

**FCS-PRODUCT CERTIFICATION  
MANUFACTURING CONFORMITY ASSESSMENT  
PROCEDURES**

# **MANUFACTURING ASSESSMENT AUDIT PROCEDURES**

## **FCS HARMONIZED REQUIREMENTS**

### **1. INTRODUCTION**

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 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.

**Through the document reference is made to the clauses of ISO 9000 with clear guidance provided as to their common interpretation, specifically related to « product certification », which is of critical importance to NCB's.**

### **2. DEFINITIONS**

The terms used in this document have the meanings defined by ISO 8402 and IECEE 03 except for:

#### **2.1. 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.

#### **2.2. 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 a certified product.

#### **2.3. Out-Worker**

An out-worker is any person who undertakes work in a place other than the factory location on component parts supplied by the manufacturer of the certified product but who has no responsibility for the quality of the completed work and whose quality is monitored by the manufacturer."

### **3. 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.

#### **4. STRUCTURE AND LAYOUT**

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 at least once per year to ensure that the necessary routines and procedures are being maintained at an acceptable standard. *Any required increased frequency will be indicated in the bilateral agreement.* 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, see *CB-FCS-104*.

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

#### **5. QUALITY SYSTEM**

**All tests specified under this clause shall be witnessed by the inspector whenever practical.**

***The manufacturer must have a documented Quality System in the factory location. Even where the manufacturer has a Quality System certified by an accredited body according to ISO 9002 - ISO 9001 the assessment by the FCS Certification Body auditor must still take place to ensure that the requirements of CB-FCS 101 are met. Where the FCS Certification Body certifies the quality system the CB-FCS 101 assessment will be concurrent.***

An ISO 9002(1)  
audit checks  
additional clauses  
4.1, 4.3, 4.4, 4.7,  
4.8, 4.12

##### 5.1. Incoming Goods Inspection

Manufacturers must ensure that all purchased material and services conform to specified requirements. 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 finished product and which are purchased from or prepared by an outside supplier, *shall* be verified as complying with the appropriate specification. (See also clauses 15 and 16 of *IECEE-03*)

Note : other materials and components may need to be checked in the Incoming Goods Area; the extent of these further checks will vary according to the nature of the item and the relationship 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

### 5.2. Certificates of Conformity

If a manufacturer relies on Certificates of Conformity *as supplementary evidence* to ensure the compliance of components with their specifications, Certificates must clearly identify the products 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 within the supplier's organization. (See also clauses 15 and 16 of IECEE-03)

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### 5.3. Production Line Inspection and Routine Tests

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.

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

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The method of monitoring adopted by a manufacturer will obviously depend on local circumstances 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 Annex A (see also *CB-FCS 104*). These tests should include such functional tests necessary to ensure that the final product is operating safely in accordance with its specification.

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

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### 5.4. Quality Control and Selected Type Tests

Quality control inspectors and/or assembly personnel must be adequately *trained and demonstrate 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 of the 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

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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 in Annex B* (see also *CB-FCS 104*).

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Cross refer to  
ISO 9002 Clauses

### 5.5. Non-conforming Products

Any non-conforming product shall be clearly identified and segregated to prevent unauthorized use, delivery or mixing with conforming products. Repaired and reworked product shall be re-

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inspected in accordance with documented procedures *and found to comply with the requirements before being accepted.*

#### 5.6. Internal Quality System Audit

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.*

### **6. 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.

*Once authorized the manufacturer shall then notify other NCB's who have granted their marks.*

### **7. TEST EQUIPMENT**

The equipment used for routine and selected type testing must be regularly calibrated and checked for correct operation. 4.11

#### 7.1. 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, results, 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.

#### 7.2. 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 re-tested 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. 4.11

### **8. RECORDS**

The manufacturer shall maintain records to *demonstrate* conformance with specified requirements. 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.

*Of special importance are :-*

- Routine Tests,
- *Other* selected *Audit/Type* Tests,

Cross refer to  
ISO 9002 Clauses

- 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.
- Incoming inspection of components/materials and certificates of conformity
- *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 microfilm are acceptable, *in all cases particular care in back up/storage is necessary.*

## **9. HANDLING AND STORAGE**

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

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## **10. FACTORY INSPECTION DOCUMENTS**

The manufacturer *shall be made* aware of the report forms and guidance documents used in IEC Audits.

Annexes: A -Requirements for Routine Tests  
B -Requirements for Selected Type Tests

**ANNEX A**  
ROUTINE TESTS

Short designation	Name	Requirement
CABL	Cables and Cords	NCB Requirements
CAP	Capacitors as components	NCB Requirements
CONT	Switches for appliances and automatic controls for electrical household appliances	NCB Requirements
HOUS	Household and similar equipment	IEC Technical Committee to examine EN 50106 with view to adopt clauses
INST	Installation accessories and connection devices	NCB Requirements
LITE	Lighting	NCB Requirements
MEAS	Measuring instruments	NCB Requirements
MED	Electrical equipment for medical use	NCB Requirements
OFF	IT and office equipment	CB-FCS 104
POW	Low voltage, high power switching equipment	NCB Requirements
PROT	Installation protective equipment	NCB Requirements
SAFE	Safety transformers and similar equipment	NCB Requirements
TOOL	Portable tools	IEC Technical Committee to examine EN 50144-1 with view to adopt clauses
TRON	Electronics, entertainment	NCB Requirements

*The minimum requirements detailed in CB-FCS 104 shall be met.*

**ANNEX B**

## SELECTED TYPE TESTS

Short designation	Name	Requirement
CABL	Cables and Cords	NCB Requirements
CAP	Capacitors as components	NCB Requirements
CONT	Switches for appliances and automatic controls for electrical household appliances	NCB Requirements
HOUS	Household and similar equipment	IEC Technical Committee to examine EN 50106 with view to adopt clauses
INST	Installation accessories and connection devices	NCB Requirements
LITE	Lighting	NCB Requirements
MEAS	Measuring instruments	NCB Requirements
MED	Electrical equipment for medical use	NCB Requirements
OFF	IT and office equipment	NCB Requirements
POW	Low voltage, high power switching equipment	NCB Requirements
PROT	Installation protective equipment	NCB Requirements
SAFE	Safety transformers and similar equipment	NCB Requirements
TOOL	Portable tools	IEC Technical Committee to examine EN 50144-1 with view to adopt clauses
TRON	Electronics, entertainment	NCB Requirements

*The minimum requirements detailed in CB-FCS 104 shall be met.*