

IECEE PUBLICATION

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

Rules of Procedure – CB FCS Scheme

Scheme of the IECEE for Mutual Recognition of Conformity Assessment Certificates for Electrotechnical Equipment and Components (CB FCS Scheme)





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IECEE PUBLICATION

Rules of Procedure – CB FCS Scheme

**Scheme of the IECEE for Mutual Recognition of Conformity Assessment
Certificates for Electrotechnical Equipment and Components (CB FCS Scheme)**

INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Rules of Procedure –

CB FCS Scheme

FOREWORD

This publication governs the Certification Body Full Certification Scheme of the IECEE for testing, certification and factory audit/inspection of electrotechnical equipment and components which includes appliances, systems, industrial and household equipment and sub-assemblies (CB-FCS Scheme).

This is 1st edition of IECEE 03. The CB-FCS scheme was described in fifteenth edition of IECEE 02 and transferred to IECEE 03.

This publication is directly related to Publication IECEE 01 containing the Basic Rules of the IECEE and IECEE02 containing the Rules of Procedure of the CB Scheme

The annexe to this publication is normative.

The text of this publication is based on the following document.

Document	Report on voting
IECEE-CMC/1753A/RM	CMC Decision

Full information on the approval of this publication can be found in the Minutes of the CMC meeting held in Oslo on June 01/02, 2016

Document Owner

CMC WG 10 “ Maintenance of the IECEE Rules and Operational Documents”

History of changes

Date	Brief summary of changes
2016-06-01	Part II of IECEE 02 Edition 15.0 was extracted and is being republished as IECEE 03 Edition 6.0. The following sub-clauses were changed: Introduction d), 3.2.2 b) & g), 3.2.3 c), e), i), 5.1, 5.2, 7.1.5

Effective date	Target revision date
2016-06-01	2019-06-01

INTRODUCTION

(Informative: Provides an overview of CB-FCS and is not part of these Rules of Procedure.)

The IECEE Certification Body (CB) Full Certification Scheme (CB-FCS) is an extension of the international IECEE CB Scheme and is an option to be exercised by the participants in the CB Scheme and by Applicants under the same IECEE management structure.

The CB-FCS is a Scheme based on the principle of mutual recognition of Conformity Assessment Certificates (CACs) and Conformity Assessment Reports (CARs) by its Members as the basis for approval or certification, at national level of products within the scope (see Clause 1 – Scope) to the standards accepted for use in CB-FCS.

The Scheme is intended to reduce obstacles to international trade that may arise from having to meet different national certification or approval criteria and processes. Participation of the various National Certification Bodies (NCBs) within CB-FCS is intended to facilitate certification or approval according to IEC standards. Where national standards are not yet completely in line with IEC standards, declared National Differences are taken into account; however, successful operation of the Scheme presupposes that national standards are reasonably harmonized with the corresponding IEC standards. Use of CB-FCS promotes the exchange of information necessary in assisting manufacturers to obtain certification or approval at a national level in one or multiple countries and regions.

Member NCBs to which an Applicant (Sub-clause 4.1.1) applies for a national certification or approval (NCBs “B”) accept the “Conformity Assessment Certificate” and associated “Conformity Assessment Report” issued by NCB “A” as a basis for such certification or approval. As a NCB B, its national standards shall be as far as possible be aligned with the IEC and its national certification procedures should as far as possible be harmonized with these Rules of Procedure. If however, differences exist, they are formally declared to the IECEE Secretariat for publication in order that Member NCBs are able to properly cover these differences when acting as NCB “A”.

CB-FCS is a product Certification System 5 as defined in ISO/IEC 17067.

Note Whether or not the NCB A issues its certification mark, it remains responsible for the ongoing conformity of the product(s) for which the CAC has been granted.

CB-FCS includes the following for the NCB A:

- a) Type testing by a laboratory accepted within the CB scheme and issuance of a CAR; and
- b) Initial Factory Inspection including evaluation of the factory’s quality management system (QMS)
- c) Issuance of the CAC
- d) Follow up Factory Inspection by NCB A, that in addition to assessing the product, the manufacturing process and the QMS, will also include re-testing of samples from production, when applicable according to the requirements NCB A and/or Body B. [See (g) and (h) and the Note in the description of ISO/IEC 17067 Certification System 5 above].

