



**SRI LANKA ACCREDITATION BOARD**  
**for CONFORMITY ASSESSMENT**

**RULES & PROCEDURES**  
*for* **ACCREDITATION OF PROFICIENCY**  
**TESTING PROVIDERS (PTP)**

# ACCREDITATION SCHEME FOR PROFICIENCY TESTING PROVIDERS (PTP)

## 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 Proficiency Testing Providers are based on ISO/IEC 17011:2017 – Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies and ISO/IEC 17043 Conformity Assessment- Requirements for Proficiency Testing. Preference will be given to Subject Specific Documents such as ISO 13528: 2015- Statistical Methods for use in proficiency testing by inter-laboratory comparisons and other relevant publications by International Organization for Standardization 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 ISO/IEC 17043, ISO 13528 and SLAB specific Criteria for Accreditation of Proficiency Testing Providers 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 Proficiency Testing Providers (PTP) seek accreditation for their PT Schemes from SLAB. Accreditation will be granted against the ISO/IEC 17043 that are auditable or verifiable. Conformity assessment schemes/criteria for Proficiency Testing Providers are reviewed periodically by the SLAB and determine their suitability.

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## 1.2 References

- Sri Lanka Accreditation Board for Conformity Assessment Act No 32 of 2005
- ISO/IEC 17011:2017 - Conformity Assessment –Requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17000: 2020 - Conformity Assessment- Vocabulary and General Principles
- ISO/IEC 17043:2010: Conformity Assessment- Requirements for Proficiency Testing
- ISO 13528: 2015: Statistical Methods for use in proficiency testing by inter-laboratory comparisons
- ISO/IEC 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories
- ISO/IEC 17020:2012 – Conformity Assessment – Requirements for the Operation of Various types of bodies performing inspection
- ISO 15189:2012/2022 - Medical Laboratories – Particular requirements for Quality and Competence
- AC-PR(P)-18 - Procedure for conducting remote assessments
- 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
- AC-RG(P) -20 - SLAB Policy on management of extraordinary events or circumstances affecting SLAB accredited bodies and their customers
- PT-RG(P)-03 - Terms & conditions for maintaining accreditation of Proficiency Testing Provider
- ILAC P10:07/2020 ILAC Policy on traceability of measurement results
- ILAC P8:03/2019 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies.
- ILAC G 18:12/2021 Guideline for describing scopes of Accreditation
- ILAC R7:05/2015 Rules for the Use of ILAC MRA Mark
- AC-RG (P)-01- Policy for Governing the use of SLAB accreditation symbols
- AC-RG(P)-06 - Policy for determination of uncertainty of measurement
- AC-RG(P)-07 - Policy on cross frontier accreditation
- AC-PR(P)-18 - Procedure for conducting remote assessment
- PT-RG(P)-04 - Specific Criteria for Proficiency Testing Providers

## 2. Accreditation Requirements

### 2.1 Accreditation Criteria

The ISO/IEC 17043 Conformity Assessment- Requirements for Proficiency Testing along with ISO 13528 Statistical Methods for use in proficiency testing by inter-laboratory comparisons and Specific Criteria for Proficiency Testing Providers, Terms & Conditions for maintaining Proficiency Testing Provider accreditation and accreditation body’s rules and procedures explained in this document are used as accreditation criteria for Proficiency Testing Providers.

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

All applicants and accredited Proficiency Testing Providers 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 to in this document are revised, the SLAB will announce on the official website ([www.slab.lk](http://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 involves a step to obtaining views of interested parties and public comments prior to publication. Therefore, applicants and accredited Proficiency Testing Providers are requested to forward any written views/suggestions directly to the SLAB.

## 2.2 Eligibility

The applicant Proficiency Testing Provider hereinafter referred as PTP must comply with all requirements of SLAB-specific criteria for PTP Accreditation indicated under 2.1 of this document.

The applicant PTP shall be a legal entity.

Where relevant, the applicant PTP or its associated subcontractors must have arrangements for participation in proficiency testing programs 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 PTP must have started quality assurance activities and conducted at least one PT Programme, internal audit, and a management review before the submission of the application.

