SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

RULES & PROCEDURES *for* ACCREDITATION OF GOOD LABORATORY PRACTICE (GLP)

ACCREDITATION SCHEME FOR GOOD LABORATORY PRACTICE (GLP)

RULES & PROCEDURES

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, Accreditation of Good Laboratory Practice (GLP) and Proficiency Testing Providers (PTP).

The work procedures of the SLAB for accreditation of Good Laboratory Practice are based on ISO/IEC 17011:2017 – Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies and OECD Guidelines for Good Laboratory Practice. Preference will be given to Subject Specific Documents published by Organization for Economic Development & Cooperation (OECD) on GLP and accreditation related publications of International Laboratory Accreditation Corporation (ILAC) and Asia Pacific Accreditation Corporation (APAC).

It is recommended to consider requirements and interpretations of OECD Guidelines for GLP and SLAB specific Criteria for GLP by R & D laboratories/facilities seeking to manage their operations and obtaining accreditation from the SLAB in order to ensure fulfilment of the requirements for accreditation. The Governing Council of SLAB or relevant advisory committees, if required, will develop specific guidelines and advice the SLAB management in the areas for which there are no ILAC, APAC or other acceptable interpretation documents available.

1.1 Scope

This document outlines the rules and procedures to be adopted when R&D Laboratories seek accreditation for their research activities from SLAB. Accreditation will be granted against the applicable OECD Guidelines for Good Laboratory Practice that are auditable or verifiable. Conformity assessment schemes/criteria for GLP are reviewed periodically by the SLAB and determine its suitability.

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
- 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 of traceability of measurement results
- AC-RG(P)-05 - Policy on in-house calibration
    - AC-RG(P)-07 - Policy on cross frontier accreditation
    - GLP-RG(P)-03 - Terms & conditions for maintaining accreditation of GLP

- GLP-RG(P)-01 – Fee Structure –Good Laboratory Practice
- GLP-GL(P)-02- Specific Criteria for GLP

Applicable OECD Documents

- Document Number 1 – OECD Principles on Good Laboratory Practice
- Document Number 2 – Compliance monitoring procedures for GLP
- Document Number 3 – Guidance for the Conduct of Laboratory Inspections and Study Audits
- Document Number 9 – Guidance for the preparation of GLP Inspection Reports
- Document Number 4 – Quality Assurance and GLP
- Document Number 5 – Laboratory Suppliers with GLP Principles
- Document Number 6 – The application of the GLP Principles to Field Studies
- Document Number 7 – The application of the GLP Principles to Short-term Studies
- Document Number 8 – The Role and Responsibilities of the Study Director in GLP studies
- Document Number 10 – The application of the Principles of GLP to Computerized Systems
- Document Number 11 – The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP
- Document Number 13 – The application of the OECD Principles of GLP to the Organization and Management of Multi-site studies
- Document Number 14 – The application of the Principles of GLP to in vitro Studies
- Document Number 15 – Establishment and control of Archives that operate in Compliance with the Principles of GLP

1.3 Terms and Definitions

Terms and definitions given in the above mentioned OECD documents and other documents of accreditation scheme for GLP are based on following references.

ISO/IEC 17000:2004 – Conformity assessment general vocabulary

JCGM 200:2012: International vocabulary of metrology (VIM) – Basic and general concepts and associated terms (VIM 3rd edition) and available at the following browsing platforms;

https://www.bipm.org/en/publications/guides/vim.html

ISO and IEC terminological databases for use in standardization available at the following browsing platforms https://www.iso.org/obp and IEC Electropedia: available at http://www.electropedia.org

2. Accreditation Requirements

2.1 Accreditation Criteria

The OECD series on Principles of Good Laboratory Practice and Compliance Monitoring along with the Specific Criteria for GLP, Terms & Conditions for maintaining GLP accreditation and accreditation body's rules and procedures explained in this document are used as accreditation criteria for Good Laboratory Practice.

Other common policies such as Metrological traceability, Participation in External Quality Assurance Activities, In-house calibration etc, identified as reference documents in this document are also considered as accreditation criteria.

All applicant and accredited GLP facilities 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 announced 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 GLP facilities are requested to forward any written views/suggestions directly to the SLAB.

2.2 Eligibility

The applicant R & D laboratory/GLP facility hereinafter referred as laboratory must comply with all requirements of SLAB specific criteria for GLP Accreditation and current version of relevant OECD Principles on Good Laboratory Practice.

