

IECEE OPERATIONAL DOCUMENT

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

Testing Laboratory Assessment Report

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IECEE-PAC/ /

(*Note: Document identification should be: "IAR" for Initial Assessment Report, EAR for Extension of Scope Assessment, "FAR" for Follow-up Assessment Report or "RAR" for Re-assessment Report and RLAR for Re-Location Assessment Report in IECEE-PAC/XXX/')

Testing Laboratory:

Fill in with complete Legal Entity name of the Testing Laboratory and country of domicile.

Date of assessment: yyyy-mm-dd

The aim of this document is to provide guidance for Assessors undertaking Testing Laboratory assessments and completing form OD-2005 Testing Laboratory Assessment Report.



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FOREWORD

Scope

To be determined.

Document Owner

PAC

History of changes

<u>Revision</u> Date	Brief summary of changes
<u>2018-02-14</u>	<p><u>The following clauses have been updated: 1.2.1 & 1.2.2 (new category ITAV added), 1.8, 3.3, 10, 15. Clauses 16, 17 and NCR page have been updated in line with the new Annex 4.</u></p> <p><u>Additional guidance text has been added to clauses 3.5, 8 and 11.</u></p> <p><u>New Annex 7: Use of non-accredited internal calibration laboratories for standards in CBTL/SPTL scope (Informative)</u></p> <p><u>New Annex 8: "Content Agreement of Assessment Report XYZ - CBTL ABC"</u></p> <p><u>New Section Infringement Report Referred to Secretariat</u></p>
2016-12-15	<p>The following clauses/Annexes have been modified: 1.5, 10, 15, 15.1, Annex 1A, 1B and 5.</p> <p>The following Annex has been deleted: Annex 1C for SATLs</p>
2016-06-01	<p>Most changes made cover the change from "MTL" to "CTF", as well as the discontinuation of SATLs.</p> <p>The following subclauses were modified: 1.5, 2.2 & 10.</p>

Effective date	Target revision <u>Next maintenance due</u> date
2017-05-17 <u>2018-06-05</u>	2020-05-17 <u>2021-06-05</u>

1 Object and field of assessment

1.1 Object

Assessment covering	IECEE Assessment	Joint Assessment	Accreditation Body	Scope of Accreditation
Initial Assessment (IAR)	<input type="checkbox"/>	<input type="checkbox"/>		
Extension of Scope (EAR)	<input type="checkbox"/>	<input type="checkbox"/>		
Re-Assessment (RAR)	<input type="checkbox"/>	<input type="checkbox"/>		
Follow-up Assessment (FAR)	<input type="checkbox"/>	<input type="checkbox"/>		
Re-Location Assessment (RLAR)	<input type="checkbox"/>	<input type="checkbox"/>		

In a Relocation Assessment Report, a statement “No Change” represents a declaration of the assessed CBTL 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.

1.2 Product Categories

1.2.1 Product Categories covered by the re-assessment

Please cross (X) as appropriate and refer to [Annex 1A](#) Standards of the current accepted scope selected for this Re-assessment for a complete list of the scope of the assessment containing details of the relevant IEC Standards and relevant experience including editions and amendments.

<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"/>	<input type="checkbox"/>	<input type="checkbox"/>
MEAS	MED	MISC	OFF	POW	PROT	PV	SAFE	TOOL	TOYS	TRON	<u>ITAV</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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.2.2 Product Categories covered by the initial/scope extension assessment

Please cross (X) as appropriate and refer to [Annex 1B](#) Initial Assessment / Scope extension Assessment Scope for a complete list of the scope of the assessment containing details of the relevant IEC Standards and relevant experience including editions and amendments.