## 3. Preparation for Accreditation

### 3.1 Preparing for Accreditation of Proficiency Testing Providers

The management of Proficiency Testing Providers (PTP) should decide initially to obtain accreditation under Proficiency Testing Provider Accreditation Scheme for its Proficiency Testing Schemes and shall take responsibility for all tasks in the development and operation of proficiency testing schemes. It is important for a PTP to make a definite plan of action for obtaining accreditation and nominate a responsible person to coordinate all activities related to the accreditation process. The person nominated should be familiar with the PTP's existing management system, related criteria such as ISO/IEC 17043 and ISO 13528 and SLAB-specific criteria for PTP and a general understanding of the operation of PT activities and test, measurement and inspection procedures and different technologies adopted by participants. SLAB will coordinate matters related to accreditation process only through the authorized representative of the PTP.

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 documents are freely downloadable documents from the SLAB website ([www.slab.lk](http://www.slab.lk)). The PTP 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.

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PTP needs to establish the status of its existing management system and technical competence with regard to the requirements of SLAB for accreditation. PTP may need to answer the following questions before making an application or filling out supported documents. Is the system documented and effective or does it need modification? Does it need to build the quality system of the PTP from a very basic level? Does it have experience in conducting proficiency/interlaboratory comparisons, subcontractors are competent and their competency evaluated?.

It must be remembered that quality management system document, which has to be included, statistical methods to align the quality system in accordance with ISO /IEC 17043 and specific criteria of SLAB. The PTP needs to establish the status of its existing quality system and technical competence with regard to the requirements of SLAB for accreditation.

It is recommended to review relevant requirements for SLAB accreditation amongst concerned staff of the PTP and fill the self- assessment checklist (PT-FM(P)-11). This will enable PTP to understand their weaknesses and strengths. The PTP must ensure that the procedures described in the management system documents are implemented.

### 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 PTP complies with the requirements. Applicant PTP shall include scope of accreditation in the Annex -01 of application (PT-FM(P)-18: Scope of Accreditation) or make reference to further document which contain same format in the application.

The scope also specifies the field of PT Schemes ( Ex. Chemical, Biological , Mechanical ), Product Group /Matrixes related to PT Schemes, specific PT Programmes offered and locations/sites where PT Activities are carried out. During the preliminary assessment process, the scope of the accreditation is discussed with the PTP in detail, and the nature and extent of the assessment will be based on the 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. In addition, verification assessment, follow up assessment, witness assessment, unannounced assessment may plan separately as required.

### 4.1 Application and Registration for Accreditation

The PTP shall submit application documents of the PTP, to SLAB. The application shall be accompanied with the prescribed application fee as described in PT- RG (P)-01. Application fee is nonrefundable. PTP has to take special care in filling the scope of accreditation for which the PTP wishes to include PT Schemes in the scope of accreditation. In case, the PTP finds any clause (in part or full) not applicable to the PTP, it shall furnish the reasons and justify the situation.

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

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

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

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

## 4.2 Special Cases

- **Additional Accreditation**

If a PTP that is already accredited wishes to expand its accreditation for a new field 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 PT Providers**

In case an applicant PTP is already accredited for the applied scope by another accreditation body with ILAC, APAC membership or ILAC/APAC MRA for Proficiency Testing, 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 with or without conducting assessment; however, any such decision will be taken at the sole discretion of SLAB.

- **Proficiency Testing Providers with subcontractors or different locations**

Applicant PTP operating through the main office and temporary locations/sites or having associated with subcontractor shall declare in the initial application or subsequent application on its PT activities in the main office, temporary locations/sites as well as subcontractors and how common management system covers both main offices, temporary locations/sites, and subcontractors. In the case of subcontractors, PTP shall ensure that subcontractors are competent for particular activities and SLAB has access to subcontractors in order to verify the fulfillment of relevant clauses and their competencies to carry out subcontracted PT activities.

## 4.3 Acknowledgement and Registration of Application

SLAB on receipt of the application documents and other relevant documents, and the fees, shall issue an acknowledgement to the PTP. After scrutiny of application for its completeness in all aspects, a unique customer reference number shall be allocated to the PTP, which shall be used for correspondence with the PTP. SLAB may request for additional information / clarification(s), if necessary

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

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 PTP or membership of any association or group, nor shall accreditation be conditional upon the number of PTPs 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 Proficiency Testing appoints one of competent Assistant Director/Deputy Director (Accreditation)/ Development officer as Authorized officer for the application and continue 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 PTP, 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 PTP. If the initial assessment cannot be conducted in a timely manner, this shall be communicated to the PTP. Authorized Officer will contact the PTP with respect to application and further information required, if any. Authorized officer is the contact person of SLAB for the applicant PTP.