The applicant laboratory shall be a legal entity.

Where relevant, the applicant laboratory must have arrangements for participation in external quality assurance programmes and its internal quality control activities and shall comply with SLAB policy for participation in External Quality Assurance Activities (AC-RG (P) -02).

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

3. Preparation for Accreditation

3.1 Preparing for Accreditation of laboratories for Good Laboratory Practice (GLP)

The management of laboratory management should decide initially to obtain accreditation under Good Laboratory Practice for its laboratory/ies or facilities carrying out research and development activities 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, R & D activities, OECD guidelines and SLAB specific criteria for GLP and general understanding of research methodologies.

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 Rules and procedures defined in this document, SLAB assessment procedure & methodology, Terms and Conditions for maintaining accreditation, fees relevant to the accreditation process and submit an application in the prescribed format. The OECD guidelines are available as freely downloadable documents (Ref. http://www.oecd.org).

Laboratory needs to establish the status of its existing management system and technical competence with regard to requirements of SLAB for accreditation. Laboratory may need to answer the following questions before making an application or filling supported documents. Is the system documented and effective or does it needs modification? Does it needs to build the quality system of the laboratory from a very basic level?

It must be remembered that quality manual is a policy document, which has to be supplemented by a set of other documents such as procedure manuals, Study plans, and work instructions etc. to align the quality system in accordance with specific criteria of SLAB. SLAB specific criteria makes reference to relevant sections of OECD guidelines.

It is recommended to review relevant requirements for SLAB accreditation amongst concerned staff of the laboratory and also sponsors/projects, if relevant. 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.

For preparing the quality manual or verifying its contents, the laboratory may get its technical personnel trained in SLAB's training programmes on management system for laboratory personnel. Such training courses will be published time to time or may be known by contacting the SLAB. All SLAB training programmes are conducted to impart knowledge on accreditation criteria and accreditation process. SLAB does not offer training for individual laboratories to develop its documents or related activities.

3.2 Scope of Accreditation

The scope of the accreditation, often referred to as the 'scope', is defined as those activities for which the SLAB has determined that the laboratory complies with the requirements. Applicant 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.

The scope also specifies the field of studies, Product Group /Matrixes related to studies , specific studies performed, method of studies/testing and locations/sites where studies are carried out. During the preliminary audit process, the scope of the accreditation is discussed with the laboratory in detail, and the nature and extent of the assessment will be based on agreed scope at the pre-assessment.

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 and re assessment.

4.1 Application and Registration for Accreditation

The laboratory shall apply to SLAB in the prescribed application form (GLP –FM(P)-01) for GLP Accreditation and along with one copy of the Quality manual and other relevant supporting documents as prescribed under clause 7 of application (GLP-FM-(P)-01).

The application shall be accompanied with the prescribed application fee as described in GLP- RG (P)-01 for GLP Accreditation. Laboratory has to take special care in filling the scope of accreditation for which the laboratory wishes to include study fields in the scope of accreditation. 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.

Name of the laboratory given in application will be continued during the accreditation process. Laboratory shall request in writing any changes to be made to the laboratory name given in application or accreditation certificate or scope of accreditation.

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

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

For foreign applicant/Accredited laboratories shall follow policy on cross frontier accreditation (AC-RG(P)-07) and accreditation fees as stated in GLP-RG(P)-01 shall be applied for applications from foreign countries.

4.2 Special Cases

- **Additional Accreditation**

If a laboratory that is already accredited and wishes other field of accreditation against any recognized and accepted standard 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 Laboratory activities**

In case an applicant laboratory is already accredited for the applied scope by another accreditation body with ILAC, APAC membership or ILAC/APAC MRA for testing/calibration laboratories and operate accreditation scheme for GLP and/or recognized under Mutual Data Acceptance process of OECD, 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.

- **Non routine cases**

In case a laboratory requests accreditation for a study filed where an established standard/ Guide is not available, SLAB, in consultation with the Technical advisory committee will decide on the suitability of criteria to be followed by the laboratory. The applicant laboratory has to submit necessary supportive documents as evidence to substantiate their claim when they seek accreditation under special cases. As result, SLAB may also require additional time for the development required competencies in the new fields and required criteria. Applicant laboratories will be notified if the SLAB requires such additional time for processing of new applications.