CB-FCS includes the following for the NCB B:

- e) Evaluate the CAC and CAR including, if necessary, direct separate consultation with NCB A to verify validity, initial inspection, follow up inspection, QMS surveillance and completeness of the CAC and CAR.
- f) Test sample(s) are requested only if there are well-founded reasons, e.g. CAC and CAR are not complete or there is a justified technical doubt.
- g) Issue the NCB B’s Certification/Mark/Licence according to its normal procedures.
- h) Accept Initial Factory Inspections carried out by NCB “A.”
- i) Accept components integrated in appliances and which have been tested/verified/ inspected by NCB “A” and used within their ratings and conditions of use.

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

Rules of Procedure –

CB FCS Scheme

1 Scope

This publication contains the Rules of Procedure of the IECEE CB-FCS Scheme for Mutual Recognition of Conformity Assessment Certificates for Electrotechnical Equipment and Components.

The requirements contained in these Rules of Procedure are additional requirements to those of the CB Scheme.

The Scope of CB-FCS covers all Product Categories and Standards that are within the Scope of the IECEE CB Scheme.

2 Normative references

The following publications contain provisions which, through reference in this text, constitute provisions of these Rules of Procedure. At the time of publication, the editions indicated were valid. The IECEE Certification Management Committee (CMC) shall decide the timetable for the introduction of new publications or revised editions or amendments of existing publications named as normative references.

IECEE Definitions

IECEE 01: Fifteenth edition 2015-10, *IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE)*

ISO/IEC 17000:2004, *Conformity Assessment – General Vocabulary*

ISO/IEC 17065: 2012, *Conformity assessment - Requirements for bodies certifying products, processes and services*

ISO/IEC 17025: 2005, *General requirements for the competence of calibration and testing laboratories*

ISO/IEC 17030:2003, *Conformity Assessment – General requirements for third party Marks of conformity*

ISO/IEC 17040: 2005, *Conformity Assessment – General requirements Peer assessment of Conformity assessment bodies and Accreditation Bodies*

ISO/IEC 17067 2013, *Conformity Assessment – Fundamentals of Product Certification and guidelines for product certification schemes*

ISO/IEC Guide 28 2004, *Conformity Assessment – Guidance on third party certification system for products*

ISO 9001: 2000, *Quality Management Systems – Requirements*

3 Rules

3.1 General

The IECEE Certification Management Committee (CMC) governs operation of CB-FCS. The CMC's responsibilities in this respect are defined in the Basic Rules of the IECEE as given in Publication IECEE 01.

When a CAC needs to be reissued (e.g. due to modification of the product) or cancelled, the rules for issuing, modifying or cancelling of CB Test Certificates apply to CACs.

3.2 Participation in CB-FCS

3.2.1 Member Body and NCB Obligations

3.2.1.1 The Member Body of an NCB applying for membership in CB-FCS and the applicant NCB, shall declare to the IECEE Secretary that the national certification or approval can be based on a CB-FCS Conformity Assessment Certificate. When other conditions have to be fulfilled, they shall also be declared for later publication in the CB Bulletin, Website, etc.

3.2.1.2 The Member Body of an accepted CB-FCS member shall inform the Secretary of the IECEE about any changes in the information given according to 4.2.1.

3.2.2 Pre-requisites for CB-FCS NCBs

To be eligible to participate in CB-FCS, the NCB must have operated within the IECEE CB Scheme during the last 3 years prior the application being submitted to the IECEE Secretariat.