#### **4.5 Document and Record Review**

##### **4.5.1 Appointment of Assessor/ Team Leader**

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

##### **4.5.2 Adequacy of Management System Documentation**

The preliminary scrutiny of the application and management system documentation is done by SLAB. The competent 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 by PTP within one month. The aim of the adequacy assessment is to determine whether the PTP is sufficiently prepared for a pre-assessment and sufficiently prepare for the accreditation process and to ascertain the compliance of the documents with the criteria specified in ISO/IEC 17025. The adequacy assessment is also meant to obtain a clear idea of the intended scope of the accreditation.

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The competent assessor/ team leader, within a month, shall inform SLAB regarding the adequacy of the management system documentation with a report, indicating inadequacies (if any) in the management system documentation which should be communicated to the applicant PTP. Based on this feedback the PTP shall take corrective actions and submit objective documentary evidence for corrective actions taken for deficiencies before not later than three months. An extension of two months may be considered based on the request/justifiable reasons. If the CAB fails to submit satisfactory corrective actions for the document and record review within five months, CAB shall submit fresh application with fee.

If the PTP satisfies the relevant requirements at the adequacy assessment stage or after the PTP 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 seven months.

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

#### **4.6 Appointment of Assessment Team**

Towards the task of 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 will propose the composition of assessment team. The PTP 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 Assessment plan**

The SLAB contacts the PTP to agree on the date(s) and schedule for the assessment. Based on this SLAB prepares the assessment Plan (PT-PL-01) and the composition of the team and send it across to the PTP

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well in advance. Authorized officer of SLAB will inform PTP regarding the witnessing of activities related to PT activities perform at the assessment. For this purpose, PTP shall include possibilities of witnessing of outsourced PT activities by the accreditation body assessors into contractual agreements with subcontractors and other related personnel and bodies providing external services, if any.

#### 4.8 Assessment

The 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, witnessing of PT activities during the assessment of the applicant PTP's or subcontractor 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. Assessments consist of an opening and a closing meeting with assessment team members and key personnel of the PTP. Therefore, PTP shall arrange required facilities to conduct meetings and the assessment.

The assessment team shall commence an 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 PTP and its subcontractors 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 including reports of PT programmes conducted by the PTP. The PTP shall demonstrate that it is competent in all the activities at all sites including temporary, mobile or subcontractor for which accreditation has been requested and provide satisfactory evidence for the competency of its subcontractors if any. With regard to the management system of the PTP, 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 system documentation, or after satisfactory corrective action by the PTP, a pre-assessment visit of the PTP shall be organized by SLAB. PTP must have eventually conducted at least one PT programme for each PT Scheme applied for accreditation and an internal audit and a management review before the pre-assessment.

The pre-assessment of the PTP is conducted to:

- a. Assess the completeness of the documentation structure of the implemented system
- b. Assess the degree of preparedness of the PTP for the initial assessment
- c. Study the scope of accreditation so that the time frame, number of assessors required in various fields and visits to sites/subcontractors of PTP, if applicable,

Pre assessment is conducted by a Team leader/Assessment team which consists Team leader/Assessor/Technical assessor/Technical expert. If required, on site witnessing may also be arranged at the pre assessment stage. 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 Proficiency Testing Provider. Assessment team verifies the man day requirement for the initial assessment and propose and report required changes and planning of initial assessment. The team leader shall submit a pre-assessment report to the PTP at the end of assessment.

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The PTP 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 PTP submits corrective actions within four to eight months, Technical Manager will decide on continuation of application based on justifiable reasons. Any failure to submit corrective actions within eight months, application shall be discontinued and inform the decision to the applicant PTP.

Upon the successful completion of pre assessment, PTP 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. PTP's competence in performing PTP 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

The assessment team reviews the PTP's documented management system, information on PT Programmes under scope and verifies its compliance with the requirements ISO/IEC 17043, specific criteria of SLAB. The documented management system, SOPs, PT Protocols, Reports, Data analysis, Work instructions etc. are assessed for its implementation and effectiveness. The PTP's technical competence to carry out PT Programmes applied for accreditation and compliance against ISO/IEC 17043 is assessed and summary of assessment and non-compliances, if identified are reported in the assessment report and nonconformity forms.

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.

