

IECEE

CB-FCS-SCHEME

OD-CB-FCS2008-Ed1.0

OPERATIONAL & RULING DOCUMENTS

Initial Factory Audit/Inspection Form & Procedure

OD-CB-FCS2008-Ed.1.0

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**IEC System for Conformity Testing and Certification
of Electrical Equipment
CB FCS Scheme**

INTRODUCTION

The IECEE CB Full Certification Scheme (CB-FCS) requires Initial Factory Audit/Inspection as part of the Certification Process. Members of CB-FCS have agreed to accept upon request Initial Factory Audit/Inspection Reports carried out by Body A for the purpose of granting their (Body B) certification mark. The Initial Factory Audit/Inspection Report is one element of the Conformity Assessment Report (CAR) which also includes a Test Report and a Conformity Assessment Certificate (CAC).

The objective of this Initial Factory Audit/Inspection is to evaluate the capability of a Factory to produce products within a consistent Manufacturing process. The aim of the Initial Factory Audit/Inspection is also to verify that the Manufacturer's Quality Management System, Assembly line, Inspection and Testing Procedures, Facilities and Equipment are set to comply with the requirements of the CB-FCS. It is further intended that this Initial Audit/Inspection should cover any declared additional certification-related requirements of CB-FCS Members.

The visit has to be pre-announced to ensure that the contact person and all relevant Personnel, documentation and test equipment are available. The Initial Factory audit/inspection should be focused on the relevant Scope of Product Category(ies) and Standard(s) associated with the product for which the CAR and CAC are to be issued.



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INITIAL FACTORY AUDIT/INSPECTION REPORT

Issued by:

(Responsible National Certification Body)

Guidance: For applicable scope, see page 2 overleaf.

Name and Location of the Factory at which the Initial Audit/Inspection was Carried Out:

Date(s) of the Initial Factory audit/inspection:

Guidance: Please report the date in the ISO format e.g. 2005-08-25

Report Ref. No.:

Guidance: The report reference number is a number assigned by the responsible national certification body for the purpose of traceability.

Scope of Product Category(ies):

Model/Type Reference of the Product(s):



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This initial factory audit/inspection covers the following:
1.0 GENERAL INFORMATION
2.0 PRODUCTION DURING THE AUDIT/INSPECTION
3.0 RECEIVING/GOODS INWARDS INSPECTION
4.0 PRODUCTION-LINE INSPECTION AND ROUTINE TEST(S)
5.0 NON-CONFORMING PRODUCTS
6.0 FUNCTIONAL CHECK OF THE REQUIRED TEST EQUIPMENT
7.0 CALIBRATION OF THE REQUIRED TEST EQUIPMENT
8.0 HANDLING AND STORAGE OF FINISHED PRODUCTS
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10.0 QUALITY MANAGEMENT SYSTEM
11.0 COMPLAINTS
12.0 CONTROL OF PRODUCT CHANGES
13.0 CONCLUSION



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Attachments to this report (*as applicable*):

- PRODUCT DESCRIPTION/CERTIFICATION REPORT
- RECEIVING INSPECTION DATA SHEET
- TEST DATA SHEET FOR ROUTINE TESTS AND PVT (Product Verification Tests)
- INITIAL AUDIT/INSPECTION FINDINGS

INSTRUCTION TO INSPECTOR/AUDITOR



The Inspector/Auditor is requested to answer the questions of this report by ticking the “Yes”, “No” or “N/A” check box respectively. In all cases, information and observations shall be given in each clause to substantiate the answer.

If “YES”, reference shall be given to appropriate parts of the quality system (Quality Manual, Quality Plans/Procedures/Working Instructions, etc). Any judgment made by the auditor/inspector shall be explained.

If “NO”: A Finding Report shall be issued.

If “N/A”: Rationale must be provided in all cases as to why the item is not applicable to the particular product(s) covered by the Audit/Inspection.

The text in *Italics* is intended to provide instructions on how to complete this report and includes explanatory notes, examples, and general guidance. This text should be deleted in the final version of the report before it is issued.

