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1. Scope

This document deals with the factory inspection procedures and tests. Manufacturers ensure that all certified products are identical, within accepted manufacturing tolerances, to the sample against which the product certification was granted.

2. Definitions

The terms used in this document have the meanings defined in ISO 9000:2000 except for:

a. LabTest

LabTest Certification Inc.

b. Factory Location/ Manufacturer's Premises

The location(s) where the final assembly and/or testing of certified products normally takes place and the Certification/Listing Mark is applied.

c. Manufacturer

Any manufacturing organization or person responsible for the final assembly (including subcontractors and out-workers), testing and/or marking of products certified by LabTest.

d. Subcontractor

Any manufacturing organization undertaking the production of any sub-assembly in accordance with the specific requirements of the Manufacturer of a certified/listed product.

e. Out-Worker

Any person who undertakes work in a place other than the factory location on component parts supplied by the Manufacturer of the certified/listed product.

f. License Holder

Any organization or person who has entered into an agreement with LabTest for the certification/Listing of the product.

g. Documented procedure

Any written document containing instructions and/or requirements related to the production and control processes of certified/listed products.

h. Factory Audit Manual

A document used by the Inspectors to assist them with an effective execution of follow up inspections and to track the history and outcomes of the all certification and listing activities relevant to a specific product. This document includes copies of the following documents and records:

- 3002 Certification and Listing Agreement and amendments
- 3003 Factory Inspection Frequency and amendments
- 3004 Initial Factory Inspection
- 3005 Past Follow up Inspections
- 3006 Past Client Complaints
- 3008 Listing Report and amendments
- Issue Management Reports related to product certification
- Manufacturer internal Corrective Actions related to product certification
- Manufacturer responses to Issue Management Reports and to Corrective Actions
- Correspondence related to suspension or withdrawals of product certification

3. General Arrangements

Factory locations of certified/listed products are inspected at the frequencies determined at the time of initial product certification, periodically revised thereafter, and documented on form # 3003 Factory Inspection Frequency.

Should inspection prove to be unsatisfactory, the certification/listing of products may be suspended until such time as procedures have again been found to be satisfactory. However, production under the certification/listing scheme may, in some cases, be allowed to continue whilst corrective action is taken, provided adequate written assurances are given by the License Holder.

During routine inspections of a Manufacturer's premises/ factory location, sample(s) of certified/listed products and/or assemblies and components may be selected for re-examination testing to verify compliance with the relevant standard.

Special inspections may be deemed necessary when a large number of unsatisfactory findings are found to the extent that conformity of the product with the standard may be endangered.

It is the responsibility of the License Holder to notify LabTest of any change of factory location of the certified product.

4. Manufacturer's Responsibility

a. General

Manufacturers are responsible for controlling by inspection or otherwise all subcontractors and out-workers. Manufacturers exercise adequate control over subcontractors and out-workers preparing assemblies or parts which have a safety implication.

b. Incoming Inspection

Manufacturers ensure that all purchased material and services conform to specified requirements. This is taken into account when selecting sources of supply and may involve close liaison on a regular basis with suppliers. Manufacturers who undertake final assembly ensure that sub-assemblies completed by sub-contractors or out-workers meet the applicable Quality Plans and/ or relevant safety requirements. Materials, components and sub-assemblies which have a safety implication on the finished product and which are purchased from or prepared by an outside supplier, are verified as complying with the appropriate specification.

Note: Other materials and components may also need to be checked at Incoming Inspection. The extent of these further checks will vary according to the nature of the item. The methods by which Manufacturers achieve these objectives is not prescribed. Procedures may be required to ensure compliance with the specifications of components.

c. Production Line Inspection and Routine Tests

Production items are inspected at appropriate stages of manufacture to ensure that piece-parts, components, sub-assemblies, wiring runs, workmanship, etc. are in accordance with the sample for which certification/listing was granted. Quality Assurance and assembly personnel are adequately briefed on 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 of the finished product. The method of inspection adopted by a Manufacturer depends on local circumstances and the type of product being manufactured. Particular attention is paid to those operations which 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 correctly made, clearances are adequate, nuts, screws and 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 the above-mentioned inspections, routine tests may be required. These are line tests performed on 100 % of the production and are normally carried out at the final stage of manufacture. These tests include such functional tests as are deemed necessary to ensure that the final product is operating safely. Normally no further operations, except for marking and packing, may be carried out after these tests.

Note: In the absence of relevant standards by the Technical Committees covering the subject, National Certification Bodies' specifications apply.