<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"/>	<input type="checkbox"/>	<input type="checkbox"/>
MEAS	MED	MISC	OFF	POW	PROT	PV	SAFE	TOOL	TOYS	TRON	<u>ITAV</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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.3 Previous Assessment Report

Previous Assessment Report Number	IECEE-PAC/ /
Previous Assessment Date	yyyy-mm-dd

1.4 Certification Schemes

<input type="checkbox"/> CB Scheme	<input type="checkbox"/> CB-FCS Scheme
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1.5 Complete legal entity name and address of the Testing Laboratory

If the Testing Laboratory is already an accepted IECEE Member and the assessment is a Scope extension the box "Accepted" should be checked.

Type	Candidate	Accepted
CBTL	<input type="checkbox"/>	<input type="checkbox"/>
SPTL	<input type="checkbox"/>	<input type="checkbox"/>

Legal Entity Name	
Address	
Contact Person	
Email	
Tel	
Mobile	
Fax	
Website	

1.6 Members of the Assessment Team

	Name	Organization	Country
Lead Assessor			
Assessor			
Assessor			
Assessor			

1.7 Place(s) and date(s) of Assessment

If multiple buildings, include all addresses, such as: ABC Testing Laboratory in City A together with DEF Testing Laboratory in City D.

Main location(s)	
If applicable, other location(s)	
Date of Assessment for main location(s) and any other location(s)	yyyy-mm-dd



1.8 Assessment Base

- [IECEE 01 Basic Rules IEC CA 01 and IECEE 01-S Basic Rules](#)
- IECEE 02 Rules of Procedure
- IECEE 02-2 IECEE Membership Procedures
- IECEE 02-3 Peer Assessment Programme Procedures
- ISO/IEC 17025
- OD-2006 Guidelines and Information for IECEE Assessments: Procedures and Documentation
- [OD-2033 Process elements related to infringements of the Rules](#)

The above documents are to be based upon the latest published editions

2 Organization

2.1 National Certification Body undertaking the responsibility for the Testing Laboratory

Legal entity name	
Address	
NCB Representative present at assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No

	Contact person located at the NCB	NCB Representative present at assessment (if different to contact person)
Name		
Email		
Tel		
Fax		

2.2 Main Laboratory undertaking the responsibility for the Specialized Testing Laboratory

This clause applies to SPTLs only.

Legal entity name	
Address	
NCB Representative present at assessment	<input type="checkbox"/> Yes <input type="checkbox"/> No



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2.3 Brief history of the Testing Laboratory

Include information about the legal entity of the Testing Laboratory and ownership. Reference ISO/IEC Guide 17025.

Complete this section for Initial Assessment and for other Assessments complete only with updates from the latest assessment

2.4 Organization of the Testing Laboratory

Include information relevant to the organization of the Testing Laboratory pertaining to the operated Scheme(s) including the interaction with its Certification Body.

If the quality management system is such that the Quality Manual and/or Quality Procedure include one or more organization charts then this could be attached as an appendix to the Assessment Report.

3 Personnel Structure

When the declared years of experience is low, the assessment team should make a professional judgment based upon interviews on the awareness and knowledge of the standards, witnessing of Test Report review, witnessing of testing and measuring as well as CV information e.g. previous employments and function, training programmes completed.

3.1 Employees

Number of overall people employed by the legal entity of the Testing Laboratory	
Number of people working in the overall <u>product</u> testing area	
Number of people involved with the <u>product</u> testing activity within the scope of this assessment	



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3.2 Responsible Managers for Testing

Name	Position (title) and field of expertise	Years of 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"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

3.3 Principal staff involved in Testing (including LTRs)

Name (indicate if LTR <u>and type</u>)	Position (title) and field of expertise	Years of 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"/>	
			<input type="checkbox"/>	<input type="checkbox"/>	

3.4 Staff involved in the Quality Management System of the Testing Laboratory

Name	Position (title) and field of expertise	Years of relevant experience	Experience checked & appropriate		To whom does the quality management system staff 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"/>	

3.5 Assessment of staff competence

When the declared years of experience is low, the assessment team should make a professional judgment based upon interviews on the awareness and knowledge of the standards, witnessing of Test Report review, witnessing of testing and measuring as well as CV information e.g. previous employments and function, training programmes completed. For LTRs indicate verification of agreements and other relevant requirements as per OD-2034.