PTP shall submit corrective actions within two months with satisfactory documentary evidence. However, depending on the severity of actions to be taken, PTP 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 from the date of initial assessment, another Initial assessment shall be arranged.

A verification assessment may be recommended for the effective implementation of corrective action and the Authorized Officer will arrange the assessment in consultation with the PTP,

- Based on the recommendations of the assessment team
- Based on the corrective actions submitted by the CAB
- Based on the recommendations of the accreditation committee In case of a verification assessment the Authorized Officer will arrange the assessment in consultation with the CAB as per Sec.4.4 of this procedure onwards

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A follow up assessment may be recommended based on the following situations and the Authorized officer will arrange the assessment in consultation with the PTP.

- By the assessment team, based on the level of establishment and implementation of the quality management system
- Base on the corrective actions submitted by the CAB
- Based on the recommendation of the accreditation committee.

In case of a follow up assessment the Authorized Officer will arrange the assessment in consultation with the CAB as per Sec.4.4 of this procedure onwards

#### 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 PTP's location, such as personnel files, PT reports, PT Protocols, PT related data, quality control charts, audit reports, management review reports, etc.;

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

**Interviews:** evaluating the expertise of the PTP's personnel and personnel associated with PT schemes and data analysis via targeted interviews.

**Witnessing:** observation of tests, sample preparation, transportation, homogeneity testing or activities related to PT programmes and examination carried out by the PTP or its subcontractor.

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

#### 4.12 Participation in external quality assurance activities

If applicable, the PTP provider or its subcontractor shall participate in external quality assurance activities as per SLAB policy for participation in external quality assurance activities (AC-RG (P)-02). It is the responsibility of PTP to make sure that the subcontractors providing testing, calibration and inspection meet PT requirements of relevant standard (ISO/IEC 17025, ISO 15189, ISO/IEC 17020).

#### 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 PTP and the consequent follow up and 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(PT-FM-46) and the recommendation given by the team and then makes its own decision on grant of accreditation.

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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 PTP in writing of the decision taken. All decisions taken by SLAB regarding grant of accreditation shall be open to appeal by the PTP as per appeal procedure (GN-PR(P)-09) within 30 days.

#### 4.14 Issue of Accreditation Certificate

As soon as a decision is taken to grant accreditation SLAB will prepare the following documents. Accreditation certificate with a unique number for identification duly signed by the Director / CEO, SLAB. This certificate specifies the date on which the accreditation was granted, the standards based on which the accreditation was granted and the period of validity of the certificate.

The accreditation certificate on PTP accreditation shall define field of PT Scheme, relevant products/matrixes, specific tests performed and specification / standard method or technique used, frequency, wherever applicable.

Terms and conditions for maintaining accreditation of PTPs, (PT-RG(P)-03) is considered as the agreement between SLAB and PTP.

This contains the rights and obligations of both parties; the party providing the accreditation and the party being accredited and signed by both parties. In addition to use ILAC MRA mark, separate agreement to be signed by the both parties. The applicant PTP must fulfil all the financial obligations payable to SLAB, before receiving the certificate(s).

A unique certificate number shall be allocated to a PTP based on PT Scheme. If a PTP wishes to have one or separate certificates for different PT Schemes that should be communicated to the SLAB at the stage of application. A schedule of accreditation shall consist Field of PT Scheme, specific PT area/ products or materials, determinant, reference methods/ procedures , limit / range, frequency, as applicable.

Terms and condition for maintaining accreditation of PTP (PT-RG(P)-03) is considered as the agreement between SLAB and PTP. This contains the rights and obligations of parties; the party providing the accreditation and the party being accredited and signed by both parties.

On grant of accreditation, the PTP is able use SLAB mark on all its PT reports, Protocols for the PT Schemes 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 customers as per the Terms and Conditions for use of SLAB Accreditation Symbol (AC-RG (P)-01). However, PTP does not allowed to use accreditation mark on PT samples distributed to participants.

Misuse of the accreditation symbol by accredited PTP may lead to suspension or withdrawal of the accreditation. If non-accredited PTP 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 PTP must continuously comply with the accreditation requirements of the ISO/IEC 17043 and “Terms and condition for maintaining accreditation of Proficiency Testing Provider (PT- RG (P)-03). In this regard SLAB will periodically review the validity of accreditation. To this end, the SLAB carries out surveillance assessments and a re-assessment within three years. During the accreditation period, the scope of the accreditation may be changed.