- **Laboratories with multi-locations/Temporary Locations /Study sites**

Applicant laboratories operating through main office and temporary locations shall declare in the initial application or subsequent application on its study activities in main office, temporary locations/sites and how common management system covers both main office and temporary locations.

4.3 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 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. In the case of appointing internal staff for document and record review, assessments and other accreditation process related activities, confidentiality & impartiality related matters are covered under the conditions of appointment of SLAB staff and signed confidentiality & impartiality statements by the relevant SLAB staff.

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

The SLAB's policies, processes /and procedures are non-discriminatory and applied in a nondiscriminatory 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 laboratory or membership of any association or group, nor shall accreditation be conditional upon the number of laboratories already accredited.

4.4 Appointment of Authorized Officer for Resource Review

Once the registration of application is completed with required documents, Technical Manager of accreditation scheme for GLP 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 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 laboratory. If the initial assessment cannot be conducted in a timely manner, this shall be communicated to the laboratory. Authorized Officer will contact the laboratory with respect to application and further information required, if any. Authorized officer is the contact person of SLAB for the applicant 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 laboratory.

4.5.2 Adequacy of Management System Documentation

As stated in section 4.1, 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. If 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 assessor /team leader to study in depth and verify the compliance in accordance with OECD guidelines and specific criteria for GLP Accreditation.

The assessor/ team leader, within 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 applicant laboratory. The laboratory shall amend the manual and also implement the

management system accordingly. Based on this feedback the laboratory shall take corrective actions and submit objective documentary evidence for corrective actions taken for deficiencies before not later than three months.

If the laboratory satisfies the relevant requirements at the adequacy assessment stage or after the laboratory has taken necessary corrective action based on the adequacy assessment, the assessment process will move into the two next steps 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 laboratory, SLAB is of the opinion that an initial assessment cannot result in accreditation, the applicant laboratory shall be informed in writing and the documents concerned will be returned to the 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 laboratory.

4.6 Appointment of Assessment Team

Towards the task of on-site assessment, 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 laboratory may lodge an objection in writing against specific team members with justifiable valid reason to do so. Such an objection shall be reviewed by the technical manager to determine the validity of the objection to ensure the impartiality and credibility of accreditation process.

If the objection is found to be valid a new team or a new member is nominated in place of the member(s) in question. If no replacement is available, it is possible that the visit will be postponed, or that a part of the scope will not be assessed until a suitable replacement is found. SLAB may also nominate one of its officers to participate in the 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.
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 laboratory to agree on the date(s) and schedule for the assessment. Based on this SLAB prepares the assessment Plan (GLP-PL-01) and the composition of the team and send it across to the laboratory well in advance. Authorized officer of SLAB will inform laboratory regarding the witnessing of activities related to studies performed at Assessment. For this purpose, laboratory shall include possibilities of witnessing of study activities by the accreditation body assessors into contractual agreements with sponsors and other study related personnel as well as relevant regulators and bodies providing external services, if any.

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 the grant of Accreditation). During both these stages, test/sampling or activities of studies witnessing during the assessment of the applicant laboratory's or client may be required. Although there are no strict demarcations for these two assessments, the objectives of these assessments may be expressed in the following manner. On site assessments consist of an opening and a closing meeting with assessment team members and key personnel of the laboratory. Therefore, laboratory shall arrange required facilities to conduct meetings and the assessment.

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 laboratory in accordance with accreditation criteria mentioned under section 2.1 of this document. In doing so, the assessment team will select a representative sample in the areas within the scope of the accreditation. The laboratory shall demonstrate that it is competent in all the activities at all sites including temporary, mobile or other for which accreditation has been requested. With regard to the management system of the 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

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 have eventually conducted an 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 study fields and visits to sites associated with studies, if applicable, for the assessment can be determined.

The team leader shall submit a pre-assessment report to the laboratory at the end of assessment.

The laboratory shall take necessary corrective action for the deficiencies and submit documentary evidences within two months. On request with justifiable reason, an extension of two months will be given. However, if the 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 corrective actions within eight months, application shall be discontinued and inform the decision to the applicant laboratory.

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

4.10 Initial Assessment

After the laboratory confirms the elimination of inadequacies of pre-assessment, SLAB shall propose composition of an assessment team. The team shall include the Team Leader (already appointed for pre-assessment or a new team leader), the assessor(s)/ technical expert(s) in order to cover various study fields within the scope of accreditation sought. In case of certain specific or types of study fields, 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 5 day training course shall be given an opportunity, to be an observer/ assessor trainee in 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 Team Leader.

