SLS Mark Product Certification Scheme
SRI LANKA STANDARDS INSTITUTION

Quality Management System Requirements
for
SLS mark Product Certification

SRI LANKA STANDARDS INSTITUTION
GUARDIAN OF QUALITY

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1. INTRODUCTION

The Product Certification scheme of the Sri Lanka Standards Institution defines the Quality Management System requirements, by which manufacturers who seek the SLS Mark for their products should establish implement and maintain the Quality Management System complied to the requirements given in one of the following two options.

a) OPTION 1

Quality Management System developed based on the following requirements.

1. Management Responsibility
2. Quality System
3. Purchasing
4. Process Control
5. Inspection and Testing
6. Control of Inspection, Measuring and Test Equipment
7. Inspection and Test Status
8. Control of Non-Conforming Product
9. Handling, Storage Packaging, Delivery
10. Control of Quality Records
11. Internal Quality Audits
12. Training

b) OPTION 2

Quality Management System developed based on ISO 9001:2015 Standard requirements.

This document serves as a guide for manufacturers who are seeking SLS Mark to establish, implement and maintain a Quality Management System within their organizations. Complying to one of the option given above is a pre-requisite to obtain SLS Mark.

If any manufacturer seeking SLS Mark certification for their products manufactured in production units in a foreign country (outside Sri Lanka) must have a valid ISO 9001 certification.

2. REQUIREMENTS FOR OPTION 1

2.1 MANAGEMENT RESPONSIBILITY

2.1.1 Quality policy

The manufacturer's management shall define and document the policy with regard to quality, The manufacturer shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

The policy should be written in a simple language to enable everybody in the organization to understand easily to gain necessary commitment from all employees of the organization in the implementation of the policy.

The focus of the company on customers, employees and suppliers in relation to quality, should be reflected in the policy statement.

2.1.2 Organization

2.1.2.1 Responsibility and authority

The manufacturer shall identify personnel who manage, perform and verify work affecting quality. The manufacturer shall also define and document responsibilities of these personnel who should have organizational freedom and authority to;

a) initiate action to prevent the occurrence of any non-conformity relating to the product and the twelve quality system requirements identified for SLS product certification scheme;
b) identify and record any problems relating to the product and quality system requirements;
c) initiate, recommend or provide solution through designated channels; and
d) verify implementation of solutions.

Further everybody in the manufacturer's organization should be made aware of;

i) their responsibility and authority, scope of actions and tasks and their impact on quality of products; and
ii) the importance of their contribution, in achieving quality requirements of products

Suitable personnel should be identified and made responsible for monitoring quality of incoming materials/components, in process semi-finished product and final products. They should be able to communicate directly with the highest level of the management for reporting quality achievements.

2.1.2.2 Resources

The manufacturer shall identify resource requirements and provide adequate resources, including trained personnel for;

a) managing and performing work; and
b) verification activities including testing and internal quality auditing

Verification resources and personnel can be the following;

i) personnel who perform testing inspection and internal quality audit, with adequate training in these areas;
ii) awareness of required or identified standards;
iii) awareness of arrangements for inspection, testing and internal audit;
iv) providing training in all relevant areas;
v) documented procedures and sufficient time to do the work;
vi) production schedule with sufficient time allocated for activities such as
vii) means to access quality records.

2.1.2.3 *Management representative*

The manufacturer shall appoint a member of the senior management to effectively implement and maintain quality system requirements for product certification. He/She should have the authority to,

a) ensure that the quality system is established, implemented and maintained in accordance with the requirements specified in this document;
b) report on the performance of the quality system to the management for review and improvement of the quality system; and
c) liaise with external parties (e.g. SLSI) on matters relating to the manufacturer's quality system.

In addition to above functions, the management representative may have other responsibilities which should not have conflicting interests.

2.1.3 *Management review*

The manufacturer's management shall review the quality system at specified intervals sufficient to ensure its continuing suitability ad effectiveness in satisfying the quality policy and objectives stated by the manufacturer. Records of reviews shall be maintained.

For this purpose the management Review Committee comprising of Senior Management Staff, chaired by the Chief Executive Officer (CEO) should meet at regular intervals to discuss.

a) audit reports;
b) adequacy of staff, testing and other equipment etc; and
c) internal and external customer feedback (customer complaints) on product performance and delivery etc.

2.2 QUALITY SYSTEM

The manufacturer shall establish, document and maintain a quality system as a means of ensuring that product conforms to requirements of the relevant Sri Lanka Standard. The manufacturers shall prepare a quality manual covering the twelve quality elements specified herein. The quality manual should be supported by several documents of lower level; namely procedures, work instructions, forms, specification, methods etc. More details could be dealt with in these documents.

The procedures should cover all twelve elements given herein. The quality manual, the top level document, should link to the procedures, and procedures to the work instructions, forms etc. The

quality manual should not contain any confidential information and such information could be given in the procedures.

