0.1 Approval and Issue

Reviewed by:

Technical Advisory Committee

Approved by:

Chief Executive Officer

Note:

1. Management Representative is responsible for issue and distribution of this document including amendments.

2. Holder of this copy is responsible for incorporation of all the amendments and Currency of the document.

0.2 Amendment Record:

Amendment No.	Date of Amendment	Nature of Amendment	Page Ref.
01	21.11.2016	Aligned to ISO 9001:2015 and ISO 17021-1:2015	2-12

1.0 Purpose and Scope

This document deals with the quality system procedures including operation of the quality plan and testing which a manufacturer is required to provide and follow, in order to ensure that all the certified products are identical within accepted tolerances to the sample(s) against which the certification was granted. This document should be taken to represent the minimum standard acceptable.

NOTES:

Through the document reference is made to the clauses of ISO 9001:2008 with clear guidance provided as to their common interpretation, specifically related to product certification, which is of critical importance to Certification Body.

2.0 Responsibility:

Assessor - for reference to the minimum standard acceptable for manufacturer's quality management system.

3.0 Associated documents:

SCS/D01: Safety certification manual

Form F18: Factory inspection report

4.0 Definition

For the purpose of this document the definitions contained doc. SYS/D01 shall apply, except for

4.1 Manufacturer's Premises/Factory Location

In this document the Manufacturer's premises / Factory Location is the location where the final assembly and/or testing of certified products normally takes place and the Certification Mark is applied.

4.2 Sub-Contractor

A sub-contractor is any manufacturing organization undertaking the production of any sub-assembly in accordance with the specific requirements of the manufacturer of acertified product.

4.3 Out-Worker

An out-worker is any person who undertakes work in a place other than the factory location component parts supplied by the manufacturer of the

certified product but who has noresponsibility for the quality of the completed work.

5.0 Resources

For the purposes of the activities defined in this document the personnel resources are identified in SYS/D03.

6.0 Manufacturer's Responsibility

It is the manufacturer's responsibility to ensure that products are manufactured in conformity with the Standards to which they were certified and to define the manufacturing quality system as per questionnaire enclosed at Annexure' A.

7.0 Structure and Layout (ISO 9001:2015 – 8.4, 8.5.1)

It is the responsibility of the Licensee to advise the Certification Body of any change of factory location of the certified product.

Audit of sub-contractors and out-workers is the manufacturer's responsibility. Manufacturer shall exercise adequate control over sub-contractors and out-workers preparing assemblies or parts which have a safety implication and shall give evidence to the auditor. Manufacturing locations of certified products will be audited to ensure that the necessary routines and procedures are being maintained at an acceptable standard. Should an audit prove to be unsatisfactory, the certification of products may be suspended until such time as procedures have again been found to be satisfactory. However, production under the certification scheme may, in some cases be allowed to continue whilst corrective action is taken, provided adequate written assurances are given by the Licensee.

During routine audits of a manufacturer's premises/factory location, sample(s) of certified products and /or assemblies and components may be selected for audit testing to verify compliance with the relevant standard.

Special audits may be deemed necessary when a large number of minor criticisms and/ or major are found to the extent that conformity of the product with the standard may beendangered.

8.0 QUALITY SYSTEM (ISO 9001:2015- 5.0,9.3.6,8.3,8.5.2,8.5.3)

The manufacturer must have a documented Quality System in the factory location as per requirements in Annexure-A. Even where the manufacturer has a Quality System certified by an accredited body to ISO 9001:2015 the assessment by the Certification Body auditor must still take place to ensure that the requirements of this document is met.

8.1 Incoming Goods Inspection (ISO 9001:2015 - 8.4 ,7.5)

Manufacturers must ensure that all purchased material and services conform to specifiedrequirements. This must be taken into account when selecting sources of supply and must involve close liaison on a regular basis with suppliers. It is the responsibility of manufacturers who undertake final assembly to ensure that sub-assemblies completed by sub-contractors or out-workers meet the Quality Plans and/or relevant safety requirements.

Materials, components and sub-assemblies which have a safety implication on the finishedproduct and which are purchased from or prepared by an outside supplier, shall beverified as complying with the appropriate specification.

