SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

RULES & PROCEDURES for ACCREDITATION of MEDICAL LABORATORIES

ACCREDITATION SCHEME FOR MEDICAL LABORATORIES

Rules & Procedures for accreditation of medical laboratories

1. Introduction

The Sri Lanka Accreditation Board for Conformity Assessment (SLAB) is the National Accreditation Authority of Sri Lanka established under Act No. 32 of 2005. The SLAB offers accreditation services to bodies that provide conformity assessment services such as testing, medical and calibration laboratories, certification bodies for systems, products and persons, inspection bodies, GHG validation/ verification bodies, recognition of good laboratory practice and Proficiency Testing Providers.

The work procedures of the SLAB for Medical laboratories, are based on ISO/IEC 17011:2017 – Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies. Preference will be given to Subject Specific Documents published by International Laboratory Accreditation Corporation (ILAC) and Asia Pacific Accreditation Corporation (APAC), wherever applicable. The Governing Council of SLAB or relevant advisory committees, if required, will develop specific guidelines and advice the SLAB management in the areas for which there are no ILAC, APAC or other acceptable interpretation documents available.

1.1 Scope

This document outlines the rules and procedures to be adopted when medical laboratories seek accreditation for their testing activities from SLAB. Accreditation will be granted against the applicable International/Regional or National Standards or widely accepted standards or guidelines that are auditable or verifiable.

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
- ILAC P8:03/2019 -ILAC Mutual Recognition Arrangement: Supplementary requirements for the use of accreditation symbols and for claims of accreditation status by accredited conformity assessment bodies
- ILAC P9-06/2014 -ILAC Policy for Participation in Proficiency Testing activities
- ILAC-P10: 01/2013 - ILAC Policy on traceability of measurement results
- ILAC-G26:11/2018: Guidance for the Implementation of a Medical Accreditation Scheme
- 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)-07 - Policy on cross frontier accreditation
- ML-RG(P)-03 - Terms & conditions for maintaining accreditation of medical laboratories

- ML-GL(P)-05- Guidelines for operating and assessing Sample Collection Centers of medical laboratories
- ML-GL(P)-02- SLAB Specific criteria for medical laboratories

2. Accreditation requirements

2.1 Accreditation Criteria

The international standard ISO 15189: Medical Laboratories –Requirements for Quality and Competence is used by the SLAB along with specific criteria developed, as applicable and required for accreditation of medical laboratories and accreditation body's rules and procedures explained in this document, Terms and conditions for maintaining accreditation and other General policies such as metrological traceability, participation in External Quality Assurance activities, etc. identified as reference documents in this document.

All applicant and accredited laboratories are advised to read this document and other related documents prior to applying 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 a step to obtain views of interested parties and public comments prior to publication. Therefore, applicant and accredited medical laboratories are requested to forward any written views/suggestions directly to the SLAB.

2.2 Eligibility

The applicant medical laboratory must comply with all the requirements of ISO 15189 standard or guideline specific to the scope/field of medical testing, if available. In addition, the applicant medical laboratory must comply with the relevant regulations (if any), specific criteria (if any) of SLAB for the scopes covered under the scope of accreditation.

In case of medical laboratories having sample collection centers at other locations, the laboratory should comply with the relevant requirements. Ref. ML-GL(P)05

The applicant laboratory shall have arrangements for participation in External Quality Assurance (EQA) activities as per AC-RG(P)-02.

The applicant laboratory shall have conducted at least one internal audit and a management review before submission of application.

3. Preparation for accreditation

3.1 Preparing for Accreditation of medical laboratories

The management of medical laboratory should first decide to obtain accreditation for their testing activity from SLAB. It is important for a medical 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 medical laboratory's existing quality system. SLAB will coordinate matters related to accreditation process only through the authorized representative of the medical laboratory.

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

A quality manual/ management system documents shall be prepared in accordance with the requirements specified in the ISO 15189, regulations, if any and this should be supplemented by a set of other documents such as procedures, standards, regulations, work instructions etc. to be in accordance with the particular quality system requirements.

The medical laboratory 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 the accreditation, often referred to as the 'scope', is defined as testing activities for which to be covered under SLAB accreditation. Applicant medical laboratory shall include scope of accreditation in the relevant section of application or make reference to further document which contain same format in the application. During the pre-assessment process, the scope of the accreditation is discussed with the medical laboratory in detail, and the nature and extent of the assessment will be based on that.

4. Accreditation process

The accreditation process consists of registration of application followed by a resource review, document and record review, pre-assessment, initial assessment, grant of accreditation, surveillance assessment and re-assessment.

