 **SRI LANKA ACCREDITATION BOARD**

 **for CONFORMITY ASSESSMENT**

**APPLICATION FORM**

***for* accreditation *of* REFERENCE**

***MATERIAL PRODUCERS***

***Instructions to the Applicant:***

1. Please submit the duly filled application along with all annexures and documents and records referred in the application and Self-Assessment Checklist (RMP-FM(P)-11).
2. Please read Rules and Procedures for Accreditation of TL/CL/ML/IB/PTP/RMP/GLP (AC-RG(P)-26), Terms and Conditions for Maintaining Accreditation (AC-RG(P)-08), Policy on governing the use of Accreditation Symbols (AC-RG (P)-01) and Specific criteria for RMP Accreditation (RMP-RG(P)-04) before filling the application.

Director /CEO



Sri Lanka Accreditation Board for Conformity Assessment

No. 44, Dedicated Economic Centre

Kirimandala Mawatha

Narahenpita

**APPLICATION FOR ACCREDITATION of REFERENCE MATERIAL PRODUCERS**

|  |
| --- |
| We apply for SLAB accreditation of our **reference material producer** as per details given below: |
|  |  |  |  |  |
| First Accreditation  |  |  | 1. Scope Extensionin the existing accredited category of reference material
 |  |
|  |  |  |  |  |
| Renewal of Accreditation |  |  | 1. Scope Extension in new category of reference material
 |  |

|  |
| --- |
| 1. **1. Reference Material Producer Details**
 |
|  |
|  | **Name of the Reference Material Producer** |  |
| Address |  |
| Telephone |  | Fax No |  |
| e-mail |  |
|  |  |  |  |
| **1.2.** | **Name of Parent Organization** **(if part of an organization)** |  |
| Address |  |
| Telephone |  | Fax No |  |
| e-mail |  |
|  |  |  |  |
| **1.3.** | **Legal status and date of establishment**(Please provide copy of registration / Relevant section of act or regulation) |
|  |  |

|  |  |
| --- | --- |
| **1.4.** | **Does the CAB undertake Reference Material Producer activities in following categories?**(If yes, please clearly indicate in the scope of accreditation) |
|  |  |  |  |  |  |
|  | 1. Independently at Permanent Facility
 |  | Yes |  | No |
|  |  |  |  |  |  |
|  | 1. Site Facility (when undertake activities at site (s))
 |  | Yes |  | No |
|  |  |  |  |  |  |
|  | 1. Temporary/Mobile Facility (when a facility is created temporarily)
 |  | Yes |  | No |

***If yes*** *– for (b) Please provide the details in the table below.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Site No** | **Site Location** **(Name & Address)** | **Activities perform at this site** | **Contact details** **(Telephone, Email)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |
| --- | --- |
| **1.5.** | *Is the CAB obtaining any Reference Material Producer activities from external providers (eg: Subcontracting of reference material production) pertaining the scope applied?* |
|  |  |  |  |  |  |  |  |
|  | Yes |  |  | No |  |  |  |
|  |  |
|  | ***If yes -*** *Please annex*  |
|  | Note: Please provide the evidence of competence (e.g. copy of accreditation certificate and scope etc.) and written contract with the subcontractor along with completed subcontractor information as above. |
|  |  |
| **2.** | **Accreditation Details** |
|  |  |
| **2.1.** | **Category of materials for which accreditation is sought** (Please tick the appropriate box)

|  |  |  |
| --- | --- | --- |
| Chemical Composition |  |  |
| Biological & Clinical Properties |  |  |
| Physical/Mechanical Properties |  |  |
| Other Properties (Please specify |  |  |