2.2.1 Procedures

The manufacturer shall prepare documented procedures to be in line with the requirement of the product certification scheme and the quality policy of the manufacturer. These procedures are required for effective implementation of the quality system.

2.2.2 Quality Plans

The manufacturer shall define and document how the quality of product which is defined by the relevant Sri Lanka Standard will be achieved. Quality plans may be in a suitable form (e.g. flow charts) to the manufacturer. The plan should have a sequence of activities in relation to a time frame. The plans also could be at different levels, that is for the whole production, testing and inspection, in process inspection and testing, final product testing etc. The plans should carry information with regard to activities, time schedules, equipment to be used, recording of quality requirements frequency of testing at different stages and sampling etc.

2.3 PURCHASING

The manufacturer shall establish and maintain documented procedures to ensure that purchased materials/components/products conform to specifications of the manufacturer, or relevant Sri Lanka Standard(s), National or International standards, or any other standards acceptable to the SLSI, and also any regulatory requirements, if applicable.

2.3.1 Supplier Evaluation

The manufacturer shall evaluate suppliers on the basis of their ability to meet manufacturer's requirements. Selection of suppliers could be based on:

a) previous performance of supplying materials;
b) third part certification; and
c) satisfactory assessment by the manufacturer.

The manufacturer shall maintain quality records of acceptable suppliers. Performance of suppliers shall be reviewed at appropriate intervals for updating the list of suppliers.

2.3.2 Verification of purchased material

The manufacturer shall define and document procedures for verification of all items purchased which will affect the quality of product.

If the need arises, the manufacturer may verify the purchased material at suppliers (vendor) premises on agreement with the supplier. In case, if the manufacturer's customer requests, by agreement or otherwise, the manufacturer may arrange verification at supplier's premises for the customer to do so.

2.4 PROCESS CONTROL

The manufacturer shall identify and plan the production process and ensure that these processes are carried out under controlled conditions. Controlled conditions include the following;

a) Documented procedures for processes which could adversely affect the product quality.
b) Use of suitable production equipment and working conditions.
c) Compliance with standards, codes of practice, quality plans and documented procedures.
d) Monitoring and control of suitable process parameters and product parameters.
e) The approval of processes and equipment
f) Criteria for workmanship, written standards/samples to display the required finish of the product.
g) Suitable maintenance of equipment to ensure continuing process capability.

The process should be controlled to prevent occurring non-conformities. The characteristics that are most critical to the product quality should be identified and controlled. Process control activities may include procedures for acceptance of materials and determining their characteristics while in process.

Where suitable, process control should include satisfactory process control methods supplemented by procedures to maintain the suitability of in-process materials, and activities needed for appropriate storage, handling and segregation.

Where the achievement of desired levels of process control is dependent upon consistent and suitable operation of process equipment and essential materials, the supplier should include the proper maintenance of such process equipment and essential materials.

2.5 INSPECTION AND TESTING

The manufacturer shall adopt documented inspection and testing procedures for the manufacturing process from receiving of materials to final product, in order to verify that the quality levels of different characteristics of the product, as specified by the relevant Sri Lanka Standard(s), are met. The inspection and testing procedures shall include each and every inspection or test which is required to be performed with a view to maintaining the quality of product. Each test and/or inspection shall be detailed in a quality plan. Records pertaining to all tests or/and inspections shall be maintained.

2.5.1 Receiving inspection and testing

All incoming raw materials, products or parts thereof shall be inspected or otherwise verified for conformity prior to their use or process with specified requirements. In case any material, product or part thereof is to be released on urgent grounds, such goods shall be clearly identified and recorded for immediate recall in the event if any non-conformity is found subsequently.

Verification of conformance to specified requirements shall be done in accordance with the Scheme of Testing and Inspection (STI), quality plan or/and the documented procedure.

In case of purchasing of any item from subcontractors, those items may be inspected at the premises of the subcontractor but the amount and nature of receiving inspection and control to be exercised shall be monitored by the manufacturer. In such cases the manufacturer shall be provided with documented evidence of conformance. The manufacturer shall bear the sole responsibility of this exercise.

2.5.2 In-process inspection and testing

The manufacturer shall inspect ant test the product during processing for required quality characteristics as proposed by the STI, company quality plan and the procedures for inspection and testing. Unless required inspections and tests have been completed or necessary reports have been received and verified, continuity of processing of the product should be withheld. In case of release of products on urgency, those products shall be able to be recalled in the event of any non-conformity is found subsequently.

2.5.3 Final Inspection and Testing

The manufacturer shall conduct all final inspections and tests on the finished product in accordance with the quality plan or procedure for inspection and testing to verify that the products satisfy the requirements of the relevant Sri Lanka Standard. Unless the products are in conformity with the relevant Sri Lanka Standard, products shall not be dispatched for further proceedings.