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#### 4.16 Surveillance

Surveillance assessment will be planned by the authorized officer, depending on the accreditation cycle. SLAB will conduct surveillance of all accredited PTP or following surveillance activities may be decided by the technical manager based on the risks associated with the activities;

- Special on-site/remote assessment
- Review of changes to PTP'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 PTP is maintaining all the requirements of the ISO/IEC 17043 and SLAB specific criteria (if any).

As planned in the assessment schedule, Authorized officer of SLAB will inform in writing the accredited PTP 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 PTP during the validity of accreditation may request to extend the scope of accreditation for which they should preferably apply 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 will inform the PTP, 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 PTP with conditions or suspend accreditation relevant to the particular nonconformity.

When a follow-up assessment/Verification 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.

The surveillance assessment process shall be completed within 10 months from the date of surveillance assessment. If the PTP fails to complete the surveillance process, the suspension procedure will be followed.

#### 4.17 Reassessment and renewal of accreditation

As planned in the assessment schedule, Authorized officer will inform in writing the accredited PTP of the re-assessment at the beginning of the year. Accredited PTP shall apply four months before the expiry of accreditation for renewal of accreditation as per the terms and conditions for maintaining accreditation of Proficiency Testing Provider (PT-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 PTP may

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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 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 testing, calibration laboratories, GLP and PTPs.

#### **4.18 Special assessments**

The SLAB may organize extraordinary assessments, unannounced or ad hock or other activities 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 PTP 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 short time between notification and execution.

Special assessment may also become necessary when changes occur in accreditation criteria, organizational structure and in management/ ownership/ location /authorized signatories and changes to PT Schemes. However, in these cases, the SLAB will give PTPs sufficient time for preparation. All costs associated with special assessments will be charged to the PTP.

#### **4.19 Changes in accreditation criteria**

If there is a change in the ISO/IEC 17043 or accreditation criteria, SLAB will inform the PTP in writing indicating the transition policy with specific period for complying with new criteria. Upon receiving such information, the PTP 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 PTP operations**

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

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#### 4.21 Reduction of the scope

During assessments by the SLAB, the accredited PTP 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 PTP 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 PTP will terminate the relevant part of the scope itself. If during an assessment it becomes clear that it is necessary to reduce accreditation for parts of the scope, the SLAB will also review the validity of the remaining accredited scope.

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

The concerned part of the scope shall be reduced if records do not demonstrate this. In this case when the entire scope is reduced, then the entire accreditation is withdrawn. However, the PTP concerned can again be granted accreditation, after submission of new application.

#### 4.22 Extension of scope

At any given moment, the PTP 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 PTP.

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/ field 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 PTP.

#### 4.23 Transfer of accreditation

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

- The PTP 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 PTP's personnel remains the same
- The basic infrastructure and other facilities are not compromised

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The PTP shall provide the SLAB with the necessary documents showing that the above conditions are met. The costs for reviewing the documents/ conducting onsite or remote review will be charged to the PTP. If all requirements are met, the new PTP retains the registration/accreditation number and receives the new accreditation documents. The surveillance and re-assessment schedule will remain unchanged.

#### 4.24 Management of Extraordinary Situations

In the event of an extraordinary situation, SLAB policy on the management of extraordinary event or circumstances effecting SLAB accredited bodies and their clients. AC RG(P)-20, shall be applied.

### 5. Obligations

#### 5.1 Proficiency Testing Provider

##### 5.1.1 General

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

##### 5.1.2 Co-operation

The PTP 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 PTP’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 PTP and related sites
- The PTP shall provide the assessment team with the necessary safety instructions, safety equipment & personnel protective equipment
- If requested, the PTP shall provide access to all relevant locations, equipment, dossiers and documents
- In case the assessment of SLAB requires the participation of clients/ /external service provider or other related bodies of the PTP, the PTP shall take measures to assure this participation; in particular PTP shall have enforceable arrangements with its clients/external service provider holding an accredited certificate, to ensure SLAB access to witness the PTP’s compliance at the PTP’s client’s/external service provider’s/subcontractor’s site.
- Assessors of SLAB shall not be put in a position where their independence and objectivity could be compromised.