Inspector's/Auditor's Name:

Inspector's/Auditor's organisation if other than the Responsible NCB:



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1.0 GENERAL INFORMATION			
1.1 Registered name and full street address of the factory at which the audit/inspection was carried out:			
<i>Full Name and Street Address in English</i>		<i>(If applicable Full Name and Street Address in Local Language)</i>	
1.2 Registered name and address of the responsible manufacturer: <i>(if different from the factory)</i>			
1.3 Registered name and address of the applicant: <i>(if different from the manufacturer)</i>			
1.4 Factory representative(s) present during the Audit/Inspection:			
Name:		Position	
Name:		Position	
Name:		Position	
2.0 PRODUCTION DURING THE AUDIT/INSPECTION			
Were the products for which the certificate is sought, or similar products, in production at the time of the visit?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>If Yes, Indicate types of certificates issued (if any) and/or certification marks on the products seen during the visit</i>			



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3.0 RECEIVING/GOODS INWARDS INSPECTION			
3.1 Are materials, components and sub-assemblies which have an impact on the safety of the finished product verified by the factory as complying with the applicable requirements, including those of the certification body(ies) concerned?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>For regional schemes, when needed, Receiving Inspection Data Sheet may be attached to the present report. Example: Identification check, Suppliers Quality Plan, Physical Inspection etc. Inspectors should describe the nature of Manufacturer's inspection.</i>			
<i>Example: YES: "There is a documented procedure on receiving inspection and there was evidence that the procedure is being followed. Receiving/Goods inspection is covered by Q.P 1234."</i>			
3.2 If the factory relies on Certificates/Declarations of Conformity or Test Results from suppliers, do these clearly identify the product, specifications, quantity of items covered, dated and duly signed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>Declaration means First-Party Attestation (ISO/IEC 17000 Clause 5.4)</i>			
3.3 Are non-conforming products/components/materials clearly identified and/or segregated to prevent their use?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
3.4 Are records from incoming inspection appropriate and kept by the factory?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>



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4.0 PRODUCTION LINE INSPECTION AND ROUTINE TESTS			
4.1 ASSEMBLY: Do the personnel have readily available up-to-date procedures, assembly instructions, photographs, drawings or reference samples of the product for the overall parts which have an impact on the conformance of the finished products?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
4.2 PRODUCTION LINE TEST: Do the personnel have readily available up-to-date procedures, work instructions, and drawings related to required testing to be carried out on the intermediate stage and the final product related to conformance of the finished product?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
4.3 Are the test results monitored for trends or recurrences and reported to the production/quality management?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>Any recurring failures should be analysed for correlations with design, changes in product or procedure for corrective action.</i>			
4.4 Are repaired and reworked products re-inspected in accordance with documented procedures?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
4.5 Do the Production Line Inspection and Routine Tests performed by the factory sufficiently cover all the applicable requirements, including those of the certification body(ies) concerned?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>Specific routine tests are provided in a separate document XXX</i> <i>(Please give details in the attached TEST DATA SHEET of the relevant tests and inspections performed by the factory).</i>			
4.6 Are the personnel involved in the assembly and quality control adequately briefed on their duties and competent to perform them?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>



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5.0 NON-CONFORMING PRODUCTS			
5.1 Does the factory identify, segregate and handle non-conforming products in an appropriate way? Is a documented procedure for this available?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

6.0 FUNCTIONAL CHECK OF REQUIRED TEST EQUIPMENT			
6.1 Is there a documented procedure for the functional checks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.2 Was the correct functioning of the test equipment verified?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.3 Are functional checks of the test equipment conducted at appropriate intervals, which will allow previous production to be re-tested if incorrect functioning is detected?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.4 Is there a documented procedure describing actions to be taken if the result of a functional check is found to be unsatisfactory?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
6.5 Are records from the functional checks appropriate (incl. traceability of the test equipment used), and kept by the factory?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>



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7.0 CALIBRATION OF THE TEST EQUIPMENT			
7.1 Is required test equipment calibrated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.2 Is the equipment provided with a label or similar method indicating the date of the last calibration and the next due date?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.3 Are records from equipment calibrations appropriate and kept by the factory?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
7.4 Do the records indicate that the calibration is traceable to National/International Metrology Standards?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
8.0 HANDLING AND STORAGE OF FINISHED PRODUCTS			
8.1 Are the finished products stored and handled in such a way as to ensure that they will not be damaged or deteriorated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>Finished Product may be a component, sub-assembly, or a product such as a Whirlpool Bath, Medical Equipment, TV set.</i>			
9.0 CONTROL OF RECORDS FROM TESTS			
9.1 Are the records from tests and inspections signed by responsible persons and duly identified for traceability? Where are the records of tests located?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>