In addition the candidate NCB shall meet the following criteria:

- a) To issue a certificate/approval/mark with a demonstrated market value,
- b) To operate a Certification program according to ISO/IEC 17067 Certification System 5 with all the product certification functions and their "elements of conformity" implemented in practice.
 - Initial assessment of compliance that includes the testing function, the certification function and the third-party certification mark function, and
 - Ongoing assessment of compliance that includes the factory inspection function, the market surveillance function and the corrective action function.
- c) To have completed, within the last three years, a minimum of 100 Factory Inspections (both Initial and Follow up/surveillance inspections) relevant to the product category(ies)/standard(s) for which the NCB is seeking acceptance,
- d) To be prepared to accept initial and follow up Factory Audit/Inspection Reports issued by the CB-FCS Members, based upon its own requirements and procedures.
- e) To have tested and evaluated during each of the last three years at least 10 products falling under the scope of the product category(ies)/standard(s) for which the NCB is seeking acceptance.
- f) To have fully declared National Differences for the product category(ies)/standard(s) for which the NCB is seeking acceptance in CB-FCS.
- g) To have fully declared its overall certification procedures and acceptance of stages of the CTF program and LTR, including any differences between its certification program and procedures and those of the CB-FCS.

3.2.3 Ongoing Obligations for all NCBs applying for membership in CB-FCS

- a) To abide by the CB-FCS Rules of Procedure.
- b) To be in good standing with respect to the IECEE Membership Fees
- c) To conform to the IECEE Peer Assessment Programme based on ISO/IEC 17065, ISO/IEC 17025 as well as ISO/IEC 17020, ISO/IEC 17030 and ISO/IEC Guide 27 (or their most current replacements).

- d) To maintain adequate internal procedures to enable quick processing of recognition of CAR(s) and CAC(s).
- e) To accept on an ongoing basis CACs and CARs based on the CTF program and LTR.
- f) To accept components that have already been tested, evaluated and certified by a CB-FCS NCB according to the IECEE Component Recognition Program
- g) To recognise CACs and CARs without additional testing if all of the CB-FCS NCB's National Differences (if any declared) are met. An Issuing and Recognizing NCB will not be authorized to issue CACs Test for a standard unless CACs for that standard are recognized by that NCB.
- h) To recognise CACs and CARs without an additional Initial Factory Audit if the audit has been carried out by NCB "A" according to the procedures declared by the NCB B.
- i) To exercise full control of its associated CBTL(s), SPTLs, CTFs and LTRs.
- j) To provide evidence of an adequate liability and indemnification coverage, the amount of which is set by the CMC (currently CHF 4,000,000).

3.2.4 Application Process for Candidate NCBs

An NCB desiring to participate in CB-FCS shall, via the Member Body of the IECEE, send a written application to the IECEE Secretariat.

In addition, the application shall contain the following:

- a written declaration by the candidate NCB that it is ready to provide for recognition of CACs and CARs as a basis for its certification or approval to specified standards.
- The date from which CACs will be recognized by the candidate NCB for their certification at national level shall also be stated for each standard for which the candidate NCB has applied for acceptance.
- Differences between its certification program and procedures and those of CB-FCS as mentioned in these Rules of Procedure shall also be indicated in the application for later publication in the CB Bulletin.

4 Procedures for handling Conformity Assessment Certificates

4.1 General

4.1.1 An application for obtaining a CAC may be made by an applicant to any Issuing and Recognizing NCB accepted to operate within CB-FCS for the relevant product category and standard. The applicant will be the holder of the CAC.

4.1.2 The applicant may be a manufacturer or act on behalf of a manufacturer. In the latter case, evidence shall be submitted that the applicant is authorized to act on behalf of the manufacturer for the application and that the manufacturer undertakes the same obligations as the applicant.

4.1.3 The application may cover one or more factories located in one or more countries, where the product is manufactured.

4.1.4 An applicant in a country with no Member Body of the IECEE and an applicant acting on behalf of a manufacturer in such a country shall pay a contribution to the costs of the IECEE in the form of surcharge for each CAC issued, the amount to be decided by the CMC (see OD-2026). The surcharge is to be collected by the NCB handling the application, and remitted to the IECEE account.

4.2 Procedure for obtaining a Conformity Assessment Certificate

4.2.1 The granting of the Conformity Assessment Certificate implies that the Issuing NCB also issues its own Certification Mark.

4.2.2 It is a requirement that the Certification Mark of the Issuing NCB be part of the CB-FCS Scheme and that the product(s) certified according to the CB-FCS, bear the NCB's certification mark.

