

OPERATING GUIDE of the CB-FCS Scheme

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OPERATING GUIDE of the CB-FCS Scheme

Introduction

General

This guide applies to accepted Members when treating orders according to the FCS procedure:

NCB

CSA International

FIMKO

LCIE

VDE

TÜV PS

IMQ S.p.A.

KEMA

NEMKO

PSB

SIQ

SEMKO

SEV

ULI

CBTL

CSA International Etobicoke
CSA International Pointe Claire
CSA International Edmonton
CSA International Richmond

FIMKO

VTT

LCIE

VDE

TÜV PS Hannover
TÜV Munich
TÜV Eschborn

IMQ S.p.A.

KEMA

NEMKO AS, Norway
NEMKO ERG, Germany
NEMKO SpA, Italy
NEMKO CW, USA
NEMKO Ltd, UK
COSMOS Corp., Japan

PSB ETC ETL

SIQ

SEMKO

ITS Testing and Certification Ltd. UK
ITS HONG KONG

SEV

UL Melville
UL Northbrook
UL Santa Clara
UL Research TP
UL Camas
UL Hong Kong

This guideline is directly based on the document mentioned below

IECEE Publ. 03, Rules and Procedures of the Scheme of the IECEE for Mutual Recognition of Conformity Assessment Certificates according to Standards for Safety of Electrical Equipment, First edition, 1995-12.

(Where deemed relevant, references to this document are given on the right hand side of the page).

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Definitions	<p>Conformity Assessment Certificate (CB-CAC): A standardised certificate document issued by Body A to the applicant in his name, establishing that the conformity assessment has been carried out in full compliance with these Rules and Procedures (clause 8).</p> <p>Conformity Assessment Report (CB-CAR): A document containing the product and factory assessment information issued by Body A to the applicant (clause 9).</p> <p>(The testing and inspection results are essential parts of this report).</p>	3.4 3.5
CB-FCS	<p>CB-FCS (CB Full Certification Scheme) is an extension of the CB scheme.</p> <p>”The CB scheme is based on mutual recognition of CB Test Certificates and associated test reports as a basis for national approval or certification between member bodies participating in the CB scheme.”</p> <p>”CB-FCS is likewise based on mutual accept of Conformity Assessment Certificates between the member bodies as a basis for national approval or certification and is meant to cover production surveillance as well as testing. In addition the testing shall cover national conditions/differences in other countries involved.”</p>	
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Supervision and control		
General	Body A is expected to operate a system of supervision and control which ensures that a product initially and during continuing production complies with the requirements of the relevant standard.	4.1
Obligations of Body A	<ol style="list-style-type: none">carry out type testing for a product based on the designated standard;carry out the initial assessment of the manufacturer’s quality control and routine testing program;carry out the initial assessment of the manufacturer’s quality system based on ISO/IEC Guide 53, annex B;to grant certification/approval for the product;issue the CB-CAC and CB-CAR;be responsible for production surveillance/quality system audits.	4.3
Obligation of Body B	<ol style="list-style-type: none">inform relevant Body A of the receipt of an application for a national certification/approval;issue of its certificate/approval and possible licence for use of its mark	4.4
Responsibilities of the applicant	<ol style="list-style-type: none">have a documented quality system in operation (ISO/IEC Guide 53, annex B);have a quality control and routine testing program to ensure continuous conformance with the requirements of the relevant IEC standards.	4.5

