



IECEE OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Instructions to Applicants and Manufacturers regarding Requirements to Production Facilities and Production Processes for manufacturing of certified products





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Equipment and Components (IECEE System)**

**Instructions to Applicants and Manufacturers regarding Requirements to
Production Facilities and Production Processes for manufacturing of certified
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INTERNATIONAL
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Introduction

This document provides help and guidance to Certification Bodies, Inspectors, Manufacturers and Applicants on how Factory Surveillance Services are conducted.

Under the IECEE-CB-FSS Factory Surveillance Service, irrespective of which CB-FSB undertakes the Surveillance, the procedures whereby Certification Bodies have factories assessed and Inspectors undertake this Surveillance are the same.

It also describes general requirements to manufacturers producing certified products with the permission using an approval mark of a National Certification Body (NCB).

These requirements are intended to achieve a reliable manufacturing process ensuring that products will be produced according to the requirements from the standards applied for certification.

Products shall have the same qualities and design as the certified sample.

This document includes requirements that the products will not be modified unless authorized by the NCB.

As basic requirements this document describes a minimum of essential quality elements needed for getting the intended level of quality and stability of the manufacturing process.

As part of the IECEE FSS required by the NCB the inspector will check the manufacturing process according to these requirements.

For clarity the document has been divided into three parts:

- Part I: Advice to the Applicants and Manufacturers
- Part II: Factory Surveillance procedures and tests which Manufacturers are expected to provide
- Part III: General requirements for manufacturers concerning production facilities and processes

Part I: Advice to the Applicants and Manufacturers

1 Introduction

The following instructions have been established to help Applicants and Manufacturers understand and correctly interpret the basic requirements of Certification Bodies when preparing for Surveillance within the IECEE-CB-FSS.

2 Conduct of the Surveillance

The Surveillance will be conducted during normal working hours.

The Manufacturer's representative or his deputy should be available within a reasonable time after being contacted from reception. The Certification Body, and hence the Inspector, will be expected to be given full access to the Manufacturer's premises and be accorded his full co-operation throughout the Surveillance. Any unwarranted or personal criticism or lack of co-operation by the Manufacturer may be reported.

Inspectors will be aware that they are at all times acting as representative of the CB-FSS and they, in their turn, are expected to behave accordingly.

At the end of the Surveillance, it will be helpful to give the Inspector an appropriate place to complete the Surveillance report so a copy can be provided to the Manufacturer's representative before leaving the factory.

3 Inspector's responsibilities

The Inspector shall establish that the Manufacturer keeps and has in operation a quality system, which ensures that products leaving the factory are at all times complying with the relevant requirements.

In order to be able to verify the Manufacturer's ability to comply, it is essential that the Inspector visit all areas necessary (such as receiving, in-process and final inspection, and laboratories etc.). When planning and conducting such Surveillance, the Inspector has to have allocated enough time so as to be able to conduct a thorough job.

Due to application of basic and additional requirements the time frame for FSS will be more than 4h as today for Factory Inspections.

Special care as to testing and record keeping will be taken where product or parts thereof have been manufactured or assembled at sub-contractors or out-workers.

It is emphasised that confidentiality of all information gathered at a Manufacturer's plant shall be maintained.

4 Scheduling Surveillances

The frequency and period of Surveillance visits are, as far as possible, scheduled in accordance with the CB-FSS.

Pre- Certificate Assessments of the Production shall be announced and arranged with the manufacturer in order to assure that all persons involved can be available.

Post- Certificate Assessments of the Production shall be announced and arranged with the manufacturer in order to assure that all persons involved can be available.

Routine Surveillances are announced unless required otherwise by NCBs.

Part II: Factory Surveillance procedures and tests which Manufacturers are expected to provide

1 Introduction

This section deals with the factory surveillance procedures and tests which Manufacturers are expected to provide and operate to ensure that all certified products are identical, within accepted manufacturing tolerances, to the sample against which the product certification was granted. This document should be taken to represent the minimum acceptable standard.