The application to the NCB (NCB A) shall contain as a minimum the following information:

- a) name and address of the applicant;
- b) name and address of the manufacturer, if different from the applicant;
- c) name(s) and address(es) of the factory(ies) where the product will be manufactured;
- d) name, trade marks or other markings by which the applicant, the manufacturer, when appropriate, and the factory can be unambiguously identified by an NCB;
- e) product identification, type designation and markings by which the product can be unambiguously identified by an NCB;
- f) copy of a valid CAR, if previously issued;
- g) any special request, such as a particular testing laboratory or use of a manufacturer's test facilities;
- h) NCB(s) to which the Conformity Assessment Certificate is intended to be transferred, if known.
- i) Evidence of an operating quality management system in place for the specific product concerned. This evidence applies to each factory as declared under c), (and could for e.g. be evidence of current registration/certification to ISO 9001).

4.2.3 The application shall be made and dealt with according to the rules of the NCB A to which the application is submitted.

4.2.4 After fulfillment of all application conditions necessary for a Conformity Assessment Certificate, the relevant NCB (NCB A) shall generally within one month arrange for the elements of conformity assessment (testing, factory inspection) of the relevant product to be carried out. If the result of the conformity assessment is favorable, the NCB concerned shall issue a Conformity Assessment Certificate and Conformity Assessment Report.

4.2.5 When the application covers more than one factory, the address of each factory shall be stated in the Conformity Assessment Certificate and the NCB shall take steps to ensure that the products from all the factories are identical

4.2.6 The application, the results of the work done and the information obtained in connection with the application for a Conformity Assessment Certificate and Conformity Assessment Report shall be confidential; however, basic identification data for the product may be published after the date of issue, unless particular confidentiality is agreed between the applicant and the NCB.

4.2.7 The NCB has the right to cancel a CAC if:

- a) CAC is misused;
- b) CAC has been issued in error;
- c) the equipment in production, as determined by factory surveillance and audit testing, no longer corresponds to the specimens tested as described in the CAC and its associated CAR;
- d) the holder of the CAC requests cancellation.

4.2.8 Disagreements between the NCB and the applicant may be dealt with according to the appeals procedure of the NCB. If the applicant is not satisfied with the result of the appeal at a national level, and if the disagreement concerns the application of these Rules of Procedure, the dispute shall be handled according to IECEE 01.

4.3 Procedure for obtaining national certification or approval

4.3.1 When an applicant applies to a NCB B for national certification or approval of a product on the basis of a Conformity Assessment Certificate, the application shall be accompanied by the following documentation:

- a) copy of a valid Conformity Assessment Certificate;
- b) copy of the associated and valid Conformity Assessment Report that covers the applicable National Differences;
- c) statement on the on-going conformity of the product

4.3.2 The NCB B shall review the documentation provided by the applicant to the extent considered necessary for the identification of the relevant product/equipment for the purpose of granting its national certification/approval.

4.3.3 If the result of the review is favourable, CB-FCS NCB's are required to issue their National Certification/Marks Licence or Approval, based on a CAC and associated CAR issued by a CB-FCS NCB A without requesting a sample(s) of the product, except as indicated below, provided that:

- NCB A has covered NCB B's national differences (if any) and this is clearly shown in the relevant Conformity Assessment Report (CAR) and Conformity Assessment Certificate (CAC).
- NCB A has included in the relevant Conformity Assessment Report (CAR) documented evidence for product identification in accordance with the CTL OP-107.
- The Applicant provides NCB B a Declaration of Identity confirming that the product(s) for which the NCB B's Certification/Approval is requested is(are) identical to the product(s) initially tested and evaluated by NCB A.

Note If the products are not identical, the CAC and CAR are not valid.

When well-founded reasons exist for doubting the identity of the product, the validity of test results or information provided, NCB B may request and evaluate a sample of the product. In such a case, NCB B shall consult with NCB A. The Applicant and the IECEE Secretariat shall be informed accordingly.