Thereafter SLAB shall fix up dates for on-site assessment of the laboratory in consultation with the laboratory, the team leader and assessor(s). SLAB may also nominate one of its officers or trainee assessors to participate in the assessment as an observer during the on-site assessment to convey his / her observations as a training component to the team leader and provide clarification on OECD guidelines, information on study fields 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, information on studies under scope and verifies its compliance with the requirements of OECD Guidelines, specific criteria of SLAB. The documented management system, SOPs, Study Plans, Work instructions etc. are assessed for its implementation and effectiveness. The laboratory's technical competence to carry out studies applied for accreditation and compliance against OECD GLP Guidelines is assessed and summary of assessment and non-compliances, if identified are reported in the assessment report and nonconformity forms.

The assessment report shall contain the evaluation of technical manpower, all relevant material examined, studies reviewed and conclusions on such reviews and witness against work procedures, study plans SOPs and OECD GLP Guidelines 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 team leader, in the formats prescribed by SLAB (GLP-FM-17).

At the end of each assessment, a closing meeting is conducted to disclose findings of the assessment. Initial assessment reports contain, assessment report, scope of accreditation, recommended authorized signatories, nonconformities and other relevant assessment records.

Initial assessment report shall also provide a recommendation towards grant of accreditation or otherwise. Assessment team is not allowed to take decisions on granting accreditation. Laboratory shall submit corrective actions within two months with satisfactory documentary evidence. However, depending on the severity of actions to be taken, 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.

In the event of appointing external Team Leader, SLAB will appoint an internal officer to coordinate with assessment team and SLAB as well as resolving management and logistic issues relevant to the assessment.

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 for compliance with the criteria; a document review can also involve records at the laboratory's location, such as personnel files, study reports, research proposals ,research data, quality control charts, audit reports, management review reports, audit files etc.;

Office assessment: an assessment at the premises of the laboratory or at sites where studies are carried out in order to assess the implementation of the system;

Interviews: evaluating the expertise of the laboratory's personnel and personnel associated with studies via targeted interviews.

Witnessing: observation of tests or activities related to studies and examination carried out by the a laboratory.

4.12 Participation in external quality assurance activities

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

4.13 Accreditation Decision

After satisfactory closure of all nonconformities, the SLAB prepares a summary of all relevant information gathered during the processing of the application, the assessment report prepared by the assessment team, additional information received from the laboratory and the consequent verification

activities. The summary report is placed before the accreditation committee which is appointed by the Governing Council as per the provision of SLAB Act. The accreditation committee for testing, calibration laboratories, Proficiency Testing Providers and Good Laboratory Practice studies the assessment reports, nonconformities and corrective actions, scope of accreditation, final report and the recommendation given by the team and then makes its own decision on grant of accreditation.

The decision on the approval of grant of accreditation shall be submitted to the Council through Director/CEO, SLAB for information. The SLAB informs the laboratory in writing of the decision taken. All decisions taken by SLAB regarding grant of accreditation shall be open to appeal by the laboratory as per appeal procedure (GN-PR(P)-09) within 30 days.

4.14 Issue of Accreditation Certificate & Schedule of Accreditation

When the recommendation results in the grant of accreditation, the Authorized Officer shall prepare the accreditation documents (Certificate, Scope, accreditation symbol, invoice for annual accreditation fee for the coming year from the date of accreditation and letter of granting accreditation). Before the grant of accreditation, the Authorized Officer shall obtain signatures on Terms and Conditions for Maintaining Accreditation (GLP- RG(P)-03) from the Laboratory.

The accreditation certificate on GLP Accreditation shall define field of study, relevant products or areas of studies, specific tests performed and specification / standard method or technique used, wherever applicable.

For studies carried out sites away from permanent facility of laboratory shall also be clearly identified in the scope of accreditation accompanying the certificate. A unique certificate number shall be allocated to a laboratory based on study fields. If a laboratory wishes to have one or separate certificates for different studies that should be communicated to the SLAB at the stage of application. Certificate, scope and letter of granting accreditation 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.

The SLAB accreditation certificate shall be valid for a period of 3 years. On grant of accreditation, the laboratory is able use SLAB mark on all its study reports for the studies which 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 and sponsors as per the Terms and Conditions for use of SLAB Accreditation Symbol (AC-RG(P)-01).
Misuse of the accreditation symbol by accredited laboratory may lead to suspension or withdrawal of the accreditation. If non-accredited laboratory uses the accreditation symbol, the SLAB can resort to legal action.

