Registration of Overseas Manufacturers

Under the Import Inspection Scheme operated by the Sri Lanka Standards Institution (SLSI), Conformity Certificate (CC) issued by registered manufacturing plant will be accepted for perusal of a consignment imported from the same manufacturing plant. If CC is acceptable, such consignments will be approved for clearance and samples will be drawn on a random basis to ensure the quality and CC issued by the manufacturing plant.

If manufacturing plant having acceptable Product Certification mark (product standard of both countries should be compatible) for the same brand and type/design of the product exported to the Sri Lanka will be approved for clearance and sample will be drawn on random basis. The particular manufacturing plant should be registered with the SLSI in order to accept Product Certification Mark.

This procedure will be valid until SLSI notifies any change of status of the registration of the manufacturing unit concerned and all those consignments manufactured in the registered unit will be approved until the change of status.

For further information please refer the **Import Inspection Scheme.**

The procedure for registration is given below.

1. General:

Products manufactured in the approved plants will qualify to be certified under this scheme. If a supplier uses more than one manufacturing plants to export to Sri Lanka all those plants need to obtain registration status separately and also number of products manufactured by the same plant need to obtain registration status separately for each product.

2. Conditions for Registration:

Three categories of manufacturing plants (2.1, 2.2 & 2.3) are identified for registration under this scheme.

Manufacturing plant with proven performance:

Manufacturing plant with proven performance will qualify for registration under this category.

Provisional Registration:

A manufacturer successfully obtaining **five consecutive approvals** under the import inspection scheme will be granted the **'Provisional Registration'** status for a period of **six months**. The period during which the above manufacturer to be assessed for this status will be based on the product under consideration.

Records of any previous quality failures will be taken into consideration before approval is granted.

Upgrading to Registration Status:

Those manufacturers who had obtained 'Provisional Approval Status' will be upgraded to registration status based on the following.

a) Obtaining ISO 9001, ISO 22001, GMP or HACCP Quality System Certification depend on nature of products for the manufacturing plant or acceptable Product Certification mark (refer Category **3** of 1.1.1 of Import Inspection Scheme for designated products) **within a period of six months**, from the date of approval for provisional registration status.

b) The SLSI will appoint a competent audit team based on the product(s) manufactured by the company to conduct a thorough assessment to verify the following;

i) To check the quality control practice and process control practice of the production process.

ii) To examine the testing facilities available with the manufacturer, assess the testing practices and capabilities and also to check the conformity of product.

iii) To determine the extent of implementation of the system given in 2.1.2.a).

iv) To report to the management of the SLSI about the status of the manufacturing facility and (i), (ii) & (iii) to make a final decision.

Manufacturing units with Quality Systems:

ISO 9001 Certified Companies:

The manufacturing plant certified for ISO 9001 Quality Management System by an agency acceptable to SLSI qualify for registration. However a **panel nominated by SLSI will visit the manufacturing facility** to report to the SLSI management on the status given in 2.1.2.b) (i), (ii) & (iii).

Other Quality Systems:

SLSI will evaluate other internationally accepted certifications such as GMP, HACCP or ISO 22001 as part fulfillment of the above requirement for Food Industries, and effective HACCP system is need to be in operation for the other requirements. **A panel nominated by SLSI in order to report on quality management systems, will visit the manufacturing facility to assess the adequacy of the quality management system is effective implementation as given under clause 2.1.2 b).**

Information on Quality Systems:

Manufacturers falling under Clause 2.1 & 2.2. shall provide detail information as given below :

i. Products manufactured,

ii. Quality System in operation,

iii. Standards used in the above system,

iv. Standards used for the product,

v. Status of calibration of the equipment used,

vi. Qualifications and experience of the technical staff associated with

production and testing,

vii. Details of records maintained,

viii. Information on applicable regulations in the country of manufacture

2.3. Manufacturing with Acceptable Product Certification Mark:

The SLSI will accept Product Certification Mark issued by other National Standard bodies (refer Category **4** of Clause **1.1.1** of Import Inspection Scheme for designated products). In case random sample fails continuously, the failures will be brought to the attention of the certification body and a **thorough evaluation of manufacturing plant will be done by a panel of the SLSI**.

3. 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 the production process under consideration, should be included in the panel.

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

4. Application for Registration:

A manufacturer shall use the form **No. FM-II-02** when applying for registration.

If the same commodity or product is manufactured at more than one factory separate applications should be submitted for each manufacturing facility.

If more than one product manufactured at same manufacturing plant separate applications should be submitted for each manufacturing facility.

5. Documents Needed:

Those seeking registration under Clause **2.2** shall provide a certified copy of currently valid Quality System registration certificate along with scope of registration (certified by the issuing authority), a copy of Quality Manual including Quality Plan, evidence for the brand ownership of the product and their test report of different types/sizes/brands to assess the conformity of the product to the relevant Sri Lanka Standard specification in addition to duly filled application. SLSI will retain the right to verify with the issuing authority to establish the authenticity of the certificate.

It will be the responsibility of the manufacturer to inform SLSI of any change of status of certification. Otherwise the registration status granted to the manufacturing unit will be cancelled.

6. Approval:

Approvals of the manufacturing plant registration status to be granted by a Committee consisting of Director General, relevant Deputy Director General, Director (Quality assurance) and relevant Assistant Director (Quality Assurance) based on the evaluation report submitted by the audit team. An expert in the field under consideration could be invited to serve to advice the Committee when required.

Fee Involved:

7. 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 settling relevant payment and compliance of the product.

8. Disputes:

Any disputes on quality will be initially brought to the notice of the manufacturer for consideration. Manufacturer is required to co-operate with investigations and assessments regarding such disputes.

9. Cancellation:

Any violation of the conditions of the above processors or registration and continuous disputes on quality will lead to cancellation of the approval with or without prior notice subject to the covering approval of the Committee.

10. Appeals:

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

11. Self Certification of Consignments:

11.1 Registered manufacturing unit shall provide a certificate of conformity in respect of the relevant Sri Lanka Standard Specification, for each consignment according to the format provided by the SLSI or an acceptable format by the SLSI with proper reference of the consignment such as commercial invoice number and / or bill of lading number.

11.2 Registered manufacturing unit, the acceptable Product Certification Mark shall be marked on the products or labels and also in the invoice, packing list and delivery note. Otherwise a sample will be drawn for conformity test and based on the test final decision will be taken.

12. Amendments:

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