4.3.4 The NCB B is generally expected to handle applications for recognition of CACs within 15 working days.

4.3.5 The NCB B will determine and administer its own fee policy for product testing, certification and inspections.

5 Factory Inspections

5.1 General

The location(s) at which the product is manufactured or assembled shall be subjected to an Initial Factory Inspection and subsequent regularly scheduled follow-up Inspections as specified in the relevant CB-FCS Operational Documents.

5.2 Object of Inspections

Inspections are intended to ensure that both the quality management system and the production process are implemented and maintained to meet the requirements of the CB FCS at the factory(ies) where the product is manufactured.

Note It is permitted to reduce the assessment of the quality management system if the Factory where the product is manufactured is currently certified/registered to ISO 9001 with a reputable accredited certification body/registrar. However, an on-site assessment is still necessary to verify continued compliance with the relevant IECEE Rules.

5.3 Initial and Follow up Inspections by NCB B

5.3.1 Unless specific provision is taken by the NCB (in Annex 1 of the CB-FCS MLA), then the NCB Bs shall accept Initial Factory Inspections carried out by NCB A under the condition that

Body A has fulfilled the general requirements and procedures for factory inspection for the CB-FCS scheme and has covered Body B's additional requirements, if any.

5.3.2 For Follow up Inspections, NCB B may require a signed agreement with NCB A. Body B may require Body A to undergo training.

5.3.3 When well-founded reasons exist for doubting the identity of the product, the validity of the Initial Factory Inspection results or information provided, NCB B shall consult with NCB A, and inform the IECEE Secretariat. If no agreement between NCB B and NCB A can be found to overcome the doubt, Body B may choose to repeat the Initial Factory Inspection.

6 Factory Surveillance Service – General principles

This Process Document details the principles and process to be followed by the operators in the CB-Factory Surveillance Service (CB-FSS), which are named CB Factory Surveillance Bodies (CB-FSB).

CB-FSS is a Service within the IECEE System for Factory Surveillances. All IECEE members are eligible to apply for operating this service.

This service can be performed:

- as a **stand-alone** service that only provides the visit and the evaluation of factory locations independently from of testing and certification. The aim of the service is the recognition of surveillance reports by other NCBs without performing own Factory Surveillances;
- as a **supplement** to a CB certification that includes the visit and evaluation of factory locations. The aim is recognition of surveillance reports by other NCBs for granting their mark without performing own Factory Surveillances.

By participating in this Factory Surveillance Services the NCBs and their associated CB-FSB agree to conform to all relevant IECEE Rules of Procedure.

During the operation of the FSS the IECEE Executive Secretary shall monitor by Peer Assessment the competence, performance, integrity and confidentiality of the relevant Factory Surveillance Department of the NCBs or their CBTLs (the CB-FSBs) on a regular basis according to the relevant requirements.

It is the responsibility of the

- individual participating NCBs to provide information about their Differences from the IECEE Initial Assessment & Periodic Factory Surveillance Procedures. The differences could be technical and non-technical.
- IECEE to manage the organisation of the trainings and workshops aiming at achieving consistent performance of Initial Assessments & Factory Surveillances.

7 Procedures for handling Factory Surveillance Reports

7.1 General

7.1.1 An application for obtaining a CB Test Certificate and / or a CB Factory Surveillance Report may be made by an applicant to any Issuing and Recognizing NCB accepted for the relevant standard resp. category.

The applicant will receive the CB Test Certificate and / or the CB Factory Surveillance Report.

7.1.2 The applicant may be:

- a manufacturer;
- act on behalf of a manufacturer. In the latter case, evidence shall be submitted that the applicant is authorized to act on behalf of the manufacturer for the application and that the manufacturer undertakes the same obligations as the applicant;

- any factory in case of the stand-alone service

7.1.3 The application may cover one or more factories within one or more countries, where the product will be manufactured.

7.1.4 An applicant in a country with no Member Body of the IECEE and an applicant acting on behalf of a manufacturer in such a country shall pay a contribution to the costs of the IECEE in the form of surcharge for each CB Test Certificate and /or CB Factory Surveillance Report issued, the amount to be decided by the CMC. The surcharge is to be collected by the NCB handling the application, and remitted to the IECEE account.