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4 Testing premises

Total premises area	m ²
Total testing laboratory area	m ²
Total testing area in the scope of recognition	m ²
Total office area in the scope of recognition	m ²

5 Power Supply System

The requirements do not address short circuit current testing, abnormal testing, switching testing and the like that relate to source capacity.

The approved power source stability requirements apply to testing of products that are connected to ordinary branch circuits found in residences and businesses - for example 120 V, 15 and 20 A; 240 V, 15 A circuits in North America and 230 V, 10 and 16 A branch circuits in Europe.

5.1 Electrical Power Supply System for Testing

	Yes	No
Is the electrical power distribution system appropriate for the scope of recognition according to ISO/IEC 17025:2005, sub-clause 5.3?	<input type="checkbox"/>	<input type="checkbox"/>

5.2 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 :	
Voltage stability: +/- 3 percent maximum	<input type="checkbox"/>
Frequency stability: +/- 2 percent maximum	<input type="checkbox"/>
Total harmonic distortion: maximum 5 percent	<input type="checkbox"/>



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	Yes	No	N/A
Do the laboratory power supplies meet additional specific criteria required by the test standard?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IEC Standard Numbers/Titles and Clauses:			

5.3 Electrical Power Supply Monitoring

The monitoring of PSD shall be made in accordance with the relevant CTL Operational Procedures.

	Yes	No
The laboratory has an operating procedure to monitor, control and record characteristics of the laboratory power supplies used for testing to ensure continued conformance with the requirements of OD-5010.	<input type="checkbox"/>	<input type="checkbox"/>
Document title: _____ Document number: _____		

5.4 Summary

	Yes	No
Is the power distribution system appropriate in the scope of recognition?	<input type="checkbox"/>	<input type="checkbox"/>
Comments about the laboratory's power distribution system and its capacity and stability for testing equipment within the scope of this assessment:		

6 Quality Management System

If the Testing Laboratory is accredited, check the most recent accreditation assessment report and the scope covered by the accreditation.

If the Testing Laboratory is not accredited or if the Testing Laboratory does not make the accreditation report available, the quality management system of the Testing Laboratory shall be examined in detail.

Briefly describe the structure of the quality system, its documentation and degree of implementation, and how it is checked for compliance with ISO/IEC 17025.

State whether reports from external/internal audits, management reviews and corrective action processes have been reviewed and other relevant items from ISO/IEC 17025.

In any case the Rules of Procedure of the relevant IECEE Schemes should be assessed in order to verify that they are duly included in the quality management system and implemented in practise and effectively.

This assessment may include, but is not limited to, e.g. Operational Documents, CTL Decisions, process of document control and provision to use the appropriate IEC Standards etc.

	Yes	No	N/A
Is the Testing Laboratory accredited by a reputable Accreditation Body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the accreditation include the product categories covered by this assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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Structure of the Quality System
Document control
Review of requests, tenders and contracts
Sub-contracting of tests
Purchasing services and supplies
Service to the client
Complaints



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Control of non-conforming work
Corrective action
Preventive action
Control of records
Internal audits
Management reviews
IECEE Rules of Procedure and Guidance



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IECEE Operational Documents
CTL Decisions
Use of appropriate IEC standards
Current decisions

7 Critical Technical Procedures

Briefly describe if the presence and appropriateness of 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 5.0 have been checked.

Equipment:
Verify that the calibration certificates include measurement uncertainty values.

Sampling:
In case of multiple factory location for the same product.

Reporting the results:
Refer to OD-2020

Accommodation and environmental conditions



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Test methods and method validation
Equipment
Measurement traceability
Sampling
Handling of test items
Assuring the quality of test results
Reporting the results



8 Subcontracted testing

Give reference to which clause(s) in the IEC standard(s) are concerned.
 Also indicate if subcontracting is permitted according to the current IECEE CTL list and whether an appropriate agreement with the subcontractor exists.