Note: Other materials and components may need to be checked in the Incoming Good Area; the extent of these further checks will vary according to the nature of the item and therelationship of its quality to the specification that the manufacturer wishes to achieve for his final products. How a manufacturer achieves these objectives is a matter for him to determine; the auditor will be seeking an effective procedure and evidence of its implementation demonstrating compliance with the components specifications.

8.2 Certificates of Conformity (ISO 9001:2015 - 8.4)

If a manufacturer relies on Certificates of Conformity as supplementary evidence to ensure the compliance of components with their specifications the certificate must clearly identity the product to which they refer, the quantity of items covered, must be signed (or stamped) with what is clearly an Inspectors' mark by a person with responsibility for Quality with in supplier's organization.

8.3 Production Line Inspection & Routine Tests (ISO 9001:2015 8.6,8.5.1)

Production should be inspected/checked at all stages of manufacture to ensure that piece parts, components, sub-assemblies, wiring runs etc. remain in accordance with the original product(s) for which certification was granted.

Additionally manufacturers may deem it prudent to introduce other checks to ensure that the general standard of workmanship is good.

The method of monitoring adopted by a manufacturer will obviously depend on localcircumstances and the type of product being manufactured.

In addition to these inspections/checks, routine tests may also be

necessary. These are line tests performed on 100% of production and are normally carried out at the final stage of manufacture. Normally no further operations, except for labeling and packaging, may be carried out after these tests. The detailed standardized requirements for routine tests are in the standard operating procedure (SOP) of the relevant standard (SCS/D07). These tests should include such functional tests necessary to ensure that the final product is operating safely.

It is required that there is evidence that the system of inspection/checks and routine tests is planned and ensure that the finished product complies with the standard to which it wasoriginally certified.

8.4 Quality Control & Selected Type Tests (ISO 9001:2015- 7.2,7.5,8.6)

Quality control inspectors and/or assembly personnel must be adequately trained anddemonstrate competence in their duties and have readily available up-to-date instructions,photographs, drawings or samples on all those parts which have a bearing on the safety ofthe finished product. Particular attention should be paid to those operations which, in themselves, have a critical bearing on the safety of the product, for example: the dressing and routing of wiring, the correct location of a safety control, that connections are tight, there are no sharp edges that can damage wiring or harm the user and that any earth bonding is satisfactory.

In addition to these quality control requirements selected type tests may also be necessary. These are tests in addition to the routine tests on samples taken randomly from the production line, in accordance with written procedures. Selected type tests shall be standardized tests for certain product categories as per the standard against which the product is certified. Also, it is required that once a year the approved product is tested to complete standard either at approved manufacturer premises or at approved test labs.

8.5 Internal Quality System Audit (ISO 9001:2015 - 9.2)

There shall be defined procedures in the factory location which ensure that all procedures used in the manufacturing process are regularly monitored.

The Quality System and related documents shall be audited at least annually.

8.6 Non-conforming Products (ISO 9001:2015 - 8.7)

Any non-conforming product shall be clearly identified and segregated to preventunauthorized use, delivery or mixing with conforming products. Repaired and reworked product shall be re-inspected in accordance with documented procedures and found to comply with the requirements before

being accepted.

9.0 Changes to Certified Product

Constructional changes on certified products (which may affect compliance with the relevant standard) must be notified to the issuing Certification Body for authorization, prior to their implementation.

10. Test Equipment (ISO 9001:2015 - 7.1.5)

The equipment used for routine and selected type testing must be regularly calibrated and checked for correct operation.

10.1 Calibration

Test and measuring equipment used for determining the safety of the products being manufactured shall be calibrated on a regular basis, at least once per year, or more depending on usage and the results of previous calibrations. All calibrations undertaken on such equipment must be traceable to National Standards. Records of calibrations undertaken for each instrument must be retained. The records shall include equipment identification; location, calibration frequency, reference standards/ equipment, measured values, deviation, result, signature and date. The test and measuring equipment shall be provided with a label or similar method indicating the last and next “calibration due” date.

10.2 Functional Check

An operational or functional check undertaken on a daily basis is desirable. Checks shall be conducted at intervals which will allow previous production to be retested, if incorrect functioning is detected. The operational or functional check can be satisfied by subjecting the test equipment to pre-determined fault conditions. The results of all these checks shall be recorded. Operators shall be instructed on what action is to be taken if a functional test is found to be unsatisfactory. In all cases subsequent corrective action taken must be recorded.

