IECEE OD-2025-B

Edition 1.2 2016-06-01

IECEE OPERATIONAL DOCUMENT

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

CTF - Customers' Testing Facility

CTF Assessment Report

(CTF Stages 3 and 4)

IECEE OD-2025-B:2016(EN)

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CTF - Customers' Testing Facility

CTF Assessment Report

(CTF Stages 3 and 4)

<Report number>

CTF name

CTF address

Date of assessment: yyyy-mm-dd

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE ZZ

FOREWORD

Scope

To be determined.

Document Owner

CMC WG 3 "Utilization of Customers' Testing Facilities"

History of changes

Date	Brief summary of changes
2016-06-01	The following sub-clauses have been updated: 1.2, 2.4, 4, 5.2, 8 The following sub-clause has been deleted: 5.3 A new Annex 6 has been added.

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

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CTF Stage 3/4 Assessment Report

< Report number >

1 Assessment details

1.1 Type of Assessment			
Initial Assessment (IA)	☐	Annual Assessment (AA)	☐
Scope Extension (SE)	☐	Follow-up Assessment (FA)	☐
Re-Location Assessment (RLA)	☐	Re-Assessment (RA)	☐

1.2 Product Categories covered by the assessment

INDA	BATT	CABL	CAP	CONT	E3	ELVH	EMC	HOUS	HSTS	INST	LITE
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
MEAS	MED	MISC	OFF	POW	PROT	PV	SAFE	TOOL	TOYS	TRON	
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	

Refer to Annex 1 Scope of CTF for a complete list of the scope of the assessment

1.3 Previous Assessment Reports – Report No. and Date

1.4 CTF Stage
Select the applicable stage(s)

☐ Stage 3	☐ Stage 4

1.5 CTF Contact Information

Contact Person	
Telephone	
Mobile	
Fax	
Email	

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1.6 Assessment Team		
	Lead Assessor	Assessor
Name		
Title and Organization		

1.7 Assessment Base
IECEE 01 – Basic rules
IECEE 02 – Rules of Procedure
ISO/IEC 17025
OD-2006 – Guidelines for assessors
OD-2048 – Third Party Utilization of Customer's Testing Facilities
OD-2034 – Operation of a Local Technical Representative (LTR) for the IECEE CTF Program **(applicable in case the assessment is conducted by an LTR or the CTF is used by an LTR)**
The above assessment base documents are to be the latest published editions

2 Organisation

2.1 NCB and Manufacturer/Applicant undertaking the responsibility for the CTF **(One assessment report per NCB)**	
Responsible NCB: Address:	Responsible Manufacturer/Applicant: Address:

2.2 Responsible persons present during the assessment of the CTF **(Other than the assessment team)**	
Responsible NCB* ☐ Name:	Name of Manufacturer/Applicant representative:
CBTL requested by the resp. NCB* ☐ Name: Address:	Name of CTF representative:

*Whenever applicable

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2.3 Brief history of the CTF
Include information about the legal status of the CTF and ownership (see ISO/IEC 17025, clause 4.1.1 and OD-2048, clause 4.1.1) **Complete this section for Initial Assessment and for other Assessments complete only with updates since the last assessment.**

2.4 Organisation of the CTF (refer to Annex 2 Organisation Chart(s))	
The testing laboratory is owned by Manufacturer/Customer	☐ Yes ☐ No
If "No", explain how continued compliance of the CTF with the relevant requirements of ISO/IEC 17025 and OD-2048, clause 4.1.2 is maintained.	

3 Personnel Structure

3.1 Employees	
Number of people working in the overall CTF testing area:	
Number of people involved with the **product** testing activity of the CTF within the scope of this assessment	

3.2 CTF Managers responsible for Testing Facility					
Name	Position (title) and field of expertise	Years of relevant experience	Experience checked and appropriate		To whom do they report?
			Yes	No	
			☐	☐	
			☐	☐	

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3.3 Principal CTF staff involved in testing					
Name	Position (title) and field of expertise	Years of relevant experience	Experience checked and appropriate		To whom do they report?
			Yes	No	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	

3.4 CTF staff involved in the Quality Management System and Calibration activities					
Name	Position (title) and field of expertise	Years of relevant experience	Experience checked and appropriate		To whom do they report?
			Yes	No	
			☐	☐	
			☐	☐	

3.5 Assessment of the CTF staff competence
Briefly describe how the staff competence was assessed e.g. interview, CV check, demonstration of technical decisions, knowledge of the standard, reviewing of the Test Reports, etc.