Compliance with these requirements will be checked during IECEE-CB-FSS Factory Surveillances.

To verify that the conditions for the production of certified products are given to ensure that a uniform manufacturing can be expected the Surveillance shall be always conducted and a complete Surveillance report (OD-4001) has to be issued even if there is no production of certified products at the time of Surveillance.

All details about the testing, test equipment and calibration are equally important even if there is no production or there are other products in production.

To verify that the conditions for the production of certified products are given to the effect that a uniform manufacture can be expected, Surveillances are to be conducted even in cases where certified products are not presently in production.

2 Definitions

For consistency, definitions are provided by applicable and accessible documents on IECEE website.

3 General arrangements

Factory locations of certified products shall be inspected once per year unless otherwise indicated to ensure that the necessary routines and procedures are being maintained at an acceptable standard. Should Surveillance prove to be unsatisfactory, the certification of products may be suspended until such time as the complete production process has again been found to be satisfactory by the NCB involved. 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 Applicant to the NCB involved.

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

It is the responsibility of the Applicant to notify the NCB of any change of factory location of the certified product.

4 Manufacturer's responsibility

4.1 General information

It is the Manufacturer's responsibility to ensure that the complete production process of the certified products continuously complies with the Factory Surveillance Procedures for the IECEE-CB-FSS as stated in this document.

The manufacturer shall exercise adequate control (e.g. by inspection or otherwise) over all subcontractors and out-workers preparing assemblies or parts which have a safety implication.

Any non-conforming product shall be clearly identified and segregated to prevent unauthorized use, delivery or mixing with conforming products. There shall be a method or procedure that ensures that repaired and reworked product are re-inspected to the same requirements as applicable to new produced products, see also part III clause 4.2.

The manufacturer shall maintain appropriate records to demonstrate conformance with the Factory Surveillance Procedures for the IECEE-CB-FSS. These records shall be made available to the Inspector. Records shall be legible and identifiable to the product and/or test equipment involved and shall be kept for a time which should be not less than the period between two Surveillance visits.

At least the following records shall be maintained as far as applicable:

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

Note: Records stored on computer or microfilm are acceptable.

Due to SR (Special Requirements) from other NCBs, Schemes or countries additional requests might occur.

4.2 Verification of purchased components and materials which have a safety implication on the certified product (Incoming Inspection)

Manufacturers shall ensure that all purchased materials, components and subassemblies comply with specified requirements. This shall be taken into account when selecting sources of supply and may involve close liaison on a regular basis with suppliers to such an extent that the Manufacturer relies on the suppliers' control procedures. It is the responsibility of the Manufacturer who undertakes final assembly to ensure that subassemblies completed by subcontractors or out-workers meet the Quality Plans and/ or relevant safety requirements.

Materials, components and subassemblies 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 part III, clause 4.1.

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 method by which the manufacturer achieves these objectives is not prescribed. Procedures may be required to ensure compliance with the specifications of components.

If a Manufacturer relies on Certificates of Conformity to underwrite the compliance of components with their specifications, certificates shall clearly identify the products to which they refer, the quantity of items covered, the specification to which the products conform, the production date and be signed or otherwise systematically issued and dated by the supplier's inspector or authorized person.

Any non-conforming product, found during incoming inspection shall be clearly identified and/or segregated in a controlled way to prevent unauthorised use.

4.3 Production Control, Inspection and Routine Tests

Production shall be inspected at appropriate stages of manufacture to ensure that piece-parts, components, subassemblies, wiring runs, workmanship, etc. are in accordance with the sample for which certification was granted. Quality Assurance and assembly personnel shall be 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 will obviously depend on local circumstances and the type of product being manufactured. Particular attention shall 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 controls, that connections are correctly made, clearances are adequate, nuts, screws and connections are tight, there are no sharps edges that can damage wiring or harm the user and that any earth bonding is satisfactory, see also part III, clause 5

In addition to the above-mentioned inspections, routine tests may be required, see also part III, clause 6. These are line tests performed on 100 % of the production and are normally carried out at the final stage of manufacture. These tests shall 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 IEC-Technical Committees specifications apply.