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Application procedures

Procedures for obtaining a Conformity Assessment Certificate (CB-CAC)	<p>The application to the NCB (Body A) shall contain as a minimum the following information:</p> <ol style="list-style-type: none">a) name and address of applicant;b) name and address of manufacturer, if different from the applicant;c) names and addresses of the factories where the product will be manufactured;d) trade name or other marking by which the applicant, the manufacturer, where appropriate, and the factory can be unambiguously identified;e) product identification, type designation and markings by which the product can be unambiguously identified;f) copy of valid CB Test Certificate, if previously issued, and Test Report if from a different NCB/CBTLg) any special request, such as a particular testing laboratory or use of the manufacturer's test facilities;h) evidence of having a quality system in accordance with CB-FCS 101 <i>Manufacturing Conformity Assessment Procedures</i> based on ISO 9002 but specifically related to <i>product certification</i>	5.1
	<p>The application shall be made and dealt with according to the rules of the NCB (Body A) to which it is submitted.</p> <p>The NCB shall generally within one month arrange for conformity assessment of the relevant product. If the result of the assessment is favourable, the NCB shall issue a CB-CAC and CB-CAR to the applicant and send at the same time a copy of the CB-CAC to the IECEE Secretary in Geneva.</p> <p>When the applicant also requests evaluation to cover national differences in different countries in which the Conformity Assessment Certification is intended to be used, the report of these results shall be attached to, and considered to be a part of, the CB-CAR.</p> <p>When the application covers more factories, the addresses of each factory shall be stated both in the CB-CAC and CB-CAR. The NCB shall take steps to ensure that the products from the factories are equal, which shall be confirmed in the CB-CAR.</p> <p>The application, the results of the work done, and the information obtained in connection with the application for a CB-CAC and CB-CAR 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.</p>	
Procedure for obtaining national certification or approval	<p>When the applicant applies to Body B for national certification or approval on the basis of a CB-CAC, the application shall be accompanied by the following documentation:</p> <ol style="list-style-type: none">a) copy of the CB-CAC;b) copy of the CB-CAR;c) copy of supplementary report covering national differences, if any;d) copy of initial assessment report CB-FCS 102 and 103 pertaining to each of the factories where the product is manufactured;e) any other material required by Body B as declared differences (see annex A).	5.2

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Initial assessment of the manufacturer's quality system

Note: Because CB-FCS 101 is widely based on ISO 9002, it is permitted to take into account certified Quality Systems (ISO 9001/9002) by a duly accredited certification body. 6
However, even where the manufacturer has a Quality System certified by an accredited body according to ISO 9001/ISO 9002 the assessment must still take place to ensure that the requirements of CB-FCS 101 are met.
Where the NCB certifies the quality system, the CB-FCS 101 assessment will be concurrent.

Purpose	The purpose of the initial on-site assessment is to determine that a quality system based on the requirements stipulated in ISO/IEC Guide 53, annex B, is implemented and maintained for the product concerned in the factory where the product is manufactured.	6.1
Quality System Application Questionnaire	To facilitate assessment, the applicant/manufacturer is required to complete and return to Body A the Quality System Application Questionnaire CB-FCS 102 that contains pertinent information which shall be provided to the NCB prior the on site Initial Assessment/Factory Surveillance.	6.2
Evaluation	An evaluation of the completed Quality System Application Questionnaire CB-FCS 102 provides an indication of whether or not the factory is likely to meet the provisions of ISO/IEC Guide 53, annex B.	6.3
On-site assessment	During the on-site assessment, will be checked for correctness the information provided in the Quality System Application Questionnaire and the Assessment Team will ensure that the quality system is effectively implemented. The NCB's Auditor will assess the Manufacturer Quality System against the Manufacturing Conformity Assessment Procedures CB-FCS 101. The results of the assessment will be reported into the <i>Manufacturing Quality System Audit Report</i> CB-FCS 103.	6.4
Previous on-site assessment	A previous on-site assessment for a product line covered under the same scope of standard(s) shall be deemed to apply for all products under the scope of the standard(s).	6.5

Type testing

General	Type testing shall be carried out by an accepted CB Testing Laboratory (CBTL) under the responsibility of the associate NCB which will undertake full responsibilities of its operation.	7.1
Test Report	The Test Report shall be the same as the common format, if available, used in the CB Scheme. It will also include rationale for tests not performed as well as for tests performed beyond those specified in the requirements, and any other information necessary to explain or clarify results (see ISO/IEC Guide 25).	7.2
Use by NCB of a Manufacturer's Test facilities	<u>Testing at manufacturer's premises (TMP)</u> and <u>Supervised manufacturer's testing (SMT)</u> is allowed according to the specification as per IECEE 02. Such resolution shall be clearly included in the Bilateral Agreement between the NCBs.	7.3

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Conformity Assessment Certificate (CB-CAC)

See sample of the Conformity Assessment Certificate (CB-CAC) in Encl. 1

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A CB-CAC is valid only when the relevant Conformity Assessment Report (CB-CAR) is attached.

