



CTF - Customers' Testing Facility

CTF Assessment Report (CTF Stages 3 and 4)

(Based on ISO/IEC 17025:2017)

<Report number>

CTF name

CTF address, country

Date of assessment: yyyy-mm-dd

1 Assessment details

1.1 Type of Assessment			
Initial Assessment (IA)	<input type="checkbox"/>	Annual Assessment (AA)	<input type="checkbox"/>
Scope Extension (SE)	<input type="checkbox"/>	Follow-up Assessment (FA)	<input type="checkbox"/>
Re-Location Assessment (RLA)	<input type="checkbox"/>	Re-Assessment (RA)	<input type="checkbox"/>

1.2 Scope covered by the assessment
Refer to Annex 1A Current accepted scope of CTF Annex 1A/B for a complete list of the assessment scope

1.3 Previous Assessment Reports – Report No. and Date

1.4 CTF Stage	
Select the applicable stage(s)	
<input type="checkbox"/> Stage 3	<input type="checkbox"/> Stage 4

1.5 CTF Contact Information	
Contact Person	
Telephone	
Mobile	
Fax	
Email	

1.6 Assessment Team			
Determine the applicable Position (Assessor, Technical Expert or Trainee) and delete the other position names			
	Lead Assessor	Assessor / Technical Expert / Trainee	Assessor / Technical Expert / Trainee
Name			
Title and Organization			

1.7 Assessment Base
IEC CA 01 – IEC Conformity Assessment Systems – Basic Rules

IECEE 02 – Rules of Procedure
IECEE 02-3 – IECEE Particular Rules of Procedure - Peer Assessment Programme
ISO/IEC 17025:2017
OD-2006 – Guidelines and Information for IECEE Assessments
OD-2048 – Utilization of Customers' Testing Facilities (CTFs)
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, unless a specific edition is indicated

2 Organization

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

Responsible NCB:	Responsible Manufacturer/Applicant:
Address:	Address:

2.2 Responsible persons present during the assessment of the CTF (Other than the assessment team)

Responsible NCB* <input type="checkbox"/> Name:	Name of Manufacturer/Applicant representative:
CBTL requested by the resp. NCB* <input type="checkbox"/> Name: Address:	Name of CTF representative:

*Whenever applicable

2.3 Brief history of the CTF

Include information about the legal status of the CTF and ownership (see ISO/IEC 17025:2017, clause 4.1.15.1 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 Organization of the CTF (refer to Annex 2 Organization Chart(s) Annex 2 Organization Chart(s))	
The testing laboratory is owned by Manufacturer/Customer	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p style="color: orange;">If "No", explain how continued compliance of the CTF with the relevant requirements of ISO/IEC 17025:2017 and OD-2048, clause 4.1.2 is maintained.</p>	

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	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

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	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

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	
			<input type="checkbox"/>	<input type="checkbox"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

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 Calibration records and Test Reports, etc.

4 CTF Testing premises

Total CTF testing laboratory area	m ²
Total CTF testing area in the scope of the assessment	m ²
Is the power distribution system sufficient/appropriate in the scope of recognition?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Annex 5 CTF Power Supply Capabilities Annex 5 – CTF Power Supply Capabilities to be completed and attached.	

5 ~~Quality Management System~~, 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No
The accreditation covers the standards covered by this assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 (Cl. 8.3), Sub-Clause 4.3	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Review of requests, tenders and contracts (Cl.7.1), Sub-Clause 4.4	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:

Subcontracting of tests, Sub-Clause 4.5	
CFTs are not permitted to subcontract testing	
Purchasing services and supplies – Externally provided products and services (Cl. 6.6), Sub-Clause 4.6	
<input type="checkbox"/> Yes <input type="checkbox"/> 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	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Control of records (Cl.8.4), Sub-clause 4.13	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Complaints (Cl. 7.9), Sub-Clause 4.8 (verify complaint resolution procedures related to laboratory operations)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Nonconforming testing work (Cl. 7.10), Sub-Clause 4.9	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Improvement (Cl. 7.7.3), Sub-Clause 4.10	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Corrective action (Cl.8.7), Sub-Clause 4.11	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Preventive action – Actions to address risks and opportunities (Cl. 8.5), Sub-Clause 4.12	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Internal audits (Cl.8.8), Sub-Clause 4.14	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:
Management reviews (Cl.8.9), Sub-Clause 4.15	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reviewed evidence:

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 17025:2017, clause 5, are available and appropriate.

Personnel (Cl. 6.2), ~~Sub-clause 5.2~~

Yes No Reviewed evidence:

Accommodation and environmental conditions (Cl. 8.3), ~~Sub-clause 5.3~~ (See also [Annex 5 CTF Power Supply Capabilities](#)~~Annex 5-CTF Power Supply Capabilities~~)

Yes No Reviewed evidence:

~~Test methods and validation of methods (Cl. 7.2)Test and calibration methods and method validation, Sub-Clause 5.4~~

Yes No Reviewed evidence:

Equipment (Cl. 6.4), ~~Sub-clause 5.5~~

E.g. attach CTF's equipment list, relevant to its scope, with sufficient information about calibration dates and periods

Yes No Reviewed evidence:

Measurement traceability (Cl. 6.5), ~~Sub-clause 5.6~~ (See also [Annex 4 Application of Measurement Uncertainty concepts](#)~~Annex 4-Application of Measurement Uncertainty concepts~~)

Yes No Reviewed evidence:
Verify that the calibration certificates include measurement uncertainty values.