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 laboratory must continuously comply with the accreditation requirements specified under section 2.1 of this document and “Terms and condition for maintaining accreditation of Good Laboratory Practice (GLP-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 laboratories or following surveillance activities may be decided by the Technical manager based on the risks associated with the activities;

- Special on-site assessment
- Review of changes to laboratory's management system and studies covered under accredited scope
- Review of performance in proficiency testing and/or other inter-laboratory comparisons, if applicable
- Conduct advanced surveillance assessment

Surveillance is aimed at examining whether the accredited laboratory is maintaining all the accreditation requirements of the SLAB. As planned in the assessment schedule, Authorized officer of SLAB shall in writing inform the accredited 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 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 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 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 laboratory of the re-assessment at the beginning of the year. Accredited laboratory shall apply four months before the expiry of accreditation for renewal of accreditation as per the terms and conditions for maintaining accreditation of Good Laboratory Practice (GLP-RG (P) -03).

Application for renewal of accreditation is similar as initial application described above 4.1. Re – application shall be accompanied with the application fee as described in the fee structure. The 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 as described in section 4.13 of this document.

4.18 Supplementary/ Special assessments

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

• Repeatedly find 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 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/ authorized signatories and changes to study fields. However, in these cases, the SLAB will give laboratories sufficient time for preparation. All costs associated with special assessments will be charged to the laboratory.

4.19 Changes in the accreditation / Specific criteria

If there is a change in the general accreditation criteria, OECD GLP Criteria, or specific criteria of SLAB, SLAB shall inform the laboratory in writing indicating the transition policy with specific period for complying with new criteria. Upon receiving such information, the 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 laboratory operations

In the event of the laboratory informing SLAB about any changes affecting the laboratory's activities and operations, SLAB may organize a supplementary/ special visit. Laboratory shall communicate this with relevant documentary evidence. The final decision is communicated to the 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 laboratory.

In case of changes in key managerial/ technical personnel such as Study Director, Principle Investigator, Quality Manager/ Technical Manager, signatory for terms and conditions, 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 above changes shall be reviewed at the next assessment and updated accordingly.

4.21 Reduction of the scope

During assessments by the SLAB, the accredited 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 laboratory is of the opinion that parts of the scope no longer conforms to the accreditation criteria or particular study is completed, it is expected that the laboratory will terminate the relevant part of the scope itself. If during an assessment it becomes clear that it is necessary to reduced accreditation for parts of the scope, the SLAB will also review the validity of the remaining accredited scope.

In order to demonstrate that a laboratory has complied with and is complying with the criteria for the complete scope of accreditation, the 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 reduced if records do not demonstrate this. If this means that the entire scope is withdrawn, then the entire accreditation is withdrawn. However, the 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 reduced.

4.22 Extension of scope

At any given moment, the laboratory can request an extension of the scope to new study fields. 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 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/ study fields 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 laboratory.

4.23 Transfer of accreditation

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

• The 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/Research team remain unchanged

• The former owner/sponsor 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 laboratory's personnel remains the same

• The basic infrastructure and other facilities are not compromised

The 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 laboratory. If all requirements are met, the new 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 Laboratory

5.1.1 General

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

5.1.2 Co-operation

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

• It shall be possible to check the compliance of the 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 laboratory and related sites

• The laboratory shall provide the assessment team with the necessary safety instructions, safety equipment & personnel protective equipment

• If requested, the laboratory shall provide access to all relevant locations, equipment, dossiers and documents related to studies

• In case the assessment of SLAB requires the participation of clients/ /external service provider or other related bodies of the laboratory, the laboratory shall take measures to assure this participation; in particular laboratory shall have enforceable arrangements with its clients/external service provider holding an accredited certificate, to ensure SLAB access to witness the laboratories' compliance at the laboratory's client's/external service provider's site.

• Assessors of SLAB shall not be put in a position where their independence and objectivity could be compromised.

5.1.3 Reporting Changes

The 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 laboratory's organizational status

• Changes in the sphere of activities or economic activities of the laboratory

• Change in management and in structure

• Policy changes

• Changes in personnel that fill key positions, such as Study Directors, Principle Investigators, managers and decision-makers and personnel with specific and unique expertise for the 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 laboratory expects the changes to have a temporary negative effect on the accredited activities, then the laboratory can request a voluntary suspension. In case of that the SLAB possesses the right to carry out extra assessments to ensure that the 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.