It is required that there is evidence that 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. Records of tests and inspections undertaken shall be maintained.

4.4 Functional Check on Test and Measuring Equipment used for Safety Tests (Dummy Test)

An operational or functional check shall be conducted at intervals which will allow previous production to be re-tested if incorrect functioning of the test- and measuring equipment used for safety (routine) tests is detected.

As a minimum daily checks are recommended at the end of the daily production, for lot production taking less than a day a check before and after the lot has been produced is recommended. The operational or functional check can be satisfied by subjecting the test equipment to pre-determined fault conditions by a simulated failure (dummy). The simulated failure shall represent the tripping limits used by the manufacturer during testing of the certified product. 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 shall be recorded.

4.5 Products seen in Production during visit - Marking of products

The Certification Mark, if applicable, shall be applied according to the regulations of the Certification Body. It is the Manufacturer's responsibility to ensure that the Certification Mark is applied only to products that comply with the requirements.

4.6 Calibration of Safety Test and Measuring Equipment

Test and measuring equipment used for determining the safety of the products being manufactured shall be calibrated or verified on a regular basis, preferably once per year, depending on usage and the results of previous measurements, see also part III, clause 7. Records of calibration/verification undertaken on the safety test- and measuring equipment and on reference equipment owned by the manufacturer shall be kept. The records should include equipment identification, location, calibration frequency, reference equipment, measured values, deviation, results, measurement uncertainty, signature and date. The calibration of the reference equipment used for calibration/verification shall be traceable to National or International Standards. The test- and measuring equipment shall be provided with a label indicating the next 'calibration due' date or a similar method providing the same level of information.

4.7 Handling and Storage

Components, materials and sub-assemblies that have been accepted during incoming inspection shall be properly identified and shall be stored in such a way (environmental conditions; Electrostatic Discharge (ESD) safe; First In / First Out (FIFO) principle) that no damage and/or reduction of properties can occur.

Finished products shall be stored and handled in such a way as to ensure that they will continue to comply with the applicable standards, see also part III, clause 4.6.

4.8 Void

4.9 Verification of Product Identification document (PID)

The PID is a separate and individual document and might be prepared on request of the client ordering the CB Factory Surveillance Service. It can be prepared either during the type approval process or after finishing the CB certification process. The basis for the PID is the documentation already compiled for the type approval test and CB certification. The PID therefore shall allow checking the consistency between type approval sample and sample in production just by a visual inspection

One part of the factory inspection within the IECEE-CB-FSS is to verify that the product in production has not been modified compared to the certified version. The PID contains all relevant data and is as such the document which enables the PID - user to perform this task.

This consistency check is a visual inspection limited to a verification of the design and structure as well as the components used. This may include assembling details if relevant for the product safety. Such details have to be made available in the PID.

Within the IECEE-CB-FSS factory inspection the product properties regarding safety and function can be verified by an intensive visual inspection of the product including the components.

The type approval sample is sufficiently described in the PID. The PID is the reference for this consistency check.

4.10 Corrective actions in response to inspector's evaluation

It is the Manufacturer's responsibility to take corrective action to any unsatisfactory finding found during the factory Surveillance. The NCB shall be informed about the corrective actions taken. Depending on the number and the seriousness of the findings, the NCB may decide to verify the implementation of the corrective actions during a special Surveillance or during the next routine Surveillance.

4.11 Quality Management System

The Manufacturer is not required to have a certified Quality system. If the Manufacturer has a Quality System certified by an accredited body according to EN ISO 9001 the inspector shall verify if the production of the certified products is covered by the scope of the certificate and if the relevant procedures cover the requirements of this document.

Note: Combined Surveillances/audits are permitted if the Quality System of the Manufacturer is audited by the same organization as the Body carrying out the subjected factory Surveillance.

