

# SRI LANKA STANDARDS INSTITUTION

## **The Registration of Overseas Laboratories**

# **GUIDELINES AND CONDITIONS FOR THE REGISTRATION OF OVERSEAS LABORATORIES UNDER THE IMPORT INSPECTION SCHEME OF THE SRI LANKA STANDARDS INSTITUTION**

Under the Import Inspection Scheme operated by the Sri Lanka Standards Institution (SLSI) those imports supported with a Conformity Certificate from an overseas laboratory recognized by SLSI will be approved for clearance and samples will be drawn on a random basis to ensure the accuracy of test report. This procedure will be valid until SLSI notifies any change of status of the laboratory concerned. The consignments certified by the laboratory will be approved until the change of status is notified.

The procedure for registration and conditions for certification are given below.

## **1. Conditions for Registration :**

Two categories of laboratories are identified for registration under this scheme.

### **1.1 Accredited Laboratories :**

Those laboratories accredited for the tests specified in the **relevant Sri Lanka Standard Specification or equivalent** by the National Accreditation Bodies in their own country or any other international body, will be recognized under this scheme subject to the condition of verifying the documents submitted by the laboratory. However a fee will be charged to cover the administrative cost involved in this process.

If such laboratory is willing to enter in to a Memorandum of Understanding (MoU) with the SLSI, following conditions will apply.

- a) The Laboratory Manual along with a copy of recently carried out Internal Audit report and a copy of the Certificate will have to be submitted to the SLSI.
- b) A fee as per B.1 of GL-II-05 (refer annex 5) have to pay along with the application.

If the SLSI is satisfied with the status of the system and the Accreditation Body, the SLSI will notify the Laboratory Management to enter into an MoU which is valid for 3 years subject to the following conditions.

- i) An annual fee of registration shall be paid within the 1<sup>st</sup> quarter of the each year.
- ii) In case any new product to be included an additional payment along with scope of accreditation to need to be submitted to the SLSI.
- iii) It will be the responsibility of the laboratory to notify the SLSI with regard to any changes in the status of accreditation.
- iv) Both parties has the right to terminate the agreement without having any liability.
- v) MoU has to be re-validated at least before the expiry date.

### **1.2 The Laboratory with Internationally Recognized Laboratory Management System without accreditation:**

These laboratories shall have a quality system based on **EN 45002** (General criteria for the assesment of testing laboratories) or **ISO/IEC Guide 17025**.

If such laboratory is willing to enter in to a Memorandum of Understanding (MoU) with the SLSI, following condition will apply.

- a) The Laboratory Manual along with a copy of recently carried out Internal Audit report and a copy of the Certificate will have to be submitted to the SLSI.
- b) A fee as per B.1 of GL-II-05 (refer annex 5) have to pay along with the application.

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- iv) Both parties has the right to terminate the agreement without having any liability.
- v) MoU has to be re-validated at least before the expiry date.

#### **1.2.1 Monitoring the Laboratory Management systems :**

On complying with the requirements of Clause **1.2.a) & 1.2.b)**, the SLSI will appoint a competent audit team to visit the laboratory and report on the status of the systems practiced, awareness of testing, acceptability of test equipments, capabilities of testing and methodology of reporting.

#### **1.2.2 Constitution of the Panel :**

Director (QA) in consultation with the relevant Assistant Directors shall nominate a competent team to carry out the Audit and submit to Director General for approval through relevant Deputy Director General.

At least two panel members of which one member who is an expert in testing should be in the panel.

SLSI could consider replacing the panel completely or partly with officials from the National Standards Institution in the country of exporting and/or other experts drawn from that country.

#### **1.3 Approval:**

Approval of the laboratory registration to be granted by a committee consisiting of Director General, relevant Deputy Director General, Director (Quality Assurance) and Director (Laboratory Services). An expert in the field under consideration could be invited to serve to advice the committee when required.

#### **1.4 Fee Involved:**

Nominal administrative cost will be charged in accordance with B1 of **GL-II-05**.

#### **1.5 Period of Validity of Registration:**

The approval is valid for three years, the registration status could be revalidated subject to fresh evaluation after three years. However the registration status will be renewed annually subject to settleing relevant payment and compliance of the product.

## **1.6 Disputes:**

Any disputes in procedures or testing will be initially brought to the notice of the laboratory for consideration. Laboratory is required to cooperate with any investigations and assessments regarding such disputes.

SLSI will decide on the acceptability of the certificates during the period of such disputes.

## **1.7 Cancellations :**

Any violation of the conditions of the registration procedures or the MoU signed with the SLSI will lead to cancellation of the registration with or without prior notice subject to the covering approval of committee (Clause 1.3)

## **1.8 Appeals :**

Appeals regarding any matter on approval to be made to the Director General, the SLSI within one month and these will be reviewed by the Council and whose decision will be final.

## **2 Amendments :**

The above procedure could be amended by the Council of the SLSI without prior notice. Concessions could be made to any party who are affected by such amendments after evaluating the cases individually.

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