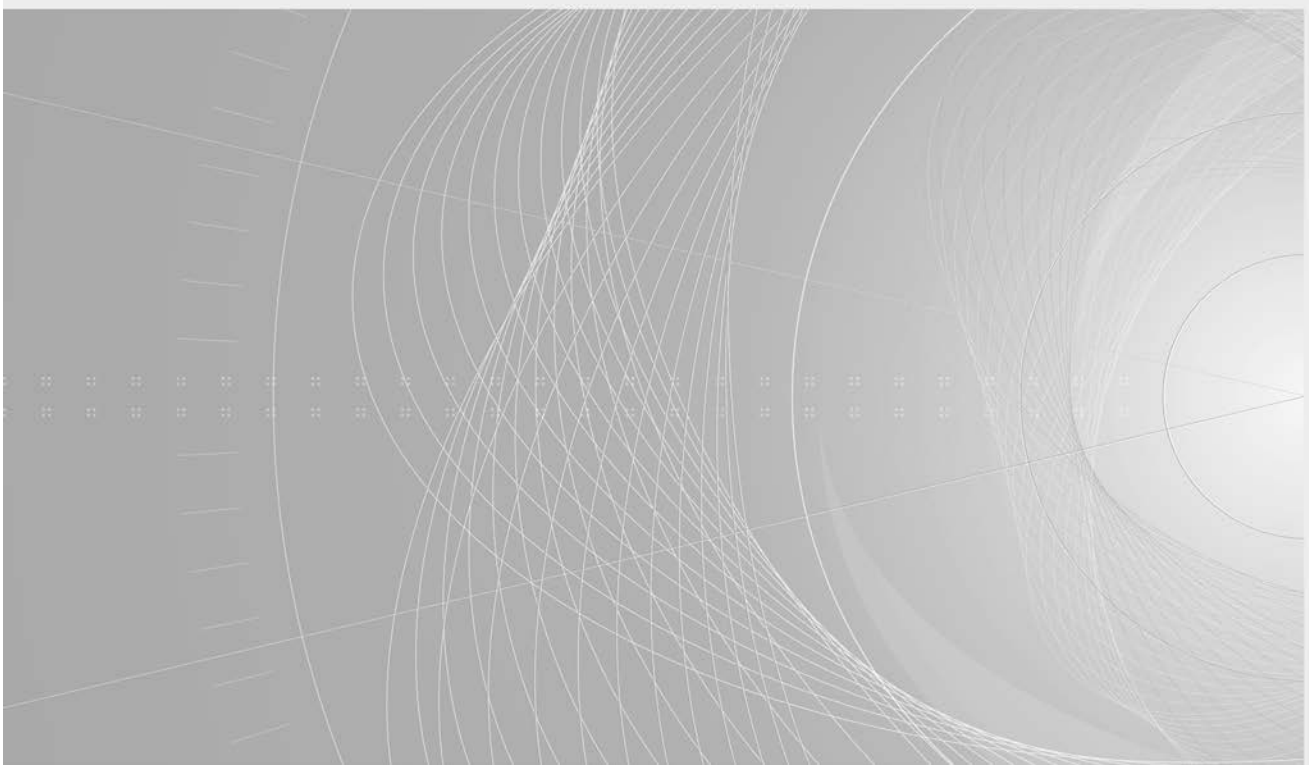


# **IECEE OPERATIONAL DOCUMENT**

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

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**Guidelines and Information for IECEE Assessments: Procedures and Documentation**





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## FOREWORD

**Document Owner**

PAC

**History of changes**

<b>Revision Date</b>	<b>Brief summary of changes</b>
2017-11-02	Clause 6 and 17.2.1 changed as per CMC decision 66/2017, 14. Clause 2 updated to include additional guidance for follow-up assessments and updating of the clause title. Clause 14 has been updated for clarification purposes.
2016-12-15	The following clause have been updated: Introduction, 1, 2, 4, 5, 7, 8, 10, 10.1, 10.2, 11, 13, 14, 17.1, 17.2.1, 17.2.2, Annex A, B, C, D, E.
2016-06-01	The following sub-clauses have been updated: Introduction. Renumbered clauses 2, 4 to 6, 8 to 12, 14, 16, 17 The following new clauses have been added: 1 and 13 General: Addition of FSB and factory surveillance references where relevant.

<b>Effective date</b>	<b>Next maintenance due date</b>
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## Introduction

The Peer Assessment programme's aim is to evaluate whether the candidate NCB and/or CBTL and/or FSB is capable and competent to test and/or certify products against a range of IEC standards and/or perform factory surveillance, whether they operate in accordance with ISO/IEC 17065 (for Certification Bodies NCBs), ISO/IEC 17025 (for the Testing Laboratory – CBTLs, SPTLs), ISO/IEC 17065 and/or ISO/IEC 17020 (for FSBs) and the applicable IECEE Rules and Operational Documents.

The assessment programme's aim is also to foster confidence among the members of the IECEE.

Note: An assessment is a "sampling exercise" and thus every aspect of the NCB/CBTL/SPTL/FSB activities cannot be covered. It does not follow, therefore, that non-conformances do not exist in areas where no assessment can be carried out.