4.12 Void

4.13 Void

4.14 Customer complaints

The Manufacturer shall record any technical complaint regarding the certified product. On a regular basis the Manufacturer shall review whether the complaints received are related to single errors or system errors. All decisions and corrective actions taken shall be recorded. The originator of the complaint shall be informed about the handling and the result of the complaint, see also part III, clause 4.5.

4.15 Changes to Certified Products

Constructional changes which may affect compliance with the relevant standard shall be notified, prior to its implementation on certified products, to the issuing NCB for their (prior) approval. The process by which the Applicant handles changes to certified products shall be described in a procedure and/or all personnel involved in the acceptance of changes shall be aware how changes to certified products are communicated with the Certification Body.

The Applicant is also responsible to inform any Manufacturer of certified products regarding the details of the certified construction. Documents in which the certified construction is specified (such as a parts list) shall be available at the Manufacturer's premises. It is to be assured that the Manufacturer shall not make changes to the certified construction (including the application of alternative components) prior to permission of the Applicant.

5 Factory Surveillance Documents

Manufacturers should be made aware of the report forms and guidance documents used during IECEE-CB-FSS Factory Surveillance Service.

5.1 OD-4001 - Factory Surveillance Report

This report is completed by the Inspector either during pre- certification Surveillances, post-certification or during routine Surveillances. The intention of completing this report during the routine Surveillance is to verify that compliance with the test and quality assurance procedures continues throughout the period for which the IECEE-CB Certification is in force.

5.2 OD-4003 Guide to Applicants and Manufacturers (this document)

This document has been established in order to provide information and guidance to Certification Bodies, Inspectors, Manufacturers and Applicants on how IECEE-CB-FSS Factory Surveillances are conducted.

5.3 Current IECEE-CFS Decisions

The inspector shall make reference to current IECEE-CFS decisions, if relevant.

5.4 Current IECEE-CFS-OP Operational Procedures

The inspector shall make reference to current IECEE-FSS-OP operation procedures, if relevant.

Part III: General requirements for manufacturers concerning production facilities and processes

1 Introduction

This section describes requirements applying as part of the IECEE- Factory Surveillance Service for any kind of production facilities used for series production of products.

Following these requirements will ensure sufficient capabilities for the production of products

- In appropriate environment
- Under controlled conditions
- Under constant and sufficient quality

- With adequate purchased and controlled components
- With adequately trained staff
- With a minimum of documented and controlled procedures or methods
- Under consideration of required routine tests
- Using verified measurement equipment

2 Definitions

2.1. Production facility

Facilities located on one place and under one address. Those facilities are setup and used for the assembling of products. This includes the production process.

2.2 Production process

Process of manufacturing products in a defined structure and sequence.

This process includes all steps from purchasing, assembling to routine tests and packaging.

2.3 QM elements

Procedures describing the production process ensuring the reproduction of products identical with the certified product.

2.4 Routine tests

Periodical tests of manufactured products monitoring and documenting the achieved level of quality and safety.

3 Production facilities

3.1 Environment

The production facilities including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate appropriate performance of the manufacturing.

The factory shall ensure that the environmental conditions do not invalidate the required product quality.

3.2 Resources

The production facilities shall be suitable for a safe production on the required quality level. All necessary tools and support installations shall be available.

3.3 Organization

The production facilities shall be adequately organized and maintained to achieve and to keep the required quality level.

3.4 Responsibilities

The production facility shall appoint one responsible person (manager) for organising and maintaining the production facility as well as the production process.

The responsibility shall include the compliance of the manufactured product with the certified sample as agreed with the NCB.

4 QM elements

4.1 Verification of purchased products/components

Purchased parts, components or materials shall be controlled regarding quantity, quality, data sheet properties, agreed properties, safety properties and approvals where applicable.

The following methods of verification are possible.

4.1.1 in house verification against specifications

4.1.2 in house verification of certificates

4.1.3 contractual delegation of verification against specifications to the supplier

4.1.4 audits of the outgoing inspection at the supplier

4.1.5 in house verification by technical measurements

4.1.6 in house verification by checking documents

4.2 Handling of non-conforming components or materials or non-conforming products from production

The factory shall have a policy and procedures or methods that shall be implemented when any aspect of its inspected components or materials or manufactured products, do not conform to these requirements, its own procedures or the agreed requirements of the NCB.