2.6 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

All inspection, measuring and test equipment used in the manufacturing process shall be controlled, calibrated and maintained in order to ensure that the measurements taken with those equipment are consistent and within the specified range. In case when test software or test hardware are used for inspection, they shall be checked as per a scheduled plan for their capability of verifying the acceptability of product.

All records including technical data with respect to these equipment shall be made available for verification, if necessary.

The manufacturer shall establish proper control procedure for use, monitoring and maintenance of inspection, measuring and test equipment. As such it is the responsibility of the manufacturer to determine measurements, accuracy required, calibration status, frequency of checking etc. These equipment shall be handled or stored as per instructions given therein and to be compatible with necessary environmental conditions. All necessary records shall be maintained.

2.7 INSPECTION AND TEST STATUS

The manufacturer shall introduce suitable means to identify products, which are awaiting for inspection inspected and passed or failed. This identification scheme shall be in line with the conduct of inspections and tests as given in the quality plan or procedures for inspection and testing and only those products which have passed the required inspection and tests shall be dispatched, used or installed. If any product is to be dispatched, used or installed prior to inspection or testing on urgent grounds, it shall be clearly identified to be recalled in the event of any non-conformity is found subsequently.

2.8 CONTROL OF NON-CONFORMING PRODUCT

The manufacturer shall take suitable steps to prevent those products which have failed to conform to the requirements of the relevant Sri Lanka Standard(s) are dispatched. Procedures shall be clearly defined to describe how non-conforming products are identified, documented, evaluated, segregated, disposed and notified to relevant parties.

The non-conforming products shall be reviewed in order to rework, repair, regarded, reject or scrap in accordance with the procedure. The manufacturer shall clearly define who shall take such decisions. All repaired and/or reworked products shall be re-inspected in accordance with the STI, quality plan and/or procedures for inspection and testing.

2.9 HANDLING, STORAGE, PACKING, PRESERVATION AND DELIVERY

The manufacturer shall maintain documented procedures for,

a) Handling of product;
b) Storage or product;
c) Packaging of product;
d) Preservation of product (if applicable); and
e) Delivery of product.

2.9.1 Handling

The manufacturer shall identify and document necessary procedures on how to prevent damage or deterioration of the product during handling. This includes in-process materials and finished products.

2.9.2 Storage

The manufacturer shall use designated areas for storage of foods. These areas shall be safe enough to prevent damage to or deterioration of the products due to temperature, humidity or any other undesirable situations. Necessary methods shall be introduced to receive and to dispatch goods from such areas.

2.9.3 Packing

The manufacturer shall make sure that the packing, packaging and marking shall conform to the relevant Sri Lanka Standard(s). Packing, packaging and marking should provide appropriate protection against damage, deterioration or contamination during storage, transportation or until the management's responsibility ceases.

2.9.4 Preservation

The manufacturer shall ensure that products are preserved, if applicable and segregated.

2.9.5 Delivery

The manufacturer shall ensure the protection of the quality of product after final inspection and /or test and while delivery to destination.

2.10 CONTROL OF QUALITY RECORDS

The manufacturer shall maintain documented procedure(s) for;

a) Identification of quality records;
b) Collection of quality records;
c) Indexing of quality records;

d) How to access quality records;
e) How to arrange/file quality records;
f) How to store quality records;
g) Maintenance of quality records; and
h) Disposition of quality records.

All the records which demonstrate conformance to specified requirements (these requirements may be company standards), and effective operation the quality system, could be considered as quality records, for example, test records, internal quality audit reports, management review reports etc.,
These quality records shall be stored in a suitable environment to prevent damage or deterioration, and in such a manner that they are readily retrievable. Retention time of these records shall be determined. Provisions shall be made to the customers or interested parties to evaluate these quality records.

2.11 INTERNAL QUALITY AUDITS

Internal Quality Audits shall be carried out to verify whether quality activities and related results comply with the documented system and also to assess the effectiveness of the Quality System.
Therefore the manufacturer shall maintain documented procedures for;

a) planning of internal Quality Audits; and
b) implementing internal Quality Audits.

The manufacturer shall use trained and qualified auditors to carry out audits in the areas (departments) where they have no direct responsibility.
Audit findings shall be recorded and brought to the notice of the responsible person in that area for any corrective action.
Management shall ensure that corrective action on non-conformities are taken on time. Follow up audit shall be carried out to certify the effectiveness of the corrective action.

2.12 TRAINING

The manufacturer shall maintain documented procedures for;

a) identification of training needs; and
b) provide training for all employees who are performing activities affecting quality

Employees who are performing special activities shall provide with,

a) appropriate education, and
b) training and experience as required

All necessary records shall be maintained.
The manufacturer shall take suitable steps to train employees in quality and other relevant areas to ensure that their competence is adequate enough to perform the assigned tasks.

3. REQUIREMENTS FOR OPTION 2

Quality Management System requirements defined in the ISO 9001:2015 Standard (*ISO 9001:2015 - Quality Management Systems – Requirements*)