4 CTF Testing premises

Total CTF testing laboratory area	m²
Total CTF testing area in the scope of the assessment	m²
Is the power distribution system sufficient/appropriate in the scope of recognition?	☐ Yes ☐ No
Annex 5 CTF Power Supply Capabilities to be completed and attached.	

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5 Quality Management, Technical and IECEE Requirements

5.1 Quality Management System

Is the CTF Accredited by a reputable Accreditation Body? (if available, append the Accreditation Certificate as Annex 3 "Accreditation Certificate(s) relevant to the CB-Scheme/CB-FCS") **If the CTF is accredited, check the scope covered by the accreditation. If the CTF is not accredited or if the CTF does not make the accreditation scope available, the quality management system of the CTF shall be examined in detail.**	☐ Yes ☐ No
The accreditation covers the product categories/standards covered by this assessment	☐ Yes ☐ No ☐ N/A
Structure of the Quality Management System	
Brief description	
The following elements are in compliance with the referenced ISO/IEC 17025 Sub-clauses:	
Document control, Sub-Clause 4.3	
☐ Yes ☐ No	Reviewed evidence:
Review of requests, tenders and contracts, Sub-Clause 4.4	
☐ Yes ☐ No	Reviewed evidence:
Subcontracting of tests, Sub-Clause 4.5	
CFTs are not permitted to subcontract testing	
Purchasing services and supplies, Sub-Clause 4.6	
☐ Yes ☐ No	Reviewed evidence: **Identify applicable procedures. Procedure name and/or titles can be provided as evidence.** **Verify all applicable consumables such as cheesecloth, tissue paper, thermocouple wire and glue, solvents, etc.** **Verify records, such as purchase orders or receipts.**
Service to the Customer, Sub-Clause 4.7	
☐ Yes ☐ No	Reviewed evidence:

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Control of records, Sub-clause 4.13	
☐ Yes ☐ No	Reviewed evidence:
Complaints, Sub-Clause 4.8 **(verify complaint resolution procedures related to laboratory operations)**	
☐ Yes ☐ No	Reviewed evidence:
Control of nonconforming testing work, Sub-Clause 4.9	
☐ Yes ☐ No	Reviewed evidence:
Improvement, Sub-Clause 4.10	
☐ Yes ☐ No	Reviewed evidence:
Corrective action, Sub-Clause 4.11	
☐ Yes ☐ No	Reviewed evidence:
Preventive action, Sub-Clause 4.12	
☐ Yes ☐ No	Reviewed evidence:
Internal audits, Sub-Clause 4.14	
☐ Yes ☐ No	Reviewed evidence:
Management reviews, Sub-Clause 4.15	
☐ Yes ☐ No	Reviewed evidence:

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5.2 Technical Requirements

The following elements are in compliance with the referenced ISO/IEC 17025 Sub-clauses: **Describe whether procedures for sample handling, component acceptance, performance of critical tests,, calibration of equipment, measurement accuracy /uncertainty, training and other relevant items from ISO/IEC 17025, clause 5 are available and appropriate.**	
Personnel, Sub-clause 5.2	
☐ Yes ☐ No	Reviewed evidence:
Accommodation and environmental conditions, Sub-clause 5.3 (See also Annex 5 CTF Power Supply Capabilities)	
☐ Yes ☐ No	Reviewed evidence:
Test and calibration methods and method validation, Sub-Clause 5.4	
☐ Yes ☐ No	Reviewed evidence:
Equipment, Sub-clause 5.5	
☐ Yes ☐ No	Reviewed evidence:
Measurement Traceability, Sub-clause 5.6 (See also Annex 4 Application of Measurement Uncertainty concepts)	
☐ Yes ☐ No	Reviewed evidence: **Verify that the calibration certificates include measurement uncertainty values.**
Sampling, Sub-Clause 5.7	
☐ Yes ☐ No	Reviewed evidence:
Handling of test items, Sub-Clause 5.8	
☐ Yes ☐ No	Reviewed evidence:
Assuring the quality of test results, Sub-Clause 5.9	
☐ Yes ☐ No	Reviewed evidence:

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Reporting the results, Sub-Clause 5.10 (See also OD-2020)	
☐ Yes ☐ No	Reviewed evidence:

5.3 IECEE Requirements for CTF Stages 3 and 4

The following elements are included in the CTF's procedures as appropriate for a CTF and implemented in practice:	
IECEE Rules of Procedure & Guidance	
☐ Yes ☐ No	Reviewed evidence:
IECEE Operational Documents	
☐ Yes ☐ No	Reviewed evidence:
CTL Decisions	
☐ Yes ☐ No	Reviewed evidence:
Use of appropriate IEC Standards	
☐ Yes ☐ No	Reviewed evidence:
Current Decisions	
☐ Yes ☐ No	Reviewed evidence:

6. Proficiency Testing Programmes (Compulsory for CTF Stages 3 & 4)

Indicate the laboratory's participation in any comparative testing programs and for new laboratories, laboratories seeking scope extension, readiness for taking part in the IECEE CTL PTP.
Indicate willingness to participation in CTL meetings for IECEE Schemes.
Also mention any relevant information about the staff participation in standards activities.

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7 Number of Non-Conformity Reports (NCR) issued

Number of NCRs appended	

8 Recommendation of the Assessment Team

This assessment has been a sampling exercise and thus every aspect of the CTF's activities has not been covered. It does not follow, therefore, that non-conformances do not exist in areas where none have been reported in this assessment report. Standard Recommendations:(Please check the appropriate recommendation)	
1. The Assessment Team recommends acceptance of the assessed CTF for the scope(s) as reported in Annex 1 Scope of CTF of this Assessment Report	☐
2. The Assessment Team recommends acceptance of the assessed CTF for the scope(s) as reported in Annex 1 Scope of CTF of this Assessment Report subject to clearance of the outstanding Non-Conformity Reports	☐
3. The Assessment Team recommends that the acceptance of the assessed CTF is postponed until a further follow-up assessment is carried out and is found satisfactory.	☐

9 Additional Information

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10 Signatures of the Assessment Team

Date: yyyy-mm-dd	
Lead Assessor	Assessor
Signature	Signature
Printed name	Printed name

11 Acknowledgement by the assessed CTF and Customer

☐ I acknowledge and agree with the content of the Assessment Report. ☐ I acknowledge the content of the Assessment Report and we disagree for the following reasons:	☐ I acknowledge and agree with the content of the Assessment Report. ☐ I acknowledge the content of the Assessment Report and we disagree for the following reasons:
CTF Representative	Manufacturer/Customer Representative
Signature	Signature
Printed name and title	Printed name and title

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Annex 1 Scope of CTF

Provide specific exclusion for or applicable clauses whichever is more practical.

Category	Standard	Details *(see note below)*

Note: For clarity and consistency, use the following terms in the Details column:

"All clauses" – where the CTF is accepted for all tests under a standard, or

"All clauses except …" (list the exceptions), or

"Accepted clauses…" (list the accepted clauses)

Annex 2 Organisation Chart(s)

Annex 3 Accreditation Certificate(s) relevant to the CB-Scheme/CB-FCS

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Annex 4 Application of Measurement Uncertainty concepts

1. Laboratory procedure for application of Measurement Uncertainty		
Does the CTF have a documented operating procedure on application of uncertainty of measurement?	☐ Yes	☐ No
Document Number:	Document Title:	

2. Measurement Uncertainty references in the CTF		
Does the CTF have access to the ISO/IEC GUM or GUIDE 98-3 "Guide to the Expression of Uncertainty in Measurement" ?	☐ Yes	☐ No
Does the CTF have access to the IEC Guide 115, “Application of Uncertainty of Measurement to Conformity Assessment Activities in the Electrotechnical Sector?”	☐ Yes	☐ No

3. Competency of CTF Staff in Measurement Uncertainty concepts		
Do **all** the laboratory staff have knowledge of the basic concepts of uncertainty of measurement?	☐ Yes	☐ No
Can the laboratory staff select instrumentation and make pass/fail decisions taking measurement uncertainty into account?	☐ Yes	☐ No
Are selected laboratory staff sufficiently expert in uncertainty of measurement to calculate measurement uncertainties associated with test equipment and testing performed?	☐ Yes	☐ No
Names of persons:		
Were the training records of the select laboratory staff checked?	☐ Yes	☐ No
Were examples of uncertainty of measurement calculations for actual tests performed in the laboratory by the select laboratory staff reviewed and found to be acceptable?	☐ Yes	☐ No
Subject example 1 Subject example 2 Subject example 3		