### 1. Scope

This document outlines the requirements for IECEE Peer Assessment of IECEE NCBs, CBTLs, SPTLs and FSBs.

### 2. Types of assessments and Assessment Teams

#### Initial Assessments

NCBs, CBTLs, SPTLs, and FSBs undergoing Initial Assessments shall be assessed by three experts, to be appointed by the Secretary of the IECEE.

At the discretion of the IECEE Secretary, the number of experts may be reduced or increased to accommodate the scope of the application and the size of the candidate.

#### Follow up Assessments

NCBs, CBTL, SPTLs, and FSBs undergoing Follow up Assessments shall be assessed by one expert, to be appointed by the Secretary of the IECEE.

At the discretion of the IECEE Secretary, the number of experts may be increased to cover the issues that will have to be assessed.

Based on the guidance of the Lead Assessor, a follow-up assessment may be recommended based on, for example, the following findings or other situations where effective implementation of corrective actions cannot be verified without onsite assessment:

- Major management system findings or excessive number of management system findings requiring significant QA changes
- Major competence findings or excessive number of competence findings
- Repeat NCRs which might severely impact the credibility of CB Test Certificates and CB Test Reports
- Missing major test equipment or facilities

#### Scope Extension Assessments

NCBs, CBTLs and SPTLs undergoing Scope Extension Assessments shall be assessed by one or more experts, to be appointed by the Secretary of the IECEE.

At the discretion of the IECEE Secretary, the number of experts may be increased to accommodate the scope of the application and the size of the candidate NCB.

Note: For FSBs scope Extension Assessments are currently not applicable.

### Re-assessments

Accepted NCBs, CBTLs, SPTLs and FSBs are re-assessed on a regular basis every **three** years. Re-assessments are carried out by a team composed of one Lead Assessor and one (Expert) Assessor. At the discretion of the IECEE Secretary, the number of Assessors may be increased if the Re-assessment also includes extension(s) of the NCB/CBTL/SPTL scope.

The three year Re-assessment cycle will take place regardless of whether the previous time-scale is met.

Example:

Normal Cycle:

2010	2011	2012	2013	2014	2015	2016
Initial Assessment	-	-	Re-assessment	-	-	Re-assessment

Breakdown in First Cycle:

2010	2011	2012	2013	2014	2015	2016
Initial Assessment	-	-	Delays occur	Re-assessment	-	Re-assessment

### Relocation Assessments

CBTLs and SPTLs undergoing Relocation Assessments shall be assessed typically by one Lead Assessor, to be appointed by the Secretary of the IECEE. This is not considered to be equivalent to a Re-assessment and will not reset the Re-assessment cycle.

At the discretion of the IECEE Secretary, the number of experts may be increased to cover the issues that will have to be assessed.

The complete OD-2005 form will be used to document a Relocation Assessment. For sections where there has been no change (with respect to the information provided in the last assessment report), the report can simply state “no change”. In general, there is no need to fill in Annexes 1A, 1B and 1C.

The assessment shall, in any case, cover the Power Supply Distribution, total Harmonic Distortion and the ambient conditions of the new location, and at least some sampling, including verification of previous NCRs. Test equipment which may have been impacted by the relocation shall be examined as well.

In a Relocation Assessment Report, a statement “No Change” represents a declaration of the assessed CBTL/SPTL that the information provided in the previous Assessment Report is still valid. Verification of this information during a Relocation Assessment may be only partial at the discretion of the Lead Assessor.

### Unified Assessments

For Unified Assessments conducted together with accreditation bodies, as described in OD-G-2003, at least one IECEE Lead Assessor is appointed who is also recognized as a competent IECEE Technical Assessor to perform these assessments and assist in preparing Assessment Reports on behalf of the IECEE.

### **3. NCB representation during an on-site assessment**

In accordance with IECEE 02-3, an NCB representative should fulfil the following criteria:

- a. It needs to be documented that this person is working for the NCB
- b. Must have the authority to sign documents on behalf of the NCB, e.g. the Assessment Report.
- c. Needs to be familiar with the NCB operations and testing facilities being assessed.
- d. Must be very knowledgeable of the IECEE Rules.

If in doubt, the representative must be able to demonstrate that he/she meets the above criteria.

### **4. Accreditation**

Where the assessed NCB, CBTL, SPTL or FSB Members can provide a valid Accreditation to ISO/IEC 17065, 17025 and/or 17020 respectively within the same or greater IECEE scope, the accreditation shall be considered to fulfil the basic IECEE management system requirements. Where the accreditation scope is lesser than the IECEE scope, the accreditation may also be considered to fulfil the basic IECEE management system requirements provided that the accredited quality management system of the NCB, CBTL, SPTL or FSB also applies to the additional activity of the laboratory within the IECEE.

In all such cases, an assessment of NCBs, CBTLs, SPTL or FSBs is required:

- to establish/confirm their technical competence, and
- to verify that the management system operates in accordance with all relevant IECEE rules and procedures.

### **5. Staff experience**

When the declared years of experience is considered to be low or not sufficient, the assessment team should make a professional judgment based upon interviews on the awareness and knowledge of the standards, Test Report review, witnessing of testing and measuring, knowledge and experience for surveillance as well as CV information e.g. previous employments and function, training programmes completed. The experience listed in an Assessment Report for a member of staff should include the overall experience of the individual member of staff and not just the experience in the assessed organization.

