /or newspapers.

11. Confidentiality

The members of the Governing Council, Accreditation Committee, assessors and SLAB officials are required to maintain strict confidentiality of the information gathered regarding the laboratories from their various documents like quality manual, procedure manual, work instructions internal reports etc. and any other related information that might have been given by SLAB, during the process of evaluation for grant of accreditation. SLAB shall impose the same obligation of maintaining secrecy on those, whom they entrust the tasks of a confidential nature, as described above.

12. Liability

SLAB shall not be responsible for any damages, which the 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 / forced withdrawal of the accreditation.

13. Amendments to the Policies and Procedures

SLAB may at any time amend the policies and procedures related to grant of accreditation, maintaining accreditation, surveillance, renewal of accreditation and the adverse decisions there on. SLAB shall inform the laboratories regarding such amendments indicating the transition period which shall be at least 6 months.

14. General rules adopted by the SLAB

14.1 The SLAB is a service organization supported with funds provided by the Government as per the provisions of SLAB Act No 32 of 2005. It functions as the National Accreditation Authority for Sri Lanka in granting accreditation to conformity assessment bodies. The methods of extending, reducing, suspending and withdrawing accreditation are described in the "Terms and Conditions for maintaining Laboratory Accreditation" (ML-RG(P)-03).

14.2 As a Statutory Body accountable to the Government of Sri Lanka, the SLAB is obliged to assist and facilitate good governance in Sri Lanka. It works in close co-operation with Government Institutions, Private agencies, and professional associations while the SLAB maintains a high level of impartiality and integrity in its activities and operations.

14.3 The SLAB is closely associated with peer accreditation bodies, and International Accreditation Forum to up grade its services continually and work towards earning recognition in accreditation activities in the International arena through mutual agreements. Please refer to SLAB documents and web site for the international recognition status achieved.

14.4 The SLAB ensures that all activities in the accreditation process are performed in a transparent manner demonstrating impartiality and confidentiality. Any staff officer of SLAB or assessor employed on SLAB's behalf shall not undertake consultancy work of a laboratory which is to be assessed for accreditation by SLAB.

14.5 The SLAB retains documentation of the CAB including the quality manual in its custody for reference purposes, time to time during the accreditation process, but unless there is any matter to be

resolved with the documentation, any assessment or operations of the CAB, all such documents will be returned to the CAB after perusal.

15. Measurement Traceability

15.1 It is the policy of SLAB that medical laboratories shall comply with the measurement traceability policy explained in AC-GL (P)-09. In the process of grating accreditation, the medical laboratories shall comply with the measurement traceability policy of SLAB and ensure that traceability of measurement to SI units is maintained.