 |
| **2.2.****2.3** | * 1. ***If the CAB is already accredited for ISO 17034 indicate the fields of and scope for which accreditation has been granted.*** (Please attach the scope of accreditation)
	2. ***If the CAB is already accredited for ISO/IEC 17025, ISO 15189, ISO/IEC 17043 indicate the fields and scope for which accreditation has been granted.*** (Please attach the scope of accreditation)
 |
| **2.4.** | ***Scope of Accreditation*** (Please indicate the Scope which accreditation is sought) ***–*** *Please attach Part A of Annexure 01 and submit a copy of all the methods/techniques mentioned in the scope of accreditation along with the application documents to SLAB.* |
| **2.5** | ***Does the CAB perform in-house calibrations?*** |  Yes |  | No |  |  |
|  |  |  |  |  |  |
|  | ***If yes –*** *Please attach the details as per Part B of Annexure 01* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **3.** | **Organization** |  |  |  |
|  |  |  |  |  |
| **3.1.** | **Senior Management** (Name, Designation) |
|  | 3.1.1. | Chief Executive of the Organization | **:** | **………………………………………………** |
|  | 3.1.2.3.1.3  | Head of the RMP with overall responsibilityPerson/s responsible for the RMP management system | **:****:** | **………………………………………………****………………………………………………** |
|  | 3.1.3. | Person/s responsible for technical operations | **:** | **………………………………………………** |
|  | 3.1.4. | Authorized Representative for SLAB | **:** | **………………………………………………** |
|  |  | Telephone: |  | Fax : |  | E-mail  |  Mobile: |  |
|  |  |  |  |  |  |  |  |
|  | 3.1.5. | Authorized signatories for signing of certificates and RM documents – Please attach Annexure 02 |
|  |  |  |  |  |
|  | 3.1.6. | Information regarding any individual or organization that has provided consultancy or following assistance towards SLAB accreditation; |
|  |  | Development of Quality Management System | **:** | **……………………………………………………** |
|  |  | Development of Technical Operations | **:** | **……………………………………………………** |
|  |  | Training | **:** | **……………………………………………………** |
|  |  | Conducting Internal Audits | **:** | **……………………………………………………** |
|  |  | Other | **:** | **……………………………………………………** |
|  |  |  |  |  |
|  | 3.1.7. | Any affiliation or relationships to SLAB | **:** | **……………………………………………………** |

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| **3.2.** | **Organization and Management Structure** |
|  | 3.2.1. | Indicate an organization and management structure of the operating departments of the RMP for which accreditation is being sought (please append) |
|  | 3.2.2. | Indicate how the RMP is related to external organizations or to its own parent organization (where applicable) |
| **3.3.** | **Employees** |
|  | 3.3.1. | Total number of employees in the organization: | ……………………………. |  |  |
|  | 3.3.2. | Number of employees involve in RMP activities: …………………………….. |  |  |
|  | 3.3.3. | Details of staff/ Trainees or Contracted persons – Please attach Annexure 03 |  |  |
| **4.** | **Equipment and Reference Materials** |
|  | 4.1. | Equipment List – Please attach Annexure 04 |  |  |
|  | 4.2. | List of reference materials – Please attach Annexure 05 |  |  |
|  |  |  |  |  |
| **5.** | **Internal and External Quality Assurance Programmes** Please attach Annexure 06 and Summary of recently participated Internal and External Quality Assurance Programmes for all methods/techniques applied for accreditation. |
|  |  |  |  |  |
| **6.** | **Self-Assessment Checklist** – Please fill Annexure 07 |
|  |  |
| **7.**  | **Please attach the following documents / records** |
|  | 7.1. | Management System Documentation |
|  | 7.2. | A lay out of the areas of operation, total build up area for RMP activities & storage facilities for finished products including provisions for maintaining environmental conditions |
|  | 7.3. | Records of Measurement Uncertainty/CMC budgets |
|  | 7.4. | Report of the last internal audit together with corrective action records. |
|  | 7.5 | Minutes of the last management review |
|  | 7.6. | CRM certificate and RM document formats |
|  | 7.7. | Calibration certificates of key instruments |
|  | 7.8. | Actions to address Risks and Opportunities |
|  | 7.9. | Documentation for (each RM/CRM produced) including Planning of production processes, Homogeneity and stability testing, Characterization and Assignment of values (and their uncertainty), Storage, Handling and Distribution of reference material |
|  | 7.10 | Signed copy of Terms and Conditions for maintaining accreditation (AC-RG(P)-08)  |