Subcontractor agreement is not needed before the subcontractable ("S") tests is actually required by the CBTL (e.g. the test is an alternate test or is not yet required for the types of products tested by the CBTL).

	Yes	No	N/A
Does the laboratory subcontract testing?	<input type="checkbox"/>	<input type="checkbox"/>	
Is the subcontracting allowed by the CTL list?	<input type="checkbox"/>	<input type="checkbox"/>	
Does the practice comply with OD-2012?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9 Important equipment borrowed or rented

Give reference to which clause(s) in the IEC standard(s) are concerned.
 Also indicate if borrow/renting is permitted according to the current IECEE CTL list and whether an appropriate agreement with the subcontractor exists.

If the rented equipment is operated by the staff of the (candidate) laboratory at the owner location, i.e. Oversize Humidity Chamber 64m3, also indicate the names and locations of these rental laboratory(ies) and how qualifications of the external testing facilities are ensured.

	Yes	No	N/A
Does the laboratory borrow or rent testing equipment?	<input type="checkbox"/>	<input type="checkbox"/>	
Please note if the borrowed/rented equipment are under the "R" or "S" on the CTL list of equipment			
Does the practice comply with OD-2012?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10 ~~Testing in Manufacturers' Testing Laboratories~~ / Customer Testing Facilities

Please report if the CBTL has appropriate documentation related to the CTF activity.

Does the Testing Laboratory carry out testing upon the request of the NCB?	Yes	No
CTF Stage 1	<input type="checkbox"/>	<input type="checkbox"/>
CTF Stage 2	<input type="checkbox"/>	<input type="checkbox"/>
CTF Stage 3	<input type="checkbox"/>	<input type="checkbox"/>
CTF Stage 4	<input type="checkbox"/>	<input type="checkbox"/>

Does the Testing Laboratory carry out assessment according to ISO/IEC 17025 upon the request of the NCB?	Yes	No
CTF Stage 1	<input type="checkbox"/>	<input type="checkbox"/>
CTF Stage 2	<input type="checkbox"/>	<input type="checkbox"/>
CTF Stage 3	<input type="checkbox"/>	<input type="checkbox"/>
CTF Stage 4	<input type="checkbox"/>	<input type="checkbox"/>

11 Proficiency Testing Programmes

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 participation in CTL meetings for IECEE Schemes.

Also mention any relevant information about the staff participation in standards activities.

Not enrolling in applicable Proficiency Testing Programs by CBTLs, SPTLs and Stage 3 and 4 CTFs is an infringement" and shall be notified to the Secretariat by filling in the Annex "Infringement Report Referred to Secretariat".



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12 Testing witnessed during the assessment

E.g. Temperature rise test, creepage and clearance distances, breaking capacity test etc.
Provide information about the equipment used, the testing methodology, general proficiency, knowledge and competence of the laboratory staff and the relevant standard and clause against which the test has been carried out.

13 Test reports reviewed during the assessment

E.g. To check the validity and completeness of the measurement reported in the Test Report, correct TRF used, list of used Test Equipment reported, proper signatures and reviewers etc.

14 Number of Non-Conformity Reports issued

Number of NCRs appended	
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15 Recommendations of the Assessment Team

This assessment has been a sampling exercise and thus every aspect of the Testing Laboratory'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:

<p>1. The Assessment Team recommends acceptance of the assessed organization as reported in Annex 1A/B/C</p>	<input type="checkbox"/>
<p>2. The Assessment Team recommends acceptance of the assessed organization as reported in Annex 1A/B/C subject to clearance of the outstanding Non-conformity Conformity Reports as appropriate.</p>	<input type="checkbox"/>
<p>3. The Assessment Team recommends that the acceptance of the assessed organization is postponed until a further follow-up assessment is carried out and is found satisfactory.</p>	<input type="checkbox"/>
<p>4. Other, please specify using similar terminology</p>	<input type="checkbox"/>

15.1 Additional Information

Add a note if the testing equipment list used was not an approved CTL list and that this item shall be considered during the next assessment



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16 Signatures of the Assessment Team

Date: yyyy-mm-dd

If the assessment team and assessed organization do not agree on email confirmation, text in "Signature" column is deleted and signatures added.