### **6. Independence of the certification decision**

- sub-clause 7.6.2 of ISO/IEC 17065 specifies "The certification decision shall be carried out by a person or group of persons (e.g. a committee, see 5.1.4) which has not been involved in the evaluation process ...". Testing and inspection, among others, are evaluation tasks.
- the IECEE procedures are very specific on this matter. OD-2048 (and OD-2020) clearly states that at least two CBTL or CTF signatures are required on the test report: "Tested by" or "Witnessed by", "Approved by" and "Supervised by". Therefore, even if the person approving the test report has had no involvement in the evaluation, he/she is still acting on behalf of the CBTL and cannot at the same time be making a decision on certification.

The person who takes the decision on certification (and signs the Certificate) shall be a person different from those who carried out the testing evaluation.

The only exception could be made in the case of NCB staff conducting witness testing. This could hypothetically involve only two individuals at the NCB: the first one witnessing tests; and the second reviewing, approving and making a decision on certification - all in one. The test report would still carry three signatures: "Tested by" (CTF), "Witnessed by" (NCB), "Approved by" (NCB) and "Supervised by". It would be redundant to involve a third individual at the NCB.

## **7. Additional information for Re-assessments**

Due to the fact that statistics show many situations related to a "0 or limited number" of issued CB-Test Certificates/Test Reports for specific product categories, the related experience and the availability of equipment shall be deeply investigated.

The Re-assessment shall include verification of the previous assessment of the accepted corrective actions implementation.

The IECEE Executive Secretary shall provide additional information about the PAC specific recommendations or other specific issues, such as administrative scope extension documentation, the PTP provider's summary of programs participated in, GNCRs, etc. related to the assessed NCB, CBTL or SPTL in the "Particular Points to be checked".

Where LTRs and/or remote certification officers are involved, they should also be assessed for example by remote means (video conference, telephone interview, etc.).

## **8. Assessment documentation**

A checklist of the documents required can be obtained in OD-2007. These documents are provided and posted on the IEC website.

The Assessment Team is informed via e-mail on how they can access the relevant assessment documentation.

It is the Role of the Lead Assessor to complete the Assessment Report(s) OD-2004 (NCBs) and OD- 2005 (CBTLs/SPTLs), OD-4006 (FSBs), however, for the sake of efficiency and to save time, it is desirable that the assessed organization pre-completes these ODs with as much information as possible by using the same (or compatible) virus free software.

It is also the role of the Lead Assessor to check the language of the Quality Manual, Quality Procedures and Working Instructions, making the request to the assessed organization to have a third party translator available during the assessment should this language not match that of the Assessment Team.

## **9. Assessment plan including witness tests**

For the sake of properly preparing the assessment, the Assessment Team under the responsibility of the Lead Assessor, shall start preparing an assessment plan at least five weeks before the on-site assessment.

The assessed Organization shall be provided with the assessment plan three weeks before the assessment takes place.

However, during the course of the opening meeting or during the course of the on-site assessment the Assessment Team can ask to add and/or delete some witness testing depending on the factual situation that may arise during the meeting, e.g. available/unavailable samples of the products, incorrect settings or equipment out of calibration, etc.

## **10. Scope of Re-assessment**

The Assessment Team under the leadership of the Lead Assessor shall determine in their Assessment Plan the standards they would like to assess through the IECEE Website where the scope of NCBs, CBTLs and SPTLs is detailed. It is the responsibility of the Lead Assessor to set up the assessment plan pertaining to the sampling of the standards to be assessed and to provide it to the assessed organization preferably during the opening meeting of the on-site assessment.

It is underlined that Scope extensions for NCBs, CBTLs and SPTLs shall be processed following the current procedure and cannot be included in the Annex 1A nor can scope extensions be processed without the formal assignment by the IECEE Secretariat.



The selection of the standards & product categories is a sampling exercise and is dependent e.g. on the competence of the Lead Assessor and Technical Assessor and the product category that is targeted, as shown in Annex A of this Operational Document. When assessing organizations with large scopes, priority should be given to particular standards not assessed in the previous assessment. Throughout the assessment, the tests to be witnessed, reports and equipment lists to be reviewed and the observations on number of certificates issued should be limited to the selected standards.

During the assessment the assessed organization must be able to provide, on the basis of the assessment plan and upon request by the assessment team, the number of relevant certificates and test reports and surveillance reports issued in last three years. The Assessment Team can then request to see these certificates, test reports or surveillance reports as appropriate (NCB, CBTL, SPTLs or FSB).

Note: if the assessed organization is not able to provide figures for the number of test reports/CBTCs for the selected standards (and for FSB surveillance reports) during the on-site assessment the Lead Assessor shall issue a non-conformity report for improper document control.

**10.1 For NCBs and CBTLs - Annex 1A of the Assessment Report:**

If the assessed organization is unable to demonstrate testing/certification experience for the selected standard, the standard should still be listed in Annex 1A with indication that there is no experience, and the "not accepted" box should be checked. However, the Assessment Team should assess through the documentation of the assessed organization that the real situation is matching the statement by the organization. Subsequently, the Assessment Team shall re-consider the sampling of the standards they would like to assess.