Conformity Assessment Report (CB-CAR)

The CB-CAR is the complete package of product and factory information developed by Body A (and made available to Body B by the applicant). It includes the following conformity assessment particulars to demonstrate that the product and the factory quality system have been fully evaluated and meets all applicable requirements:

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for the product:

- a) applicant documentation;
- b) product description (including photographs);
- c) product construction evaluation methods, if not described in the relevant standard, CB Bulletin or covered by CTL decisions;
- d) product descriptive report;
- e) identification of standards and requirements;
- f) test methods, if not described in the relevant Standard, CB Bulletin or covered by CTL decisions;
- g) test data;
- h) test results;
- i) test result observations;
- j) rationale for tests performed and tests not performed;
- k) rationale for decisions made concerning acceptability;
- l) interpretations of requirements that affect the product;
- m) engineering information;

for the factory:

evidence of an operating quality system for the specific product process that is concerned by the FCS Conformity Assessment:
CB-FCS 103/102 (optional ISO 9000 Certificate)

Surveillance/Audits /Inspections

Inspection audits

Routine inspection audits shall generally take place twice a year but may be more or less frequent depending on the relevant product category and the consistency of requirements put on the manufacturer regarding routine and selected tests.

11.1

The audit inspection shall comprise routine assessment of:

- a) operation of the quality plan, and
- b) the quality system.

The routine quality system audit inspection shall be such that over a period not exceeding two years the quality system will be assessed in its entirety.

11.2

In no case shall the frequency of visits be less than one per year.

Note: Because CB-FCS 101 is widely based on ISO 9002 it is permitted to take into account certified Quality Systems (ISO 9001/9002) by a duly accredited certification body.

However, even where the manufacturer has a Quality System certified by an accredited body according to ISO 9001/ISO 9002 the assessment must still take place to ensure that the requirements of CB-FCS 101 are met.

Where the NCB certifies the quality system, the CB-FCS 101 assessment will be concurrent.

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Audit visits	<p>If Body B so requires, audit visits shall be unannounced and will generally take place twice a year, but may be more or less frequent depending on the relevant product category as well as production rate and negative audit findings. Until further harmonization the frequency of Factory Audits shall be agreed between the NCBs in their bilateral Agreement.</p> <p>During the visit, the inspector shall, according to the test programme:</p> <ol style="list-style-type: none">verify the test records of the routine and lot (or selected) tests carried out since the previous visit;select samples for witnessed testing and witness the tests;select samples for re-testing	12.4.1
Documentation	<p>The CB-FCS documentation used during surveillance shall be:</p> <p>CB-FCS 101; CB-FCS 102; CB-FCS 103; ISO 9002.</p>	11.3
Surveillance for Body B	<p>When Body A has been entrusted for surveillance by Body B, the confidential surveillance report CB-FCS 103/102, together with any corrective action of previous discrepancies, shall be passed to Body B.</p>	11.4
Charges	<p>Charges shall be recovered by Body A either in the charges for the actual visit or on the basis of a fee according to agreed tariffs.</p>	11.5
Surveillance recognition	<p>The use of Harmonized procedures CB-FCS 101 and Harmonized forms CB-FCS 102/103 implies Mutual recognition of factory audits.</p>	11.6
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Audit testing		
Objectives	<p>To ensure that products certified under CB-FCS continue to meet the required specifications described in the applicable standard(s), audit tests shall be carried out.</p>	12.1
Types	<p>The following audit tests are considered:</p> <ol style="list-style-type: none">tests carried out by the manufacturer during the production (routine testing);tests carried out by the manufacturer during an audit visit and witnessed by an inspector of the inspection body (witness testing);tests carried out by a CBTL (re-testing);tests carried out by the manufacturer during production on a sampling basis (lot testing or selected testing).	12.2
Obligations of the manufacturer	<p>The manufacturer shall retain records of the test results of the routine and selected tests for a period of at least two years and make these available for review and verification by the visiting auditor.</p>	12.3.1
Testing programmes	<p>NCBs shall determine programmes for routine testing, witness testing, and re-testing.</p>	12.5
Reporting	<p>Reports of all audit tests shall be forwarded to all relevant NCBs B with which NCB A has signed a Bilateral Agreement.</p>	12.6
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Recognition of components