The Lead Assessor confirms that confirmation has been received from all parties in Section 16 that their printed names is accepted in lieu of a signature.

	Printed name	Signature
Lead Assessor		
Assessor		
Assessor		
Assessor		

17 Acknowledgement by the assessed organization

We acknowledge and agree with the content of the Assessment Report.

We acknowledge the content of the Assessment Report and we disagree for the following reasons:

The representatives of the assessed organization in Section 17 confirm that authorization has been given to the lead assessor that their printed names are accepted in lieu of signatures below and all associated NCR, if any.

Date: yyyy-mm-dd

	Printed name	Signature
Testing Laboratory Representative		
NCB Representative		



Annex 1A Standards of the current accepted scope selected for this Re-assessment

Product Category:

The assessment team completes this column.

List the corresponding Product Category for each standard selected for this assessment.

Standard:

The assessment team completes this column with the standards selected for this reassessment.

List the standards, including the publication year, of the selected scope of the assessment

Number of Test Reports issued during the last three years:

The assessed organization should provide this information during the assessment.

Test Reports completed can also include projects based on the equivalent National Standard.

Assessment team acceptance:

The assessment team completes this column based upon the on-site assessment.

Where experience is insufficient the "No" box shall be checked.

The assessed organization can provide a claim of competence to the IECEE Secretariat to keep this standard(s) in the scope of acceptance.

Example:

Product Category	Standard	Number Test Reports issued during the last three years	Assessment Team acceptance	
			Yes	No
MED	IEC 60601-2-10:1987	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>
MED	IEC 60601-2-11:1997	9	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

Product Category	Standard	Number Test Reports issued during the last three years*	Assessment Team acceptance	
			Yes	No
OFF	IEC 60950-1:2005	333	<input checked="" type="checkbox"/>	<input type="checkbox"/>
OFF	IEC 60950-1:2005/AMD1:2009	333	<input checked="" type="checkbox"/>	<input type="checkbox"/>

* experience also includes equivalent national/regional standards.



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Product Category	Standard	Number of Test Reports issued during the last three years	Assessment Team acceptance	
			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"/>
			<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"/>	<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: For the organization's full scope please see the IECEE Website



Annex 1B Initial Assessment / Scope extension Assessment Scope

Product Category:

The assessed organization completes this column.
List the corresponding Product Category for each standard-

Standard:

The assessed organization completes this column -with all the standards requested for this assessment.
List the standards, including the publication year, of the requested scope of the assessment

Number of Test Reports issued during the last three years:

The assessed organization should provide this information during the assessment.
Test Reports completed can also include projects based on the equivalent National Standard.

Assessment team acceptance:

The Assessment Team completes this column based upon the on-site assessment.
Where experience is insufficient the "No" box shall be checked.

Example:

Product Category	Standard	Number Test Reports issued during the last three years	Assessment Team acceptance	
			Yes	No
MED	IEC 60601-2-10:1987	5	<input checked="" type="checkbox"/>	<input type="checkbox"/>
MED	IEC 60601-2-11:1997	9	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

Product Category	Standard	Number Test Reports issued during the last three years*	Assessment Team acceptance	
			Yes	No
OFF	IEC 60950-1:2005	333	<input checked="" type="checkbox"/>	<input type="checkbox"/>
OFF	IEC 60950-1:2005/AMD1:2009	333	<input checked="" type="checkbox"/>	<input type="checkbox"/>

* experience also includes equivalent national/regional standards.