**8. Willingness to undergo Assessment**

**We declare that**

* We are aware of and will abide by the Terms and Conditions for maintaining accreditation (AC-RG(P)-08) to be signed by both parties, which is enclosed.
* We agree to comply fully and continually fulfill the requirements of ISO 17034:2016 and SLAB requirements for the accreditation of RMP.
* We agree to comply with accreditation procedures and pay all costs for activities related to accreditation process as per Terms and Conditions for maintaining accreditation (AC-RG(P)-08) & Fee Structure (RMP-RG(P)-01) available in SLAB website: [www.slab.lk](http://www.slab.lk).
* We agree to co-operate with the assessment team appointed by SLAB for assessment of all relevant documents by them and their visits to those parts of the RMP/site that are part of the scope of accreditation.
* We declare that all the information provided is true and accurate to the best of our knowledge. I’m aware that giving any fraudulent information will lead to termination of the accreditation process.

|  |  |
| --- | --- |
| Signature of Chief Executive |  |
| Name & Designation |  |
| Date & Place |  |

***…………………………………………………………………..***

***For office use only***

|  |  |  |  |
| --- | --- | --- | --- |
| A. | Check whether the following have been submitted | To be checked by the Management Assistant | To be checked by the TM/Authorized Officer |
|  | Annexure 01 - *Scope of Accreditation* |  |  |
|  | Annexure 02 - Authorized signatories for issue of certificate/RM Documents |  |  |
|  | Annexure 03 - Details of staff |  |  |
|  | Annexure 04 - Equipment List |  |  |
|  | Annexure 05 - List of reference materials |  |  |
|  | Annexure 06 - Internal and External Quality Assurance Programmes |  |  |
|  | Annexure 07 - Self-Assessment Checklist |  |  |
|  | Method/Techniques mentioned in the Scope of accreditation |  |  |
|  | Organization and management structure |  |  |
|  | Evidence for the legal status of the entity |  |  |
|  | Summary of recently participated Internal and External Quality Assurance Programmes |  |  |
|  | Management System Documentation |  |  |
|  | A lay out of the areas of operation, total build up area for RMP activities & storage facilities for finished products including provisions for maintaining environmental conditions |  |  |
|  | Records of Measurement Uncertainty/CMC |  |  |
|  | Report of the last internal audit together with corrective action records. |  |  |
|  | Minutes of the last management review |  |  |
|  | CRM Certificates and RM documents formats |  |  |
|  | Calibration certificates of key instruments |  |  |
|  | Actions to address Risks and Opportunities |  |  |
|  | Documentation for (each RM/CRM produced)-Planning of production processes-Homogeneity and stability testing-Characterization and Assignment of values (and their uncertainty)-Storage, Handling and Distribution of reference material |  |  |
|  | Signed copy of Terms and Conditions for maintaining accreditation (AC-RG(P)-08)  |  |  |
|  | Information about sub-contractor (if applicable): -List of subcontractors with activity-Evidence of sub-contractor(s)competence-Contract with sub-contractor(s) |  |  |
|  |  |  |  |
|  | ***Case File number:***  | **Assigned by:**  | **Verified by:**  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| To be filled by the Technical Manager / Deputy Technical Manager before assigning the application to Authorized officer

|  |  |  |  |
| --- | --- | --- | --- |
|  A. | Comments on the case file | : |  |
| B. | Allocation of Case file | : |  |
| C. | Allocation for Document Review | : |  |

Date: …………………… Technical Manager/Deputy Technical Manager: ……………………….. |

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| --- |
| To be filled by the Authorized officer  |
| A. | Check whether the SLAB fulfills the following; |  |
|  Is the activity area of CAB under the purview of SLAB | Yes / No |
|  Can the initial assessment be performed in a timely manner | Yes / No |
|  If yes, state the duration | …………………………….. |
|  Has the SLAB Competence on accrediting the CAB | Yes / No |
| B. | Are all functions of CAB performed at one siteIf No, indicate the specific activities  | Yes / No |
|  |  |
| C. | Time estimation (Number of man days) for initial assessment | : ……………………………………………………. |
|  |  |  |  |
| D.  | Remarks of Authorized Officer | : ……………………………………………………………………………...……………………………………………………………………………….……………………………………………………………………………….……………………………………………………………………………….………………………………………………………………………………. |
|  | Date: …………………… Authorized Officer: …………………………….. |