11. RECORDS (ISO 9001:2015 – 7.5)

The manufacturer shall maintain records to demonstrate conformance with specified equipment. Records of all the tests undertaken must be maintained, trends monitored and the results reported regularly to the production control and management authorities. These records must be made available to the Auditor at any time. Records shall be legible and identifiable to the product and, or test equipment involved.

- Routine Tests

- Other selected audit/type tests
- Functional checks of test and measuring equipment,
- Calibration of test and measuring equipment,
- Customer complaints and corrective action,
- Records of action taken on identified non conforming products.
- Internal audit and corrective action

Note: The question of the length of time for retention of records requires specific attention in the light of legal circumstances and recognition arrangements. Records stored on computer or micro-film are acceptable, in all cases particular care in back up/ storage is necessary.

12.0 Handling and Storage (ISO 9001:2015 - 8.5.4)

The finished products shall be packaged, stored and handled in such a way as to ensure that they will continue to comply with the applicable.

13.0 Factory Inspection Documents

The manufacturer shall be made aware of the report forms and guidance documents used in audits, including the relevant standard operating procedures.

ANNEXURE - 'A'

MANUFACTURER QUALITY SYSTEM QUESTIONNAIRE

1.0 MANUFACTUFRER'S REGISTERED/BRAND NAME AND FACTORY

LOCATIONS:

TELEPHONE:

TELEFAX:

TELEX:

E MAIL:

DIRECTIONS FOR REACHING THE FACTORY (NEAREST RAILWAY STATION, AIRPORT, ATTACH PHOTOCOPY OF LOCAL MAP (IF POSSIBLE)

2.0 MANUFACTURER'S OFFICE ADDRESS

(IF DIFFERENT FROM ABOVE)

TELEPHONE:

TELEFAX:

TELEX:

E-MAIL:

3.0 APPLICANT'S NAME AND ADDRESS (LICENCE HOLDER):

(IF DIFFERENT FROM ABOVE)

TELEPHONE:

TELEFAX:

TELEX:

E-MAIL:

4.0 GIVE THE NAME, DEPARTMENT AND OFFICE ADDRESS OF THE CONTACT PERSONS LOCATED IN THE FACTORY AND THE MANAGEMENT REPRESENTATIVE RESPONSIBLE FOR PRODUCT

CERTIFICATION.

CONTACT PERSON IN FACTORY FUNCTION:

DEPUTY CONTACT PERSON IN FACTORY FUNCTION:

MANAGEMENT REPRESENTATIVE FUNCTION:

NOTE: - THIS MANAGEMENT REPRESENTATIVGE MAY BE LOCATED OUTSIDE THE FACTORY e.g. AT THE HEAD OFFICE

5.0 APPROXIMATE TOTAL NUMBER OF EMPLOYEES IN THE FACTORY AND SIZE RELATED TO THE EXTENT OF THIS APPLICATION:

6.0 SPECIFY WHICH COMPONENTS ARE PURCHASED FROM OUTSIDE SUPPLIERS SUCH AS SWITCHES, LAMPHOLDERS, CORDSETS, MOTORS, TRANSFORMERS, SUB-ASSEMBLIES OR PARTS OF COMPONENTS SUCH AS SPRINGS, CONTACTS, ETC.,

7.0 DESCRIBE THE SYSTEM WHICH THE MFR PROPOSES TO UTILIZE TO DEMONSTRATE COMPLIANCE WITH THE FOLLOWING ITEMS OF DOC SCS/DO2

PROVIDE CROSS REFERENCE TO DOCUMENTED QUALITY SYSTEM IN OPERATION AND QUALITY PLAN FOR EACH PRODUCT LINE, AND ENCLOSE ONE COPY OF DOCUMENTS.

A) INCOMING GOODS INSPECTION

CERTIFICATE OF CONFORMITY

B) PRODUCTION LINE INSPECTION AND ROUTINE TESTS

C) QUALITY CONTROL AND SELECTED TYPE TESTS

D) NON CONFORMING PRODUCTS

E) INTERNAL QUALITY SYSTEM AUDIT

F) CHANGES TO CERTIFIED PRODUCT

G) TEST EQUIPMENT CALIBRATION

Signatures with name _____

Designation _____

Date _____