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Product Category	Standard	Number of Test Reports issued during the last three years	Assessment Team acceptance	
			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"/>
			<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"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>



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Annex 1C Assessment Scope for Specialized Facility

Name of the Test	Standard	Clause of the Standard	Assessment Team acceptance	
			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"/>
			<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"/>	<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"/>



Annex 2 Organization chart

If the quality management system is such that the Quality Manual and/or Quality Procedure include one or more organization charts then this could be attached in this Annex.

The Assessment Team shall not request the assessed organization to draft a dedicated Organization chart simply for the purpose of completing this Annex or clarifying the information provided in the body of this report.



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

Annex 4 Application of uncertainty of measurement concepts in the Testing Laboratory

Laboratory procedure for application uncertainty of measurement:

As a minimum, the Testing Laboratory's operating procedures require calculation and reporting of uncertainty of measurement, when required by the testing standard or the customer.

1. Laboratory procedure for application uncertainty of measurement	Yes	No
Does the Body have a documented operating procedure on application of uncertainty of measurement?	<input type="checkbox"/>	<input type="checkbox"/>
Document title:	Document number:	

2. Uncertainty of measurement references in the Laboratory	Yes	No
Does the Body have access to the ISO/IEC Guide 98-3, Guide to Expression of Uncertainty in Measurement?	<input type="checkbox"/>	<input type="checkbox"/>
Does the Body have access to the IEC Guide 115, "Application of Uncertainty of Measurement to Conformity Assessment Activities in the Electrotechnical Sector"?	<input type="checkbox"/>	<input type="checkbox"/>

3. Competency of Laboratory staff in uncertainty of measurement concepts	Yes	No
Does <u>all</u> the laboratory staff have knowledge of the basic concepts of uncertainty of measurement?	<input type="checkbox"/>	<input type="checkbox"/>
Can the Laboratory staff select instrumentation and make pass/fail decisions taking uncertainty of measurement into account?	<input type="checkbox"/>	<input type="checkbox"/>
Are selected laboratory staff sufficiently expert in uncertainty of measurement to calculate measurement uncertainties associated with test equipment and testing performed?	<input type="checkbox"/>	<input type="checkbox"/>
Names of person(s):		
Were the training records of the selected laboratory staff checked?	<input type="checkbox"/>	<input type="checkbox"/>
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"/>	<input type="checkbox"/>
Subject Example 1:		
Subject Example 2:		
Subject Example 3:		

4. Laboratory compliance with the uncertainty of measurement requirements	Yes	No
Does the Body comply with all the above Measurement Uncertainty Requirements?	<input type="checkbox"/>	<input type="checkbox"/>

Annex 5 “Independence and impartiality” including “Commercial consultancy”

Note: If this Annex has been completed at least once and the organization is accredited according to ISO/IEC 17025, this Annex does not have to be completed again, except for clause 0. If the CBTL/SPTL is not accredited, this Annex needs to be completed during each Assessment.

0. Compliance with ISO/IEC 17025	Yes	No
The CBTL/SPTL has a valid accreditation to ISO/IEC 17025.	<input type="checkbox"/>	<input type="checkbox"/>

1. General Operating Procedure	Yes	No
Does the Laboratory have a documented procedure for independence and impartiality that as a minimum includes the following while carrying out conformity assessment activities: a) to be objective, b) to identify, avoid, mitigate and manage conflicts of interest, and c) to ensure independence, so as to increase the amount of trust, confidence and value that those activities have in the market place	<input type="checkbox"/>	<input type="checkbox"/>
Document title: _____	Document number: _____	

2. Reference Document	Yes	No
Does the Laboratory have access to ISO/IEC 17025:2005 and in particular Sub-clause 4.1.4 (including Note 2, 4.1.5 B) and 4.1.5 d)?	<input type="checkbox"/>	<input type="checkbox"/>