7.1.5 Unless otherwise agreed between the applicant and the NCB, the tests shall be carried out by an accepted CBTL and surveillance shall be carried out by an accepted CB-FSB on the request of the NCB.

Specific rules for utilization by an NCB of customers' testing facilities for testing are given in OD-2048.

7.2 Procedure for obtaining CB Factory Surveillance Reports

7.2.1 The application to the Issuing and Recognizing NCB shall contain as a minimum the following information:

- name and address of the applicant;
- name and address of the manufacturer, if different from the applicant;
- names and addresses of the factories where the product is manufactured;
- name, trademarks or other markings by which the applicant, the manufacturer, when appropriate, and the factory can be unambiguously identified by an NCB;
- type designation and markings by which the product can be unambiguously identified by an NCB.

If the application is:

- submitted together with an application for a CB certificate this application will provide the required information.
- related to an already established CB certificate a copy of the certificate will provide the required information and a copy should be attached to the application

7.2.2 The application shall be made and dealt with according to the rules of the Issuing and Recognizing NCB to which it is submitted. That NCB shall inform the applicant about the relevant rules and procedures and about the Factory Surveillance Differences.

7.2.3 Upon receipt of an application for a CB Factory Surveillance Report, the relevant Issuing and Recognizing NCB shall within one month arrange for Surveillance of the relevant factory. If the result of the Surveillance is favourable, the NCB concerned shall issue a CB Factory Surveillance Report to the applicant.

7.2.4 The applicant may also request additional activities to cover Factory Surveillance Differences in countries/NCBs in which the CB Factory Surveillance Report is to be used.

If additional Surveillances or activities have been carried out, a report of the results may be attached to, and considered to be a part of, the Factory Surveillance Documentation.

7.2.5 The application, the results of the work done and the information obtained in connection with the application for a CB Factory Surveillance Report shall be confidential. However, basic identification data may be published after the date of issue, unless particular confidentiality is agreed between the applicant and the Issuing and Recognizing NCB.

7.2.6 Disagreements between an Issuing and Recognizing NCB and an applicant may be dealt with according to the appeal procedure of the NCB.

If the applicant is not satisfied with the result of the appeal at national level, and if the disagreement concerns the application of these Rules, the dispute may be referred to the Board of Appeal of the IECEE.

7.3 Procedure for recognition of CB Factory Surveillance Reports

7.3.1 When an applicant applies to a Recognizing or to an Issuing and Recognizing NCB for acceptance of a Factory Surveillance Report, the application shall be accompanied by a copy of the CB Factory Surveillance Documentation and, if relevant, with attached reports covering Factory Surveillance Differences.

7.3.2 When applying for acceptance of a CB Factory Surveillance Report, an applicant shall follow the rules of procedure applicable in the country and/or by that NCB concerned and shall confirm readiness to comply with all the relevant national provisions regarding, for example, routine Surveillances, and payment of fees, as if the factory had been inspected in accordance with the procedures valid in that country and/or by that NCB.

7.3.3 The NCB shall examine the submitted CB Factory Surveillance Report to the extent considered necessary for the identification of the relevant equipment and for the recognition of the CB Factory Surveillance Report.

If the result of this examination is favourable, national certification or approval shall be granted by the NCB without additional surveillance following its own statutes and rules of procedure. However, if the Factory Surveillance Report does not cover declared Factory Surveillance Differences, if any, arrangements shall be made with the Applicant to carry out the additional Surveillance.

The NCB retains the right to perform surveillance at the factory to ascertain whether or not the factory complies with the relevant requirements. Such additional surveillance should be kept to a minimum.

7.3.4 The NCB may challenge the CB Factory Surveillance Report when it is more than one year old or when the requirements to which it was issued are no longer in force.

7.3.5 The NCBs are encouraged to handle applications for recognition of CB Factory Surveillance Report within 15 working days.

7.3.6 Should the NCB receiving a CB Factory Surveillance Report for recognition consider it to have been issued in error, the NCB that issued the report shall be informed as soon as possible. If the NCBs involved arrive at different conclusions, the case may be referred to the Board of Appeal of the IECEE.

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