5.1.4 Financial Obligations

The 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 GLP-RG(P)-01. A laboratory shall take prompt actions to settle such payments. If a laboratory does not make payment on time, the SLAB sends a reminder. If payment still not made then, the suspension procedure will begin. If there are payments outstanding during the initial phase of the accreditation process, the SLAB has the right to halt the accreditation process until payment is done.

5.2 SLAB

5.2.1 Behavior of Assessment Teams

The assessment team will limit its assessment activities to an investigation of whether the 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 laboratories that may compromise their neutral role in assessments. Assessors shall follow the health and safety instructions of the laboratory being assessed.

5.2.2 Confidentiality

SLAB shall treat all the information obtained or created during the accreditation process of laboratories /sources other than the laboratories as strictly confidential, unless otherwise required to be disclosed under a requirement of sponsors or 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 laboratory and studies shall not be disclosed, outside the SLAB without written consent of that particular laboratory, unless otherwise required by law or particular sponsor agreed under contractual arrangements. Any information about a laboratory obtained from other sources is not shared with that 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 laboratory persistently failing to meet the requirements of accreditation criteria, and/or violating the Rules and procedures and Terms and Conditions agreed upon at the stage of granting accreditation. On CAB's request, the scope may also be suspended, withdrawn or reduced. SLAB 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 Suspension within the given period, accreditation shall be withdrawn/reduced with immediate effect. The decision will be informed to the laboratory and published in the web site. SLAB may issue a revised certificate/schedule of accreditation.

6.1 Suspensions

During the suspension period, the laboratory may not make use of the accreditation symbol or in any other way actively refer to the accredited status of its research activities.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 laboratory may request a voluntary suspension from the SLAB if it is temporarily unable to comply with the accreditation criteria. In such circumstances, the laboratory is not permitted to make use of the logo or refer to the accredited status. It is not possible to submit a request for a voluntary suspension during the period that a SLAB assessment is being carried out.

6.2 Withdrawals and reduction

The accredited laboratory and the SLAB can withdraw/reduce the scope of accreditation. From the moment of withdrawal/reduction, the 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 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 laboratory brings the Accreditation into grave disrepute, the SLAB will impose the withdrawal/reduction. SLAB informs the laboratory of the withdrawal/reduction in writing. After a withdrawal, the SLAB will not accept an application for accreditation from the same 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 laboratory or applicant laboratory and the SLAB with regard to:

• The interpretation of a requirement of a standard/GLP principles;

• The working procedure of the SLAB.

The 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 laboratories.

In both these cases Director/CEO, SLAB or the panel appointed by him/her will investigate the complaints. The complaints will be handled in accordance with the Procedure for Complaint handling (GN-PR(P)-08), which is available on SLAB website.

7.3 Appeals

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

8. Publicity

SLAB shall publish the details of scope of accreditation & accreditation status of the accredited laboratories along with their contact addresses and suspension/withdrawal of accreditation status in SLAB web site. SLAB posts all Rules and Procedures, Terms and Conditions, Fee Structures, Specific Criteria's and Applications and supporting documents and subsequent changes in the SLABs official website. 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 laboratory may suffer as a result of any action or negligence by those who are carrying out the tasks on behalf of SLAB and any failure to the grant of accreditation or abeyance/suspension/withdrawal of the accreditation, and neither shall SLAB be held responsible for any damage whatsoever, caused to any party by the acts of laboratory. Laboratory shall have adequate provisions (Insurance coverage or reserve) to cover liabilities arisen from its operation.

Informative Annexure

Contents of GLP Manual

The contents of a GLP Manual will include but may not be limited to the following. Reference should be given to the procedures or other references, where ever necessary.

- Introduction to Test Facility/Organization
- References
- Definitions of Terms
- Scope of Study and GLP
- GLP Statement
- Organization and management
- Staff responsibilities and Authorities
- Review of Study
- Sampling
- Quality Assurance Programme

- Facilities
- Apparatus, Materials and reagents
- Test systems
- Test and reference standards/items
- Standard Operating Procedures
- Study planning and management
- Performance of Study
- Reporting of Study
- Storage and retention of records, materials and reports