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9.2 Are these records maintained and kept for an appropriate period? (Normally minimum one year, unless otherwise specified by the applicable requirements).	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

10.0 FACTORY CAPABILITY AND INTEGRATED QUALITY MANAGEMENT SYSTEM			
10.1 Does the factory have a documented Quality Management System?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
10.2 Does the factory regularly perform internal audits of its quality management system, and periodically check that all documented procedures, including those required for certification, are followed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
10.3 Are records from internal audits and corrective actions available and are they sufficiently detailed to demonstrate that the Quality Management System is effective? Are management reviews carried out on a regular basis?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
10.4 Are the personnel carrying out the internal audits and checks mentioned in 10.2, appropriately trained and, in addition, independent of the process being audited?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

11.0 COMPLAINTS			
11.1 Does the factory have a documented system for handling complaints?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
11.2 Does the factory review complaints from customers or others, and take appropriate action?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>



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11.3 Are records kept of the complaints and of corrective actions taken?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>

12.0 CONTROL OF PRODUCT CHANGES

12.1 Is there a documented procedure covering control of product and production process changes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
12.2 Does the procedure cover the review and approval of product or production process changes by the responsible management?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
12.3 Are there provisions to ensure that the concerned certification body has accepted these changes to the product construction or production process before their implementation?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
12.4 Does such procedure cover changes to relevant product markings and any accompanying product information?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>The relevant procedure are related to type/model designation, markings, warnings, user instructions etc.</i>			
12.5 Is there an up-to-date parts list or similar evidence available specifying the components/parts to be used during production of the products?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>



FINDINGS

List a summary of the Findings, the details will appear in the Finding Report, Appendix 1

It is intended that once the findings are overcome the released version should not include this section and the Appendix 1.

It is also intended that once the findings are overcome then the released version should have clearance on all itemised requirements in this report and will include the appropriate supporting information for each item. (Boxes ticked "No" should be converted into "Yes" and the comments should be appropriately modified.)

13.0 CONCLUSION

Example: The audit has confirmed that the Manufacturer has in place an effective system to ensure that the product produced is representative of the product that was originally tested/evaluated by the certification body and determined to comply with the relevant requirements will comply with the certification requirements on an on-going basis.

Recommendation



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Time in the factory: _____ hours.

A copy of this report is provided to the undersigned contact person in the factory, who confirms to be aware of the contents by signing for receipt.

Date:	Date:
Auditor/Inspector's name (<i>printed letters</i>):	Contact person's name and position (<i>printed letters</i>):
Signature:	Signature:

ACKNOWLEDGEMENT BY THE AUDITED FACTORY:

- We acknowledge and agree with the content of this Initial Factory Inspection Audit Report
- We acknowledge the content of this Initial Factory Inspection Audit Report and we disagree with the content as reported in the following clauses/sub-clauses and/or findings

Date:
Contact person's name and position (<i>printed letters</i>):
Signature:



TEST DATA SHEET

Attachment page no. _

Routine Tests on 100% of the products produced

PRODUCT CATEGORY:

INSULATION CLASS:

If the below format is not suitable for the product category concerned, please edit to suit or use a blank sheet). Also the IECEE secretariat may be contacted to check if relevant CTL lists are available).

TESTS		% check	Test value applied	Time	Factory limits. applied	Failure indicated by	Remarks***	W
								R
a. Earth continuity			V A	s	Ohm max.			
b. Insulation resistance			V d.c.	s	MOh min.			
c. Leakage current			V		mA max.			
Dielectric strength	Basic insulation		V	s				
	Supplementary insulation		V	s				
	Reinforced insulation		V	s				
e. Load deviation*								
f. Functional test**								

*) Indicate method used (hot/cold, at mains voltage, low voltage resistance check, etc.).

**) Are all controls and components checked during the test ?

***) W = Test witnessed by the inspector, R = According to records



FINDING Report

Number of Findings:	Date: Format: yyyy-mm-dd
Finding description:	
Finding description:	
Finding description:	