Testing/certification experience for national/regional standards that are reasonably harmonized with the equivalent IEC/ISO standards can be counted as experience if no experience can be demonstrated for the IEC/ISO standards. This shall be clearly indicated, for example:

Product Category	Standard	Number of Test Reports issued during the last 3 (three) years*	Assessment Team acceptance	
			Yes	No
OFF	60950-1:2005**	333	<input checked="" type="checkbox"/>	<input type="checkbox"/>

\* experience also includes equivalent national/regional standards.

\*\* scope excludes subcategory RT

The Assessment Team will then complete the blank Annex 1A listing only those standards which have been selected from the current scope and checked during the assessment. They will provide their acceptance recommendation by ticking YES or NO as appropriate.

It is obvious that the Assessment Team assigned for the next round of the Re-assessment shall take into account the previously selected standards and shall determine their sampling based upon this.

**10.2 For FSBs – Annex 1 of Assessment Report (OD-4006):**

If the assessed organization is unable to demonstrate surveillance experience the "not accepted" box should be checked.

Surveillance experience from inspection programs/schemes similar to the FSS may be considered

	Program/Scheme	NCB	Number of Surveillance Reports issued during the last three years	Assessment Team acceptance	
				Yes	No
	HOUS	XYZ	25	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	OFF	ABC	15	<input type="checkbox"/>	<input checked="" type="checkbox"/>

## 11. Documentation to be made available during the assessment of NCBs

During the preparation of an on-site assessment the Lead Assessor may request the following documentation to be made available during the assessment:

- a) Information about the authority under which the certification body operates;
- b) A documented statement of its product certification system, including its rules and procedures for granting, maintaining, extending, suspending and withdrawing certification;
- c) Information about the evaluation procedures and the certification process related to each product certification system;
- d) A description of the means by which the organization obtains financial support and general information on the fees charged to applicants and to suppliers of certified products;
- e) A description of the rights and duties of applicants and suppliers of certified products, including requirements, restrictions or limitations on the use of the certification body's logo and on the ways of referring to the certification granted;
- f) Information about procedures for handling complaints, appeals and disputes;
- g) A directory of certified products and their suppliers;
- h) Agreement/Contract between the NCB and associated CBTL(s) as per IECEE 02-2
- i) Agreement/Contract between the NCB and associated CTFs
- j) Complete certification files of each product category, including CB Test Certificates (or CB FCS CAC) and associated Test reports (or CB FCS CAR).
- k) IEC standards as per the scope
- l) IECEE-CMC list of current decisions
- m) IECEE 01, IECEE 02, IECEE 03 (if applicable), Operational Documents
- n) IECEE-CTL Decision Sheets and Operational Procedures
- o) C.V. of involved staff
- p) List of National Differences
- q) List of Regulatory requirements
- r) IECEE Training provided to NCB's staff and associated CBTL(s)/SPTL(s)
- s) Quality Manual and other associates procedures (at least the index in English).
- t) Impartiality and Confidentiality policy

### Additional Documentation required for CB-FCS assessments/Re-assessments:

- u) Information about the Factory Inspection department (however named) capability (if any)

**In addition to assessing the NCB against ISO/IEC 17065, the Assessment Team should focus on:**

- Knowledge of the personnel responsible for the area audited on CB & CB-FCS (if applicable) procedures
- Document control of standards

- Procedures relevant to:
    - a) grant, maintain, withdraw and, if applicable, suspend certification
    - b) Re-evaluation; in the event of changes significantly affecting the product's design or specification that the product may no longer comply with the requirements of the certification process.
  - Application of the relevant IECEE-CMC and CTL procedures
  - Review on randomly-checked completed \*"down-stream/up-stream" files,
- \* Files that contain all information including, for example, application from Applicant/Manufacturer, setting of the type testing programme, Test Report, certification decision, etc.

**Tip:** Select CB Test Certificates from the IECEE CBTC On-line System and track the certification process over the corresponding CBTL/SPTL file.

## **12. Documentation to be made available during the assessment of CBTLs/SPTLs**

During the preparation of an on-site assessment the Lead Assessor may request the following documentation to be made available during the assessment:

- a) Completed Test Reports and associated measurement records
- b) IEC Standards and related IEC interpretation sheets and CTL Decision Sheets
- c) Working instructions, Testing procedures/methods
- d) IECEE Blank Test Report Forms related to the scope for which the CBTL/SPTL has been accepted
- e) Testing proficiency experience (PTPs completed)
- f) Calibration records
- g) Calibration Services and Calibration Traceability
- h) List of defined Testing Equipment/facilities
- i) C.V. of involved staff
- j) List of National Differences
- k) List of Regulatory requirements
- l) Measurement Uncertainty and Accuracy procedure(s)
- m) Sample Identification procedure
- n) Quality Manual\* and associated procedures that support the Quality Manual
- o) Impartiality and Confidentiality policy

\* If the Quality Manual and associated procedures are not in English, at least the index and headings must be in English.