Acceptance of components	<p>For all electrical components for which an IEC standard exists, Body A shall accept the component either on the basis of an existing CB-CAC or of an existing mark or certificate of a participant in the CB Scheme, which assures both conformity to the relevant IEC standard and a minimum agreed level of surveillance.</p> <p>For all electrical components for which no IEC standard exists, Body A shall state that the component has been evaluated against a relevant standard, which shall be indicated. If this is not possible, the component shall be tested as a part of and together with the conditions occurring in the end product, as well as be subject to surveillance as part of the end product.</p>	15.1
Non-acceptance of components	<p>If, for a certain type of component, a Body B is not in position to recognize the component on this basis stated in 15.1, it shall have declared such non-acceptance by indicating the additional tests required. This information shall be included in the CB Bulletin. In these cases, Body B shall also accept the results of such additional testing carried out by Body A.</p>	15.2
Evidence of successful testing	<p>Some NCBs require for legal purposes evidence of the successful testing of some components. In such circumstances, when acting as Body B an NCB is entitled to obtain the test report it requires from the component manufacturer, or, upon authorization from the component manufacturer, from Body A.</p>	15.3

Requirements concerning surveillance for electrical components

General	<p>The NCB granting its own mark of conformity to electrical components, and wishing that the mark be recognized when certification of a product is sought, shall follow the provisions described below.</p>	16
Requirements imposed on the manufacturer	<p>The manufacturer shall have an adequate quality control. The manufacturer shall carry out sufficient tests to ensure that the components will continue to comply with the standards, as agreed with the NCB.</p> <p>In the absence of standardized IEC routine tests, Annex A of CB-FCS 101 applies.</p> <p>By agreement between the NCB and the manufacturer, tests conducted frequently as a part of the manufacturer's quality control system may be accepted as covering these requirements, if they are conducted according to the intent of the standard.</p> <p>If component standards specify routine tests, the requirements of these standards shall apply.</p>	16.1
Surveillance to be carried out by the NCB	<p>The NCB is responsible for ensuring that the surveillance visits are carried out at least at the frequency indicated in the table below and shall carry out check tests on the specimens as stated in the same table.</p> <p>During the surveillance visits, the NCB shall verify that the tests are carried out regularly by the manufacturer, with satisfactory results.</p> <p>If the component is manufactured on the production line, the quality system of which has been verified by a NCB participating in CB-FCS or certified against ISO 9001 or ISO 9002, the frequency of surveillance visits and the number of check tests required is reduced as specified below.</p>	16.2

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Table 1 - Frequency of surveillance visits and number of check tests

	According to Annex B of ISO/IEC Guide 53		Certified to ISO 9001/ ISO 9002	
	Option No. 1	No. 2	Option No. 1	No. 2
Frequency of surveillance visits per year	1	2	1 each 2 years	1
Number of specimens for the check tests per year	1 sample of specimens specified by the standard per factory per each basic type	0	1 sample of specimens specified by the standard per factory	0

Enclosures

1. Conformity Assessment Certificate