The system of inspection and routine tests is planned and ensures that the finished product complies with the standard to which it was originally certified/listed. Records of tests and inspections undertaken are maintained. Trends are monitored and the results reported regularly to the production control and management authorities. Any

non-conforming product is clearly identified and segregated to prevent unauthorized use, delivery or mixing with conforming products. Repaired and reworked product are re-inspected in accordance with documented procedures including at least the same requirements as applicable to new produced products.

d. Functional Check on Test and Measuring Equipment for Safety Tests

An operational or functional check are conducted at intervals which will allow previous production to be re-tested if incorrect functioning is detected, typically on a daily basis. The operational or functional check can be satisfied by subjecting the test equipment to pre-determined fault conditions. The results of all these checks are recorded. Operators are instructed on what action is to be taken if a functional test is found to be unsatisfactory. Subsequent corrective action taken are recorded.

e. Marking of products

The Certification/Listing Mark are applied according to the requirements of LabTest. Manufacturer ensures that the Certification/Listing Mark is applied only to products that comply with the requirements.

f. Calibration of Safety Test and Measuring Equipment

Test and measuring equipment used for determining the safety of the products being manufactured is calibrated regularly, the frequency depending on usage and the results of previous calibrations. All calibrations undertaken on such equipment are traceable to National Standards. Records of calibrations undertaken for each instrument are kept. The records include equipment identification, location, calibration frequency, reference equipment, measured values, deviation, results, signature and date. The test and measuring equipment is marked by a calibration label or similar method indicating the next 'calibration due' date.

g. Handling and Storage

Finished products are stored and handled in such a way as to ensure that they will continue to comply with the applicable standards.

h. Product Verification Tests

These tests are in addition to the production line inspection and routine tests and are performed on samples taken randomly from the production line, in accordance with documented procedures. The tests may be carried out at a location other than the Manufacturer's premises but results are available together with the information about test and measuring equipment used, including calibration. Product verification tests may be standardized or may not be required for certain product categories.

In cases where there are no requirements, Manufacturers determine the need, nature and frequency of these tests and the sampling rate, taking into account the

construction of the product, the nature of the standard, the results of the original type tests, inspections and routine tests, the quality control and the quantity of products manufactured. Since the product verification tests need not to be identical to the type tests specified in the relevant standard, Manufacturers may choose the most appropriate methods.

Manufacturers ensure that appropriate corrective actions are taken in the case that the results of the product verification tests are found to be unsatisfactory. A documented procedure describing these actions is available.

LabTest representative will check that the Manufacturer's obligation is adequately fulfilled.

i. Records

Manufacturers maintain appropriate records to verify conformance with specified requirements. These records are made available to the LabTest Inspectors. Records are legible and identifiable to the product and/or test equipment involved. These records are kept for a minimum period between eight follow up inspections. At least the following records are maintained:

- Incoming inspection of components (including Certificates of Conformity)
- Routine Tests
- Product Verification Tests
- Functional checks of test and measuring equipment
- Calibration of test and measuring equipment
- Results of internal audits
- Customer complaints and corrective action

Note: Records stored on computer or microfilm are acceptable

j. Corrective actions in response to inspector's evaluation

Manufacturers take corrective action to any unsatisfactory finding found during the LabTest follow up inspections. LabTest is informed about the corrective actions taken. Depending on the number and the seriousness of the findings LabTest may decide to verify the implementation of the corrective actions during a special inspection or during the next routine inspection.

k. Quality system

If the Manufacturer has a Quality System certified by an accredited body according to ISO 9001:2000, LabTest inspectors check if the relevant procedures cover the requirements of this document.

l. Audits of the Quality System

The Manufacturer regularly monitor all documented procedures used in the manufacturing and control process of certified/listed products.. This monitoring include at least verification that the procedures, instructions and guidelines are up-to-date and properly applied by personnel (including the keeping of records). The results of the monitoring are recorded, including corrective actions taken. Personnel independent from the production process carry out the monitoring.

m. Non-conforming Products

Non-conforming products are clearly identified and/or segregated to prevent unauthorized use. The process for handling non-conforming products is described in documented procedures.

n. Customer complaints

Manufacturers record any complaint regarding the certified/listed product. Manufacturers review regularly whether the complaints received are related to single errors or system errors. All decisions and corrective actions taken are recorded. The originator of the complaint is informed about the handling and the result of the complaint.

o. Changes to Certified/Listed Products

Prior to modifications to certified / listed products, Lab Test is notified and asked for approval of all constructional changes which may affect compliance with the relevant standard. The process by which the License Holder handles changes to certified/listed products is described in a documented procedure. All personnel involved in the implementation of changes is aware of this procedure.

The License Holder informs Manufacturers of certified/listed products regarding the details of the certified/listed construction. Documents in which the certified/listed construction is specified (such as a parts list) are available at the Manufacturers' premises. Manufacturers state in a documented procedure that no changes will be made to the certified/listed construction (including the application of alternative components) without written permission from the License Holder.

5. Factory Inspection Documents

Manufacturers are made aware of the report forms and guidance documents used in follow up inspections:

- 3002 Certification and Listing Agreement and amendments
- 3003 Factory Inspection Frequency and amendments
- 3004 Initial Factory Inspection
- 3005 Past Follow up Inspections
- 3006 Past Client Complaints
- 3008 Listing Report and amendments

- Issue Management Reports related to product certification
- Manufacturer internal Corrective Actions related to product certification
- Manufacturer responses to Issue Management Reports and to Corrective Actions