3. Knowledge, training and decision making	Yes	No
Does the Laboratory staff have knowledge of the basic concepts of independence and impartiality?	<input type="checkbox"/>	<input type="checkbox"/>
Were the training records of the Laboratory’s staff checked?	<input type="checkbox"/>	<input type="checkbox"/>
Does the Laboratory’s selected staff have sufficient knowledge in the principles of independence and impartiality to provide initial training and retraining to other staff?	<input type="checkbox"/>	<input type="checkbox"/>
Names of person(s): _____		
Were examples of training programs of the Laboratory’s staff reviewed and found to be sufficient?	<input type="checkbox"/>	<input type="checkbox"/>
Does the Laboratory’s staff select and make pass/fail decisions taking the principles of independence and impartiality into account?	<input type="checkbox"/>	<input type="checkbox"/>
Are the Laboratory’s decisions based on objective evidence of conformity (or nonconformity) obtained by the Laboratory’s staff?	<input type="checkbox"/>	<input type="checkbox"/>
Are the Laboratory’s decisions influenced by other interests or parties?	<input type="checkbox"/>	<input type="checkbox"/>

4. Documentation and Implementation	Yes	No
Does the Laboratory have documented and implemented (on an on-going basis) sufficient procedures to ensure the independence and impartiality of all staff?	<input type="checkbox"/>	<input type="checkbox"/>

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<p>Does the Laboratory have documented and implemented (on an on-going basis) sufficient procedures to ensure that the remuneration of staff is free from pressures and inducements and is not dependent on the number, outcome of the result of their activities?</p> <p>Note: It is recognized that the source of revenue of the Laboratory is its customers paying for its services and that this is a potential threat to independence and impartiality.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Does the Laboratory have documented sufficient procedures for the identification, review, resolution and prevention of conflict of interest (including “commercial consultancy”) where conflicts of interest are suspected or proven (including subcontracted personnel) and does the Laboratory keep records of such reviews and decisions?</p>	<input type="checkbox"/>	<input type="checkbox"/>

5. Marketing and advertising materials	Yes	No	N/A
Do the Laboratory’s marketing materials give the impression that “commercial consultancy” activities are offered?	<input type="checkbox"/>	<input type="checkbox"/>	
Is the Laboratory linked to an organization that provides “commercial” consultancy services?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there a documented policy/procedure to ensure that there is an effective separation between all conformity assessment activities and consultancy services?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the Laboratory’s certification staff participate in “commercial consultancy”?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Staff declarations	Yes	No
Does the Laboratory require all staff acting on its behalf to declare any potential conflict of interest?	<input type="checkbox"/>	<input type="checkbox"/>

7. Compliance	Yes	No
<p>Does the Laboratory comply with all the above independence and impartiality principles on an ongoing basis?</p> <p>Note: If the answer to this item is NO a Non-Conformity Report must be issued</p>	<input type="checkbox"/>	<input type="checkbox"/>

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 CBTL 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 CBTL use the current methodology of IECEE Guide OD 2044?				<input type="checkbox"/>	<input type="checkbox"/>
Does the CBTL 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"/>

Annex 7 Use of non-accredited internal calibration laboratories for standards in CBTL/SPTL scope (Informative)

This is informative for PAC data collection.