##### 5.1.3 Accreditation symbol

Accredited PTPs have the right to use the applicable accreditation symbol. As such, on grant of accreditation, the PTP may use SLAB accreditation symbol on letterheads, brochures and any other material issued to its clients including the certificates. However, such usage shall be confined within the scope of accreditation. The PTP shall comply with the “Policy on governing the use of the accreditation symbol” (AC-RG(P)-01). If the policy of the PTP is to use the accreditation symbol for PTP pertaining to accreditation scope all reports issued on accredited scopes shall carry the accreditation symbol.

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Misuse of the accreditation symbol by accredited PTP may lead to suspension or withdrawal of the accreditation. If non-accredited PTP uses the SLAB symbol, the SLAB can resort to legal actions.

#### 5.1.4 Reporting Changes

The PTP 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 PTP’s organizational status
- Changes in the sphere of activities or economic activities of the PTP
- Change in management and in structure
- Policy changes
- Changes in personnel that fill key positions, such as Authorized signatories, Quality and Technical managers and decision-makers
- 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 PTP expects the changes to have a temporary negative effect on the accredited activities, then the PTP can request a voluntary suspension. In case of that the SLAB possesses the right to carry out extra assessments to ensure that the PTP 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 PTP 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 PT-RG (P)-01. A PTP shall take prompt actions to settle such payments. If a PTP does not make payment on time, the SLAB sends a reminders and late payment charges may apply. 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 PTP 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 PTPs that may compromise their neutral role in assessments. Assessors shall follow the health and safety instructions of the PTP being assessed.

#### 5.2.2 Confidentiality

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SLAB will treat all the information obtained or created during the accreditation process of PTPs /sources other than the PTPs 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, assessment team, or other bodies or individuals acting on behalf of the SLAB.

Confidential information related to any PTP and studies shall not be disclosed, outside the SLAB without written consent of that particular PTP, unless otherwise required by law or particular sponsor agreed under contractual arrangements. Any information about a PTP obtained from other sources is not shared with that PTP, unless agreed by the source.

## 6. Suspensions, Withdrawals and Reductions

Suspension, Withdrawal and Reduction of scope of accreditation arises, in the event of a PTP 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 will take decision on suspension of accreditation for a maximum of four months or Withdrawal/Reduction of accreditation with immediate effect. Any failure to rectify the issues related Suspension within the given period, accreditation shall be withdrawn/reduced with immediate effect. The decision will be informed to the PTP and published in the web site. SLAB may issue a revised certificate/schedule of accreditation.

### 6.1 Suspensions

During the suspension period, the PTP may 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.

If the PTPs actions to reinstate accreditation within 4 months another two months maximum will be given to complete of reinstating procedure. Any failure to rectify the issue related to suspension within the given period accreditation shall be withdrawn or reduced with immediate effect by the Director/ CEO and decision will be informed to the accreditation committee. If the decision is to suspend or withdraw or reduce accreditation Director/CEO shall inform the PTP of the decision in writing and may issue a revised certificate or schedule of accreditation.

A PTP may request a voluntary suspension from the SLAB if it is temporarily unable to comply with the accreditation criteria. In such circumstances, the PTP 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 PTP and the SLAB can withdraw/reduce the scope of accreditation. From the moment of withdrawal/reduction, the PTP will have to refrain from using the accreditation symbol or otherwise

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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 PTP 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 PTP brings the Accreditation into grave disrepute, the SLAB will impose the withdrawal/reduction. SLAB informs the PTP of the withdrawal/reduction in writing. After a withdrawal, the SLAB will not accept an application for accreditation from the same PTP 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 or applicant PTP and the SLAB with regard to:

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

The PTP 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 takes a decision. The decision will be communicated to the parties in writing. All dispute if any arising out of SLAB decision, that remains unresolved through internal mechanism provided by SLAB are subjected to the alternate dispute resolution (Arbitration), if fails can initiate litigation within the jurisdiction of the courts in Sri Lanka, exclusive the jurisdiction of the courts in Sri Lanka.

### **7.2 Complaints**

The SLAB distinguishes two types of complaints:

- Complaints about the SLAB and its personnel on behalf.
- Complaints about registered or accredited PTPs.

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**

PTPs 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**

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SLAB will publish the details of scope of accreditation & accreditation status of the accredited PTPs 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 on the SLABs official website. PTPs are required to implement such changes as per instructions given by the SLAB.

## 9. Liability

SLAB will not be responsible for any damages, that the PTP 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 PTP. PTP shall have adequate provisions (Insurance coverage or reserve) to cover liabilities arisen from its operation as well as lost or damages to PT items /samples related to PT programmes.

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