4. Laboratory/Facilities compliance with the Measurement Uncertainty requirements		
Does the CTF comply with all the above Measurement Uncertainty Requirements? (if No, NCR to be issued)	☐ Yes	☐ No

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Annex 5 CTF Power Supply Capabilities

1. Electrical Power Distribution System for Testing	
Is the electrical power distribution system appropriate for the scope of recognition according to ISO/IEC 17025:2005, Sub-clause 5.3?	☐ Yes ☐ No

2. Electrical Power Supply Stability		
When not otherwise specified in the testing standard, laboratory power sources used for testing meet the following criteria, at the point where testing is performed under both loaded and no-load conditions, according to CTL-OP110: ☐ Voltage stability: +/- 3 percent maximum ☐ Frequency stability: +/- 2 percent maximum ☐ Total harmonic distortion: 5 percent maximum		
The laboratory power supplies meet additional specific criteria required by the test standard?	☐ Yes ☐ No ☐ N/A	
IEC Standard numbers/titles and clauses:		
Comments about the laboratory's power distribution system including its capacity and stability for testing equipment within the scope of this assessment		

3. Electrical Power Supply Monitoring	
The laboratory/facilities has/have an operating procedure to monitor, control and record characteristics of the laboratory/facilities power supplies used for testing to ensure continued conformance with the requirements.	☐ Yes ☐ No
Document Number:	Document Title:
The laboratory's/facilities' operating procedure requires the laboratory power supply characteristics to be checked upon initial installation, modification and repair, and periodically thereafter	☐ Yes ☐ No
The laboratory's/facilities' operating procedures require monitoring of critical characteristics specified by the test standard (e.g. voltage) throughout the performance of the test.	☐ Yes ☐ No

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Annex 6 Testing Laboratory Risk Management Review Capabilities

(These requirements apply to assessment of the capability of Testing Laboratories to apply Risk Management requirements of ISO 14971 and document the objective evidence of conformity required by the Standard.)

1.1 Laboratory procedure for Risk Management	Yes	No
Does the CTF have a documented operating procedure on application of risk management?	☐	☐
Document title: Document number:		
1.2 Risk Management References in the Laboratory	**Yes**	**No**
Does the CTF use the current methodology of IECEE Guide OD-2044?	☐	☐
Does the CTF apply the relevant edition of ISO 14971 in requesting objective evidence for compliance with this standard?	☐	☐
1.3 Competency of Laboratory Staff in Risk Management Concepts	**Yes**	**No**
Were the training records, CVs and other risk management qualifications of the select laboratory staff checked?	☐	☐
Do the laboratory personnel involved in risk management evaluations have knowledge of the risk management requirements in ISO 14971?	☐	☐

Principal Staff Involved In Risk Management Evaluation

Name	Position (Title) and Field of Expertise	Years of Relevant Experience	Experience Checked & Appropriate		To whom do they report?
			Yes	No	
			☐	☐	
			☐	☐	
			☐	☐	

Can the Laboratory staff select appropriate risk management file information and make pass/fail decisions taking risk management concept into account?	☐	☐
Do the reviewed Test Reports show objective evidence of compliance demonstrated by comments and specific references to manufacturer's Risk Management documents?	☐	☐
1.4 Laboratory compliance with the Risk Management requirements	**Yes**	**No**
Does the Body comply with all the above Risk Management Requirements?	☐	☐

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Non-Conformity Reports

Non-conformity Report No	/	**Date**	YYYY-MM-DD
Categories concerned			
Clause / Sub-clause of Non-Conformity			
Non-conformity description			
Lead Assessor		Management Representative	
Signature and printed name		Signature, printed name and title	
Root Cause of Non-conformity			
Proposed Corrective Action(s)			
Implementation date		Management representative	
YYYY-MM-DD		Signature, printed name, title and date	
Proposed Corrective Action(s) acceptance			
Acceptance, no further verification required			☐
Acceptance, further verification of implementation is required, without on-site follow-up assessment			☐
Acceptance, further verification of implementation is required, with on-site follow-up assessment			☐
Lead Assessor (Signature, printed name and date)			

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Non-conformity Report No	/	**Date**	YYYY-MM-DD
Categories concerned			
Clause / Sub-clause of Non-Conformity			
Implementation verified and final clearance provided by Lead Assessor			
Lead Assessor signature, printed name and date			

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