**In addition to assessing the CBTL/SPTL against ISO/IEC 17025, the Assessment Team should focus on:**

- a) The Laboratory's procedures for achieving traceability of records/measurements
- b) Procedures for calibration, verification and maintenance of equipment
- c) The personnel competence and capability to carry out tests on selected clauses of the standards;
- d) The adequacy between the testing requirements and the testing facilities necessary to complete the testing programme
- e) The operational staff's understanding of sensitive requirements of relevant standards and CTL decisions ;
- f) The review of selected Test Reports linked with the "Up-stream/down-stream" of the responsible NCB;

- g) The procedures agreed with the NCB regarding the acceptance of critical component;
- h) The effectiveness of the power supply system (voltage stability, current, distortion percentage, electric schematics, previous campaign of tests aimed to check the suitability of the system);
- i) The subcontracting of tests and the relevant documentation (agreements, list of instruments, distances from the subcontracted laboratory, compatibility with test sequences.
- j) Some other matters, not yet covered at present by Operational Documents, such as the existence of SPTLs owned by the assessed organization.
- k) The Proficiency Testing Programmes undergone/undergoing.

The Re-assessment Team should also focus on previous Assessment Reports and clearance of related NCRs, and additional information arising from current issues dealt with by the IECEE Secretariat.

Note: In order to verify these requirements the candidate CBTL/SPTL is requested to repeat some significant tests under the scope of the application.

### **13. Documentation to be made available during the assessment of FSBs**

During the preparation of an on-site assessment the Lead Assessor may request the following documentation to be made available during the assessment:

- a) Completed Surveillance Reports
- b) CFS Decision Sheets, Routine Test Requirements, PIDs
- c) Working instructions, Surveillance procedures/methods
- d) C.V. of involved staff
- e) Special Requirements (OD-4003-SR)
- f) Sample Identification procedure
- g) Quality Manual\* and associated procedures that support the Quality Manual

Impartiality and Confidentiality policy

Documentation of Surveillance Experience

- h) Objective evidence that the candidate FSB:
  - is an integral part, such as a department, division, branch or subsidiary of the relevant NCB, or
  - is under the complete technical and legal control of the relevant NCB, or
  - a written agreement clearly outlining the commitment, duty and responsibility of both the candidate FSB and the relevant NCB to follow IECEE Rules.
- i) Organization Charts of the candidate FSB
- j) OD-4006 duly “pre-filled in” to the best extent possible
- k) AD 006, Table to declare Special requirements
- l) Registration of at least one IECEE-Factory Inspector
- m) Documented evidence about training and qualification for its Factory Inspectors.

\* If the Quality Manual and associated procedures are not in English, at least the index and headings must be in English.

In addition to assessing the FSB against ISO/IEC 17065 or ISO/IEC 17020, the Assessment Team should focus on:

- a) The Surveillance Body's procedures for achieving traceability of records/measurements
- b) The personnel competence and capability to carry out surveillance;
- c) The procedures agreed with the NCB;

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The Re-assessment Team should also focus on previous Assessment Reports and clearance of related NCRs, and additional information arising from current issues dealt with by the IECEE Secretariat.

#### **14. Acceptance of standards and product categories**

Standards listed in Annex 1A/B of OD-2004 and OD-2005 must detail the Standard publication year and the Amendment as applicable.

For Initial Assessments, Follow-up Assessments and Scope Extension Assessments, the assessed NCBs/CBTLs/SPTLs shall show evidence of certification/ testing experience for determined IEC standards or equivalent national/regional standard.

Note: testing/certification on the basis of national/regional standard can be taken into account if the relevant standards are reasonably harmonized to IEC standards.

Experience of NCBs/CBTLs/SPTLs is considered sufficient when at least 10 Certificates/Test Reports have been issued during the last 3 years for the product category applied for but at least one Certificate/Test Report for each standard applied for (generally disregarding editions and amendments).

CTF stage 1 (including LTR experience) can be taken into account to show compliance with the above rules, however the experience by the CBTL shall exceed 50% of the required minimum.

For Part 2 standards, where only one project was completed during the last three years, it must be based on testing at the CBTL.

Experience of FSB is considered sufficient when:

- a) Within the last 3 (three) years, at least 20 surveillances have been performed. Surveillance experience from inspection programs/schemes similar to the FSS may be taken into consideration.
- b) the FSB is providing documented evidence about training and qualification for its Factory Inspectors.

As a result of the assessment of the NCBs/CBTLs/SPTLs experience the Lead Assessor's shall either:

- a) Tick the box(es) "Accepted" in the relevant part of Annex 1 of OD-2004 and/or OD-2005 when at least 10 Certificate/Test Report have been issued during the last 3 years for the product category applied for but at least one Certificates/Test Reports for each standard applied for.
- b) To tick the box(es) "Not Accepted" in the relevant part of Annex 1 of OD-2004 and/or OD-2005 when less than 10 Certificates/Test Reports have been issued during the last 3 years for the product category applied for or no Certificates/Test Reports for each standard applied for.

#### **15. Issuance of Assessment Reports**

Assessment Reports should be completed, agreed, signed and dispatched to the IECEE Secretariat after the final meeting that takes currently place at the end of the assessments but no later than 10 working days after the assessment. In special circumstances the Lead Assessor, in consultation with the IECEE Secretariat, may be given extra time to forward the final Assessment Report to the IECEE Secretariat.