4.1. Application and Registration for Accreditation

The medical laboratory shall submit application documents (ML-FM (P) -01 –Application form, ML-FM (P)-02 –Self assessment questionnaire and quality manual / management system documentation) of the medical laboratory and other relevant documents to SLAB.

The application shall be accompanied with the prescribed application fee stated in the fee structure (ML-RG (P)-01). Application fee is nonrefundable. The medical laboratory has to take special care in fill in the scope of accreditation for which the medical laboratory wishes to apply. In case, the medical laboratory 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 medical laboratory may withdraw its application or discontinue accreditation process before granting accreditation. In such case, applicant medical laboratory shall settle all due payments, if any.

For foreign applicant/accredited medical laboratories shall follow Policy on cross frontier accreditation (AC-RG (P)-07) and accreditation fees as stated in ML-RG(P)-01.

List of documents required at the application stage is given the questionnaire (ML-FM(P) -02).

4.2 Special cases

- **Additional accreditation**

If a medical laboratory that is already accredited wishes a second accreditation or a 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 system and certain specific areas as decided by SLAB.

- **Already accredited medical laboratory activities**

In case an applicant medical laboratory is already accredited for the applied scope by another accreditation body with ILAC, APAC membership or ILAC/APAC MRA, the 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. In such circumstances, the SLAB may grant accreditation after an assessment; however, any such decision will be taken at the sole discretion of SLAB.

4.3 Acknowledgement and registration of application

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

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

If, on the basis of documents and information provided by the medical laboratory, SLAB is of the opinion that an assessment cannot result in accreditation, the applicant medical laboratory shall 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 shall not be conditional upon the size of the applicant medical laboratory or membership of any association or group, nor shall accreditation be conditional upon the number of medical laboratories already accredited.

4.4 Appointment of authorized officer & resource review

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

A resource review (Technical review) will be carried out by the authorized officer in consultation with Technical manager and collect additional information from the medical laboratory, 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 shall be communicated to the CAB.

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

4.5 Document and record review

4.5.1 Appointment of Assessor/ Team leader

The SLAB shall appoint a competent internal Assessor/Team Leader from the pool of assessors to carry out document and record review on the documented management system adopted by the applicant medical laboratory.

4.5.2 Adequacy of quality management system documents

The Team Leader/Assessor with the assistance of SLAB will commence the assessment process with an adequacy assessment of document and record review based on the application submitted within one month. The aim of the adequacy assessment is to determine whether the medical laboratory is sufficiently prepared for the accreditation process and to ascertain the compliance of the documents with the criteria specified in ISO 15189. The adequacy assessment is also meant to obtain a clear idea of the intended scope of the accreditation.

The Team leader/Assessor, shall inform SLAB regarding the adequacy of the management system documentation with a report (ML-FM-05), indicating deficiencies (if any) in the documentation which in turn should be communicated to the applicant medical laboratory. Based on this feedback the medical laboratory tale corrective actions and submit objective documentary evidence not later than three months.

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

The document and record review process shall be satisfactorily completed within six months.

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

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

4.6. Appointment of Assessment Team

Towards the task of on-site assessments, the Team leader shall be assisted by a team of Assessors/ Technical Experts who will be appointed by SLAB as appropriate with the scope of accreditation and in accordance with the criteria adopted for the selection of assessment team. The SLAB shall propose the composition of assessment team. The medical laboratory may lodge an objection in writing against specific team members with justifiable reason to do so. Such an objection shall be reviewed by the relevant Technical Manager to determine the validity of the objections to ensure the impartiality and the credibility of the accreditation process. If the objection is found to be valid, a new team or a new member is nominated in place of the member(s) in question. If no replacement is available, it is possible that the visit will be postponed, or that a part of the scope will not be assessed until a suitable replacement is found.

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

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

4.7 Onsite assessment plan

The SLAB contacts the medical laboratory to agree on the date(s) and schedule for the assessment. Based on this SLAB prepares the assessment plan (ML-PL-01) and the composition of the team and send it across to the medical laboratory well in advance. Assessment plan is prepared for each and every assessment.

4.8 Onsite Assessment

The Onsite Assessment will be carried out two stages namely pre-assessment and initial assessment (initial assessment is the final assessment for grant of accreditation). The assessment team shall commence an on-site 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 are confirmed. During the assessment, the assessment team will assess the documentation and implementation of the management system as well as the competence of the medical laboratory in accordance with the ISO 15189 and specific criteria (if any) of SLAB. 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 medical laboratory, the assessment team shall be able to assess at least one complete cycle of the internal audit and management review.