Sampling (Cl. 7.3), ~~Sub-Clause 5.7~~

Yes No Reviewed evidence:

Handling of test items (Cl. 7.4), ~~Sub-Clause 5.8~~

Yes No Reviewed evidence:

Assuring the quality of test results (Cl. 7.7.1), ~~Sub-Clause 5.9~~

Yes No Reviewed evidence:

Reporting the results (Cl. 7.8), ~~Sub-Clause 5.10~~ (See also OD-2020)

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.

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 <u>acceptance</u> of the assessed CTF for the scope(s) as reported in <u>Annex 1A Current accepted scope of CTF Annex 1A/B</u> of this Assessment Report	<input type="checkbox"/>
2. The Assessment Team recommends <u>acceptance</u> of the assessed CTF for the scope(s) as reported in <u>Annex 1A Current accepted scope of CTF Annex 1A/B</u> of this Assessment Report subject to clearance of the outstanding Non-Conformity Reports	<input type="checkbox"/>
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.	<input type="checkbox"/>

9 Additional Information

--

10 Signatures of the Assessment Team

Choose the applicable Position (Assessor, Technical Expert or Trainee) and delete the other position names

Date: yyyy-mm-dd		
Lead Assessor	Assessor / <u>Technical Expert /</u> <u>Trainee</u>	Assessor / <u>Technical Expert</u> <u>/ Trainee</u>
Signature	Signature	Signature
Printed name	Printed name	Printed name

11 Acknowledgement by the assessed CTF and Customer

<input type="checkbox"/> I acknowledge and agree with the content of the Assessment Report. <input type="checkbox"/> I acknowledge the content of the Assessment Report and we disagree for the following reasons:	<input type="checkbox"/> I acknowledge and agree with the content of the Assessment Report. <input type="checkbox"/> 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

Annex 1B Initial / Scope Extension Assessment Scope

Provide specific exclusion(s) or applicable clause(s), whichever is more practical. Witnessing by LSV applies to CTF Stages 3 and 4. A checked box means "Yes".

<u>Standard</u>	<u>Details (see notes below)</u>	<u>Accepted for witnessing by LSV ? (see Note 2)</u>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>
		<input type="checkbox"/>

Note 1: 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)

Note 2:

LSV: Live Stream Video

Clauses that have been assessed and accepted for witnessing by Life Stream Video shall be specifically listed.



Annex 2 Organization Chart(s)

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

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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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" ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the CTF have access to the IEC Guide 115, "Application of Uncertainty of Measurement to Conformity Assessment Activities in the Electrotechnical Sector?"	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Can the laboratory staff select instrumentation and make pass/fail decisions taking measurement uncertainty into account?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are selected laboratory staff sufficiently expert in uncertainty of measurement to calculate measurement uncertainties associated with test equipment and testing performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Names of persons:	
Were the training records of the select laboratory staff checked?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No

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 <u>17025:2017, sub-clause 6.3?</u> 17025:2005, Sub-clause 5.3?	<input type="checkbox"/> Yes <input type="checkbox"/> 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 OD-5010:	
<input type="checkbox"/> Voltage stability: +/- 3 percent maximum <input type="checkbox"/> Frequency stability: +/- 2 percent maximum <input type="checkbox"/> Total harmonic distortion: 5 percent maximum	
The laboratory power supplies meet additional specific criteria required by the test standard?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> 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	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No

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?					<input type="checkbox"/>	<input type="checkbox"/>
Document title:						
Document number:						
1.2 Risk Management References in the Laboratory					Yes	No
Does the CTF use the current methodology of IECEE OD-2044?					<input type="checkbox"/>	<input type="checkbox"/>
Does the CTF apply the relevant edition of ISO 14971 in requesting objective evidence for compliance with this standard?					<input type="checkbox"/>	<input type="checkbox"/>
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?					<input type="checkbox"/>	<input type="checkbox"/>
Do the laboratory personnel involved in risk management evaluations have knowledge of the risk management requirements in ISO 14971?					<input type="checkbox"/>	<input type="checkbox"/>
Principal Staff Involved In Risk Management Evaluation						
Name	Position (Title) and Field of Expertise	Years Relevant Experience	Experience Checked & Appropriate		To whom do they report?	
			Yes	No		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
			<input type="checkbox"/>	<input type="checkbox"/>		
Can the Laboratory staff select appropriate risk management file information and make pass/fail decisions taking risk management concept into account?					<input type="checkbox"/>	<input type="checkbox"/>
Do the reviewed Test Reports show objective evidence of compliance demonstrated by comments and specific references to manufacturer's Risk Management documents?					<input type="checkbox"/>	<input type="checkbox"/>
1.4 Laboratory compliance with the Risk Management requirements					Yes	No
Does the Body comply with all the above Risk Management Requirements?					<input type="checkbox"/>	<input type="checkbox"/>

Non-Conformity Reports

Non-conformity Report No	/	Date	YYYY-MM-DD
Standard(s) 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			<input type="checkbox"/>
Acceptance, further verification of implementation is required, <u>without</u> on-site follow-up assessment			<input type="checkbox"/>
Acceptance, further verification of implementation is required, <u>with</u> on-site follow-up assessment			<input type="checkbox"/>
Lead Assessor signature, printed name and date			
Implementation verified and final clearance provided by Lead Assessor			
Lead Assessor signature, printed name and date			