#### **16. Non-Conformity Reports**

Root causes of the Non-conformities raised by the Assessment team and the proposed corrective actions to overcome such non-conformities do not need to be completed at the time of the assessment if the assessed organization needs time to investigate further the non-conformities.

In these circumstances the root causes and proposed corrective actions shall be provided to the Assessment Team 1 month from the time the Assessment Report is provided and Signed by the parties, unless otherwise notified by the Secretariat.

In all circumstances the root causes for NCRs shall be reported.

In clearance of an NCR, the Lead Assessors shall provide to the IECEE Secretariat copies of final completed NCRs without the evidence documentation. Important information related to the NCR that is recommended to be considered by the future Assessment Team may be included by the Lead Assessor within the cleared NCR. In case extraordinary issues are encountered during the assessment and/or clearance process of the NCR(s), the IECEE Secretariat may be contacted for support.

## **17. Additional issues for Re-Assessments**

**17.1** When the assessed NCBs/CBTLs/SPTLs cannot show evidence of certification/ testing experience for determined standards since the last Re-assessment yet wishes to maintain these standards in its scope, they may provide Claims of Competence (OD-2021, Part 3) one month from the IECEE Secretariat notification of publication of the assessment report.

When the assessed FSBs cannot show evidence of surveillance experience, they may provide Claims of Competence (OD-2021, Part 4) one month from the IECEE Secretariat notification of publication of the assessment report.

Since the Claim(s) of Competence processing is outside the task of the Assessment Team, if the latter is provided with the Claim(s) of Competence during the on-site Re-assessment, the Lead Assessor shall:

- a) Tick the box(es) “not accepted” in the relevant part of Annex 1A of OD-2004 and/or OD-2005 and Annex 1 of OD-4006.
- b) Request the assessed organization to send the Claim(s) of Competence to the IECEE Secretariat for further processing.

The aim of the Claims of Competence Part 3 and part 4 is to enable NCBs, CBTLs, SPTLs and FSBs to demonstrate that, although no test/certification/surveillance to standards/programs covered within the IECEE Scope was completed since the last Re-assessment, the organization and the staff have the competence for acceptance. The required evidence shall include , but not be limited to, the following:

- List of required test equipment and procedures
- National accreditation
- Experience, within the last three years, with the same or similar international, national or other standards/programs.

In the event no test/surveillance reports based on the same or similar international, national or other standards/programs completed within the last three years, are provided, the Secretariat may require further scrutiny of the other evidence provided.

Claims of Competence to maintain standards/programs in the scope of acceptance is exclusively related to Re-assessments and shall not be taken into account for Initial or Scope Extension Assessments.

### **17.2 Guidance on Assessment of NCBs Conducting CTF Activities**

**17.2.1** The assessment of NCBs conducting CTF activities must cover the following elements:

- a) NCB must have a comprehensive procedure for managing CTF activities, in accordance with OD-2048, that includes:
  - i) Ensuring that all NCB personnel involved in CTF-related activities are fully trained for this purpose;
  - ii) Verification that the NCB has copies of completed CTF Assessment Reports

OD-2048-F2 CTF Assessment Report (CTF Stages 1 and 2)

OD-2048-F3 CTF Assessment Report (CTF Stages 3 and 4)

- iii) Providing to the CTF all relevant IECEE information and documents, such as procedures, decisions and TRFs, and ensuring that their standards are up to date.
  - iv) Assessment of technical competence of CTF staff (e.g. standards and CTL decisions) and facilities (equipment, calibration, and lab accommodations);
  - v) Initial Assessment, Re-assessment, on-going control, and decisions on progression of the CTF in accordance with the CTF procedures;
  - vi) Maintaining a sustained program of supervision that includes of witnessing of tests and monitoring of the quality management system at the CTF;
  - vii) Approval the test programs for which CB Test Reports are prepared;
  - viii) Reviewing test reports prepared by the CTF;
  - ix) Where a NCB performs CTF work without involving a CBTL/SPTL, having appropriate procedures and resources for direct CTF operations.
- b) Verification of NCB staff competence to perform CTF activities should address:
- i) Qualification, training and experience in the assessment of laboratories to ISO/IEC 17025;
  - ii) Understanding and proper use of the relevant IECEE ODs, such as OD-2048.
- c) Verification of effective implementation of CTF procedures should include:
- i) Checking existence of CTF assessment plans;
  - ii) Review of the Assessor selection process;
  - iii) Review of examples of CTF Assessment Reports, including checking Assessors' competence records;
  - iv) Reviewing the process of NCR resolution;
  - v) Ensuring that there are appropriate agreements between the NCB, CBTL, SPTL and the CTF;
  - vi) Registration of the Customer's Testing Facility (CTF) with the IECEE Secretariat, and the maintenance of the correct details in the IECEE register of CTFs;
  - vii) Issuing CB Test Certificates correctly to identify CTF operations;
  - viii) Ensuring the CTF's participation in applicable CTL Proficiency Testing Programs;
  - ix) Arranging all other required tests that are not carried out at the CTF;
  - x) Adjusting the Stage of the CTF, as may be necessary, if any of the changes noted in clauses 10.4.2 and 10.4.3 occur.