4.9 Pre assessment

Upon completion of document and record 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 medical laboratory 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, if applicable

Pre assessment is conducted by a Team Leader/Assessment team which consists Team Leader/Assessor/ Technical Assessor/Technical expert. At the end of pre assessment, assessment team complete pre assessment report and deficiencies identified during the pre-assessment and obtain the acknowledgement for recommendation and findings from the medical laboratories. Assessment team verifies the man day requirement for the initial assessment and propose and report, required changes and planning of initial assessment

Medical laboratory shall take necessary corrective actions on the deficiencies and submit the documentary evidences to SLAB within two months. On request with justifiable reason an extension of two months will be given. However, if the medical laboratory submits corrective actions within four to eight months and wishes to continue the application, a fresh Pre-assessment shall be conducted. Any failure to submit documentary evidences within eight months, the application shall be discontinued and informed the decision to applicant medical laboratory.

Upon the successful completion of pre-assessment, medical laboratory shall be notified and request to prepare for initial assessment.

4.10 Initial assessment

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

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

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

Medical laboratory shall submit corrective actions within two months with satisfactory documentary evidence. However, depending on the severity of actions to be taken, medical laboratory may take additional time up to one year 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 one year another Initial assessment shall be arranged. If follow up assessment is recommended, it shall be conducted within six months from the date of Initial assessment and corrective actions for remaining non-conformities shall be submitted within two months. If the corrective actions cannot be submitted within one year from the date of Initial

assessment, another Initial assessment shall be arranged. Based on the corrective actions submitted the assessment team may recommend to conduct on-site verification of effective implementation of corrective actions.

4.11 Assessment techniques

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

- **Document review**: assessing quality system documentation etc. for compliance with the criteria; a document review can also involve records at the medical laboratory's location, such as personnel files, quality control charts, audit reports, management review reports, audit files etc.;

- **Office assessment**: an assessment at the premises of the medical laboratory in order to assess the implementation of the system;

- **Interviews**: evaluating the expertise of the medical laboratory's personnel via targeted interviews.

- **Witnessing**: Observing the testing activities carried out at the premises and visits to SCCs to ensure samples are properly collected, stored and transported to the main medical laboratory for testing.

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

4.12 Participation in External Quality Assurance activities (EQA)

The medical laboratory shall participate in EQA activities as per SLAB policy for participation in EQA activities (AC-RG(P)-02).

4.13 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 report prepared by the assessment team, additional information received from the medical laboratory and the consequent verification activities. 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 for medical laboratories studies the assessment reports, nonconformities and corrective actions, scope of accreditation, final report (ML-FM-46) and the recommendation given by the team and then makes its own decision on grant of accreditation.

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

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

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

4.14 Issue of accreditation certificate and schedule

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

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

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

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

Terms and condition for maintaining accreditation (ML-RG(P)-03) is considered the agreement between SLAB and medical laboratory. This contains the rights and obligations of parties; the party providing the accreditation and the party being accredited and signed by both parties. The applicant medical laboratory must fulfil all the financial obligations payable to SLAB, before receiving the certificate(s).

4.15 Post accreditation assessments

The SLAB accreditation certificate shall be valid for a period of 3 years unless specified by the SLAB. During the validity of accreditation, the medical laboratory must continuously comply with the requirements of the ISO 15189 and "Terms and conditions for maintaining accreditation" (ML-RG (P)-03). In this regard SLAB shall periodically review the validity of accreditation. To this end, the SLAB carries out surveillance assessments annually and a re-assessment within three years. During the accreditation period, the scope of the accreditation may be changed.

4.16 Surveillance

The frequency of surveillance is one year from the date of granting accreditation. SLAB shall conduct annual surveillance of all accredited medical laboratory or 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 medical laboratory's management system
- Review of performance in proficiency testing and/or other inter-laboratory comparisons
- Conduct advanced surveillance assessment

Surveillance is aimed at examining whether the accredited medical laboratory is maintaining all the requirements of the ISO 15189 and SLAB specific criteria (if any).

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

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

If there are remaining nonconformities with a justification by the Technical manager considering the associated risks, a letter of continuation of accreditation may be sent to the medical laboratory 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.

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

4.17 Reassessment and renewal of accreditation

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

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

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

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

4.18 Supplementary/ Special assessments

The SLAB may organize supplementary/ special visits under the following circumstances:

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

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

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

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

4.19 Changes in the accreditation / Specific criteria

If there is a change in the ISO 15189 or in the accreditation criteria, SLAB shall inform the medical laboratory in writing indicating the transition policy with specific period for complying with new criteria. Upon receiving such information, the medical laboratory must confirm to SLAB's transition policy on implementation of changes. SLAB may assess the implementation of changes during surveillance and re assessments or conduct special assessment.