<u>0. Internal Calibration Laboratory</u>		<u>Yes</u>	<u>No</u>
<u>Does the laboratory perform internal calibration?</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>1. Scope of calibrations performed by the internal calibration laboratory</u>		<u>Yes</u>	<u>No</u>
<u>Does the internal calibration laboratory have a controlled calibration list identify all test equipment which is internally calibrated?</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>Were examples of calibration records available?</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>Sampling of internal calibrated test equipment</u>		-	-
<u>Description</u>	<u>Equipment Identification (i.e. Asset Number)</u>		
<u>2. Dedicated calibration standards</u>		<u>Yes</u>	<u>No</u>
<u>Does the calibration laboratory have controlled calibration methods, i.e. procedures, for each item of test equipment which is internally calibrated?</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>Does the laboratory have documented procedure for the validation of the internal calibration methods?</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>Does the laboratory have a documented operating procedure for the calibration and maintenance of equipment used for calibration?</u>		<input type="checkbox"/>	<input type="checkbox"/>
Document title: _____ Document number: _____			
<u>Does the laboratory have a dedicated and secure storage location for the calibration standards and related equipment.</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>3. Uncertainty of measurement in calibration</u>		<u>Yes</u>	<u>No</u>
<u>Does the laboratory have access to and working knowledge of the ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement?</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>Do internal calibration certificates/reports fulfill the requirements of IECEE?</u>		<input type="checkbox"/>	<input type="checkbox"/>
<u>Do internal calibration certificates/reports include the measurement results and the measurement uncertainty statements for the calibrations?</u>		<input type="checkbox"/>	<input type="checkbox"/>



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<u>4. Assurance of quality of internal calibrations</u>	<u>Yes</u>	<u>No</u>
<u>Does the laboratory have participation in proficiency or comparison testing related to calibration?</u>		
<u>Does the laboratory established a traceability chains for equipment calibrated internally?</u>	<input type="checkbox"/>	<input type="checkbox"/>

<u>5. Control of internally calibrated equipment?</u>	<u>Yes</u>	<u>No</u>
<u>Does the internal calibration laboratory have a procedure to distinguish internally calibrated test equipment from other test equipment?</u>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Document title: _____ Document number: _____</u>		

<u>6. Laboratory compliance with IECEE requirements for internal calibration</u>	<u>Yes</u>	<u>No</u>
<u>Does the internal calibration laboratory undergo annual audits by a qualified auditor or a metrologist (refer to OD 5011)?</u>	<input type="checkbox"/>	<input type="checkbox"/>



Annex 8 “Content Agreement of Assessment Report XYZ - CBTL ABC” – this is not part of the report and shall be deleted upon finalization of the report

The following text, in an e-mail to the Lead Assessor, should be used by entities being assessed and technical assessors, as a confirmation of agreement, in lieu of signature in the report, by selecting the one of the standardized paragraphs below, as applicable.

Dear XYZ (Lead Assessor)

Assessed Organization

As representative of the assessed organization, we agree with the content of Assessment Report XYZ in lieu of signatures within the report and NCRs.

Technical Assessor

As technical assessor, I agree with the content of Assessment Report XYZ in lieu of my signature within the report.



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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	
<u>Signature (if required) and printed name</u> Signature and printed name		<u>Signature (if required) and printed name</u> Name: Signature, printed name and title	
Root cause of non-conformity			
Proposed Corrective action(s)			
Implementation date		Management representative	
YYYY-MM-DD		Signature <u>(if required)</u> , printed name, title and date	



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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 (S signature <u>(if required)</u> , printed name and date) <u>Signature:</u> <input type="checkbox"/> <u>The Secretariat has received an email confirmation from the Lead Assessor in lieu of a signature accepting the content of this NCR.</u>	
Implementation verified and final clearance provided by Lead Assessor	
Lead Assessor signature <u>(if required)</u> , printed name and date <u>Signature:</u> <input type="checkbox"/> <u>The Secretariat has received an email confirmation from the Lead Assessor in lieu of a signature accepting the content of this NCR.</u>	



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Infringement Report Referred to Secretariat (not published)

If the assessment team and assessed organization do not agree on email confirmation, text in "Signature" row is deleted and signatures added.

<u>Infringement Report No</u>	<u> </u> / <u> </u>	<u>Date</u>	<u>YYYY-MM-DD</u>
<u>Infringement Type</u> (From OD-2033)			
<u>Infringement description and objective evidence</u>			
<u>Lead Assessor</u>		<u>Management representative</u>	
<u>Name:</u>		<u>Name:</u>	
<u>Signature:</u>		<u>Signature:</u>	

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