**17.2.2** For Stage 4, the NCB is required to appoint a representative to the IECEE Peer-Assessment Team. This appointed representative may also be acting during the Peer-Assessment as Assessor. In case of multiple NCBs (see clause 14 in OD-2048) each NCB involved with this CTF shall appoint a representative to the Assessment Team.

## **18. Multiple testing locations**

**18.1** Two testing sites can be considered as one single testing entity (CBTL) if the Laboratories have:

- same quality management system;
- same laboratory manager.

The distance between the two locations must be less than 1 hour away (by any means). However, if it is less than 15 minutes away (by any means) no extra assessment time required, if it is more than 15 minutes away (by any means) an extra day assessment may be requested. If the other location is more than 1 hour away, then it cannot be a single CBTL.

**18.2** Adding additional testing sites to an existing CBTL

If a new location is added for a new category or significant new number of Standards in an existing Product Category a Scope Extension Assessment is required.

If a new location is added to expand existing Product Category(s) without significant number of new Standards a Relocation Assessment is required.



**Annex A Example of sampling of standards & product categories**

Category	Scope of the CBTL	Sampling made during the on-site Re-assessment
<b>HOUS</b>	IEC 60335-1:2010 IEC 60335-1:2010/AMD1:2013 IEC 60335-1:2010/AMD2:2016 IEC 60335-2-10:1987 IEC 60335-2-10:1987/AMD1:1991	IEC 60335-2-10:1987 IEC 60335-2-10:1987/AMD1:1991
<b>OFF</b>	IEC 60950:1999 IEC 60950-1:2001 IEC 60950-1:2005	IEC 60950-1:2001
<b>TRON</b>	IEC 60065:1998 IEC 60065:2001 IEC 60065:2001/AMD1:2005 IEC 60065:2001/AMD2:2010	IEC 60065:2001 IEC 60065:2001/AMD1:2005 IEC 60065:2001/AMD2:2010

## **Annex B Publications pertaining to measurement uncertainty**

- 1) ISO/IEC Guide 98-3, Guide to the expression of uncertainty in measurement.
- 2) IECEE Guide 115, Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector.
- 3) NIST Technical Note 1297 – 1994, Guidelines for evaluating and expressing the uncertainty of NIST measurement results.  
<http://emtoolbox.nist.gov/Publications/NISTTechnicalNote1297s.pdf>
- 4) Tutorial & Examples Website – National Institute of Science and Technology.  
<http://physics.nist.gov/cuu/Uncertainty/index.html>
- 5) JAB Note 4, Estimation of measurement uncertainty (electrical testing/high power testing), The Japan Accreditation Board for Conformity Assessment, 2003.
- 6) Examples Website – Examples of Uncertainty of Measurement Calculations.  
<http://spiff.rit.edu/classes/phys376/uncert.html#single>

## **Annex C Particular issues for assessment of Risk Management called out by the 3rd edition of the IEC 60601-1**

### **C.1 Staff training, experience and qualification**

To be considered qualified and competent for certification of products to IEC 60601-1 3rd edition, involved staff must have training and experience in applying risk management per the ISO 14971 standard.

### **C.2 CBTL/SPTL capabilities**

As a minimum, IECEE Assessors should verify that the CBTL/SPTL:

- properly uses the TRF for IEC 60601-1:2005(3rd Edition)/AMD1:2012 (correct TRF version)
- understands when risk management is applicable
- understands and correctly uses OD-2044 and OD 2055
- is capable of reviewing Risk Management Files, and in particular
- can make informed decision when deviation from IEC 60601 requirement is acceptable
- can evaluate and approve a manufacturer's justification that the residual risks resulting from applying alternative means of construction are equal to or less than residual risks resulting from a direct application of the requirements of IEC 60601
- can apply the flowchart of figure B.1 of annex B of the ISO 14971

### **C.3 Documentation for Assessors during the assessment of CBTLs/SPTLs**

a) Required:

- Sample (completed) Test Reports, including Risk Management Tables
- Associated measurement records for Test Reports,
- CBTL/SPTL defined method for ensuring consistency in the evaluation of Risk Management Files,
- Training records.

b) Supplemental (optional):

- Critical elements (Manufacturer provided objective evidence) from the Risk Management File.

### **C.4 Subcontracting**

Risk management File evaluations are not subcontractable.

Note: This would be considered nonconformity.

### **C.5 Assessment of the 60601-1 3rd evaluations performed by the CBTL/SPTL**

**C.5.1** The Assessor should verify that CBTL/SPTL evaluation of the Risk Management File includes the following:

- Reference to manufacturer's RM team
- Risk Management policy and acceptance criteria established for the evaluated medical device
- Intended use of Electrical Medical Device
- Measures introduced to ensure the device performs safely and effectively in its intended environment
- Essential performance identified
- The risks associated with EMD identified

- Risks assessed against acceptance criteria
- Effectiveness of introduced measures verification
- Evaluation of the need for defining test methods or compliance criteria

**C.5.2** The Assessor should verify that the CB Test Reports address the following:

- Was the policy leading to acceptance criteria reviewed?
- Were hazards identified and documented?
- Were protective measures taken from IEC 60601 series or from other published standards?
- Were any identified hazards not covered by the IEC 60601 standard addressed by the manufacturer following the applicable elements of their Risk Management process per ISO 14971?
- When applicable, did the manufacturer identify alternative means to provide an equivalent safety level to IEC 60601 series of standards?
- Was the Risk Management File reviewed and the review documented?
- Were Risk Management tables in the TRF completed according to the Guide?
- Did the manufacturer apply the Risk Acceptability Criteria to Risk Acceptability decisions?
- Were references to Risk Management documents provided?
- Did CBTL/SPTL collect and document sufficient evidence and justification?