4.20 Changes affecting the medical laboratory operations

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

4.21 Reduction of the Scope

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

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

The concerned part of the scope shall be withdrawn if records do not demonstrate this. If this means that the entire scope is withdrawn, then the entire accreditation is withdrawn. However, the medical laboratory concerned can again be granted accreditation for the Standard and the scope involved, under the same registration number after submission of application as scope extension and a full assessment of areas withdrawn.

4.22 Extension of Scope

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

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

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

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4.23 Transfer of Accreditation

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

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

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

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

5. Obligations

5.1 Medical laboratory

5.1.1 General

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

5.1.2 Co-operation

The medical laboratories 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 medical laboratory's management system within the criteria;
- It shall be possible to gain insight into the relationship between the documented system and the Standard via an up-to-date review;
- It shall be possible to observe the activities at the medical laboratory.
- The medical laboratory shall provide the assessment team with the necessary safety instructions, safety equipment & personnel protective equipment;
- If requested, the medical laboratory shall provide access to all relevant locations, equipment, dossiers and documents;
- Assessors of SLAB shall not be put in a position where their independence and objectivity could be compromised.

5.1.3 Accreditation Symbol

Accredited medical laboratories have the right to use the applicable accreditation symbol. As such, on grant of accreditation, the medical laboratory may use SLAB accreditation symbol on letterheads, brochures and any other material issued to its clients including the reports. However, such usage shall be confined within the scope of Accreditation. The medical laboratories shall comply with the Policy on governing the use of accreditation symbol (AC-RG (P)-01).

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

5.1.4 Reporting Changes

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

- Changes in the legal, commercial or medical laboratory's organizational status;
- Changes in the sphere of activities or economic activities of the medical laboratory
- Change in management and in structure;
- Policy changes;

- Changes in personnel that fill key positions, such as managers and decision-makers and personnel with specific and unique expertise for the medical laboratory;
- Changes in location and other resources that can have a significant influence on the accredited activities carried out;
- Significant changes in working procedures.

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

5.1.5 Financial Obligations

The medical laboratory will receive an invoice for all the accreditation activities carried out by the SLAB. The amount invoiced will depend on the number of man-days worked; the applicable fee and other costs be found in ML-RG(P)-01 & ML-GL-06. A medical laboratory shall always take prompt actions to settle such payments. If an medical laboratory does not make payment on time, the SLAB sends a reminder. If payment still made, the suspension procedure will begin. If there are payments outstanding during the initial phase of the accreditation process, the SLAB has the right to halt the accreditation process until payment is done.

5.2 SLAB

5.2.1 Behavior of Assessment Teams

The assessment team will limit its assessment activities to an investigation of whether the medical laboratory complies with the applicable criteria. In doing so, Assessors will make use of the relevant criteria documents, scope-related documents (including standards, descriptions of methodology, diagrams etc.) and generally accepted interpretations. Assessors may not accept any gifts, presents etc. from medical laboratory that may compromise their neutral role in assessments. Assessors shall follow the health & safety instructions of the medical laboratory being assessed.

5.2.2 Confidentiality

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

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

obtained from other sources is not shared with that medical laboratory, unless agreed by the source.

6. Suspensions, withdrawals and reductions

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

SLAB shall 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 to Suspension within the given period, accreditation shall be withdrawn/reduced with immediate effect. The decision will be informed to the medical laboratory and published in SLAB web site. SLAB may issue a revised certificate/schedule of accreditation.

6.1 Suspensions

During the suspension period, the medical laboratory 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 procedure. In exceptional cases, the Director/CEO, SLAB may extend the period for further period of six months.

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

6.2 Withdrawal and reduction

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

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

When SLAB determines that a suspension of full/part of the scope of accreditation, has not been lifted within the applicable period or if evidences are found to substantiate that the medical laboratory brings the accreditation into grave disrepute, the SLAB will impose the withdrawal/reduction. SLAB informs the medical laboratory of the withdrawal/reduction in

writing. After a withdrawal, the SLAB will not accept an application for accreditation from the same medical laboratory within a period of six months.

7. Disputes, complaints and appeals

7.1 Disputes

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

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

The medical laboratory can report the existence of such dispute to the Director/CEO, SLAB in writing. The Director/CEO, SLAB will consult with the parties involved and with the Technical Advisory Committee and takes a decision. The decision will be communicated to the parties in writing.

7.2 Complaints

The SLAB distinguishes two types of complaints:

- Complaints about the SLAB and its Assessors.
- Complaints about registered or accredited medical laboratories.

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

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

7.3 Appeals

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

8. Publicity

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

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

9. Liability

SLAB shall not be responsible for any damages, which the medical 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 grant of accreditation or abeyance / suspension / withdrawal of the accreditation, and neither shall SLAB be held responsible for any damage whatsoever, caused to any party by the acts of medical laboratory.

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