The policy and procedures or methods shall ensure that:

- a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of manufactured products, as necessary) are defined and taken when nonconforming work is identified;
- b) an evaluation of the significance of the nonconforming work is made;
- c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;
- d) where necessary, the NCB and/or customer is notified and work is recalled;
- e) the responsibility for authorizing the resumption of work is defined.

4.3 Records and documentation

The factory shall retain records of incoming inspection results and routine test results as well as calibration documents for routine test instruments, staff records and purchasing documents, for a defined period.

The records and documents shall include the identity of personnel responsible for the matters recorded or activities done.

QM elements shall be documented as controlled documents which includes a review and release procedure.

4.4 Self assessment / internal audits (if requested by CB or certification scheme)

The factory shall periodically, conduct internal audits of its production to verify that manufactured products continue to comply with the requirements of specifications and are manufactured in line with the relevant procedures or methods and documents.

The internal audit program shall address elements of the management system and the manufacturing process including the routine testing activities.

Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

NOTE The cycle for internal auditing should normally be completed in one year.

When audit findings cast doubt on the effectiveness of the operations or on the quality of the manufactured products , the factory shall take timely corrective action, and shall notify the NCB and customers in writing if investigations show that the manufactured products may have been affected regarding safety.

The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective actions taken.

4.5 Customer complaints

The factory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the factory.

4.6 Handling and storage of components/materials and final products

The factory shall have procedures or methods for the transportation, receipt, handling, protection, storage, retention and/or disposal of components or materials or manufactured products, including all provisions necessary to protect the integrity of the components and materials as well as manufactured products.

The factory shall have procedures or methods and appropriate facilities for avoiding deterioration, loss or damage to the components or materials or manufactured products during storage, handling and manufacturing.

5 Production process

5.1 Training of the personnel

The factory management shall ensure the competence of all who does manufacturing or performs routine tests.

When using staff that is undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

The factory management shall formulate the goals with respect to the education, training and skills of the manufacturing personnel. The factory shall have procedures or methods for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the factory. The effectiveness of the training actions taken shall be evaluated.

5.2 Production documents up to date and available

The factory shall use appropriate procedures or methods for all manufacturing processes.

These include the preparation of documents for production.

The factory shall have instructions on the use and operation of production equipment, and on how to perform the production process.

This includes documents or methods describing the production stages and the product being manufactured; especially where the absence of such instructions could jeopardize the quality and safety of the manufactured product.

All instructions, standards, manuals and reference data relevant to the work of the factory shall be kept up to date and shall be made readily available to personnel

5.3 Production process adequate to ensure safety and quality

The factory shall use appropriate methods and procedures for all manufacturing processes.

These include purchasing, handling, transport, storage of components and materials as well as manufactured products and routine tests. This production process has to be adequately controlled and verified.

5.4 Production controls during manufacturing process

Where appropriate for safety and quality of manufactured products check or control measures shall be taken on different stages of production on manufactured products.

Especially controls regarding safety conditions shall be done if miss-assembling cannot be detected later on routine tests.

5.5 Functional checks and Product Verification Tests (PVT)

Where appropriate functional checks shall be done as part of the final quality control measures. PVT shall be done when required by certification rules or schemes.

6 Routine tests

Routine tests have to be done according to the following requirements:

- as required in relevant standards
- as required by the NCB
- as required by certification schemes
- as documented in the PID

All routine test results have to be documented and stored. The basic level is set by the FSS and additional requirements can be required by the NCB(s) whose certification marks are applied.

7 Calibration of routine test equipment

All equipment used for routine tests shall be suitable for the intended purpose and calibrated before being put into service. The factory shall have a procedure or method for the calibration of its routine test equipment.

The calibration of this equipment shall be designed and operated so as to ensure that calibrations made are finally traceable to the International System of Units (SI) (Système international d'unités).

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