### **C.6 Completion of Annex 6 of OD-2005**

The results of the evaluations as outlined in D.1 thru D.5 are reported in Annex 6 of the assessment report OD-2005.

### **C.7 Assessment of EMC CBTLs/SPTLs having IEC 60601-1-2:2014 in its scope**

IEC 60601-1-2:2014 includes key Risk Management requirements that are tightly integrated within both these standards. IEC 60601-1-2:2014 requirements cannot be addressed without Risk Management and Essential performance, which also requires the application of Risk Management according to ISO 14971.

Consequently, the EMC CBTLs/SPTL having IEC 60601-1-2:2014 in their scope shall be able to demonstrate adequate competency and training in Risk Management as required in accordance with the standard ISO 14971:2007, Medical Devices – Application of risk management to medical devices.

### **C.8 Reference documents**

- 
- OD 2044, Guidelines for Risk Management in Medical Electrical Equipment
- OD 2055, Document on Medical Electrical Equipment in the CB Scheme according to the IEC 60601 and IEC/ISO 80601 Series of Standards
- **OD-2020, clause 3.4.2.2, Note 3 Use of the verdict N/E**

## **Annex D Duties, Responsibilities and Code of Conduct for IECEE Peer Assessors**

### **Introduction**

The IECEE Peer Assessment concept and practice are part of the foundation of the IECEE System. The marketplace success of the primary IECEE deliverable, the mutual acceptance of Certificates and Test Reports, is based entirely on the participants' confidence in each other's technical competence and integrity. In the business world, confidence is based on ongoing verification.

The IECEE Assessments, and other related activities for verifying competence, are the responsibility of all IECEE participants, the NCBs, CBTLs, SPTL and FSBs, who have assigned this role to the Lead and Technical Assessors that they appointed.

### **General**

The IECEE Assessors have the following duties and responsibilities:

- Complete (and have the NCB endorse) the Assessor application form - Questionnaire for Assessors and Factory Inspectors, AD-001, and submit it to the IECEE Secretariat.
- Attend IECEE Assessor Training every three years and pass the required examinations.  
If an Assessor misses the tri-annual training workshop on his/her continent, the training must be taken in the following year, in a different region, to retain the active Assessor status.
- Be thoroughly familiar with all Operational Documents utilized in IECEE Assessments.
- Make decision on accepting assessment assignments from the IECEE Secretariat within two weeks, by returning a signed Peer Order Confirmation Form to the Secretariat.
- Carry out assessments and complete IECEE Assessment Reports in accordance with IECEE 02-3 and OD-2006 and the relevant CMC and PAC Decisions.
- Conduct assessments in a professional, courteous and efficient manner, keeping in mind the overall concept of Peer Assessment and mutual cooperation.
- Provide technical support for the IECEE Secretariat where an independent technical review is needed for:
  - IECEE Assessments involving "Conditional Acceptance", or
  - The Secretariat's decisions on administrative scope extensions.

### **Lead Assessors**

Additionally, it is a duty of the IECEE Lead Assessors to:

- Act as Assessment Report Reviewers when appointed by the IECEE Secretariat.

### **Code of Conduct for IECEE Peer Assessors**

To promote the highest standards of professional conduct, efficiency and integrity in IECEE Assessments, and to provide positive reinforcement for the mutual confidence among the IECEE members, the following is the Code of Conduct for IECEE Peer Assessors.

- The Lead Assessor makes contact with the Technical Assessor(s) and the organization to be assessed shortly after accepting the assignment - to establish an initial timeframe for the assessment. The NCB must be copied on this correspondence.
- All Assessment Team members review the relevant information in advance of the assessment and come well prepared.
- The Assessment Team members must exercise a high level of personal and professional discretion in dealing with the management and staff of the assessed organization under all conditions, including :

- Showing respect for each individual,
  - Making the staff being questioned feel “at-ease”,
  - Directing any conclusions towards the organization rather than individuals,
  - Discussing options for resolution of the NCRs (where root causes have been properly identified) and for providing acceptable evidence of completion,
  - Politely declining “excessive hospitality” if in the opinion of the Lead Assessor it can impact the effectiveness, the process or the integrity of the assessment.
- All financial arrangements related to the cost of the assessment must be strictly in accordance with the IECEE rules in OD-2026, and must be handled only prior to and after completion of the assessment.
  - The NCB must be copied on all correspondence related to NCR resolution of their CBTLs/SPTL and must be notified promptly if the Lead Assessor identifies potential obstacles to timely resolution.

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