IECEE OD-2005-2

Edition 1.0 2018-12-127

IECEE PROVISIONAL OPERATIONAL DOCUMENT

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

Testing Laboratory Assessment Report
(Based on ISO/IEC 17025:2017)

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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

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FOREWORD

Scope

To be determined.

Document Owner

PAC

History of changes

Revision Date	Brief summary of changes
2018-11-30	This document, OD-2005-2, is a modified, alternative version of OD-2005, intended to cover compliance with ISO/IEC 17025:2017). The following key changes were made to OD-2005, ed. 3.4: - All references to "quality" in "quality management system" have been deleted." The term "management system" replaced "quality system". - The edition year "2017" has been added in all references to ISO/IEC 17025. - In Clause 2.2.,"Main Laboratory" has been replaced by " NCB or Supervising CBTL" - In Clause 6, under Structure of the Management System, a statement and a check-box have been added to confirm that only Option 1 may be used. - ISO/IEC 17025:2017 clause numbers and some different clause titles have been added for reference in the management system sections.

Effective date	Next maintenance due date
2019-01-01 This is a Provisional Document for Optional Use at this time.	

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1 Object and field of assessment

1.1 Object

Assessment covering	IECEE Assessment	Joint Assessment	Accreditation Body	Scope of Accreditation
Initial Assessment (IAR)	☐	☐		
Extension of Scope (EAR)	☐	☐		
Re-Assessment (RAR)	☐	☐		
Follow-up Assessment (FAR)	☐	☐		
Re-Location Assessment (RLAR)	☐	☐		

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

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

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

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~~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.

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

1.3 Previous Assessment Report

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

1.4 Certification Schemes

☐ CB Scheme	☐ CB-FCS Scheme

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	☐	☐
SPTL	☐	☐

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

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 17025:2017
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	☐ Yes ☐ 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~~ NCB or Supervising CBTL undertaking the responsibility for the Specialized Testing Laboratory

This clause applies to SPTLs only.

Legal entity name	
Address	
NCB Representative present at assessment	☐ Yes ☐ No

2.3 Brief history of the Testing Laboratory

Include information about the legal entity of the Testing Laboratory and ownership.
Reference ISO/IEC ~~Guide~~ 17025:2017.

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 product testing area	
Number of people involved with the product testing activity within the scope of this assessment	

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	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	

3.3 Principal staff involved in Testing (including LTRs)

Name (indicate if LTR and type)	Position (title) and field of expertise	Years of relevant experience	Experience checked & appropriate		To whom do they report?
			Yes	No	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	

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	
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	

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.

4 Testing premises

Total premises area	**m²**
Total testing laboratory area	**m²**
Total testing area in the scope of recognition	**m²**
Total office area in the scope of recognition	**m²**

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~~2017, sub-clause ~~5~~6.3?	☐	☐

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	☐
Frequency stability: +/- 2 percent maximum	☐
Total harmonic distortion: maximum 5 percent	☐

	Yes	No	N/A
Do the laboratory power supplies meet additional specific criteria required by the test standard?	☐	☐	☐
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.	☐	☐
Document title: Document number:		

5.4 Summary

	Yes	No
Is the power distribution system appropriate in the scope of recognition?	☐	☐
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.
OD-2017 Checklist, Ed. 2.0 (for ISO/IEC 17025:2017) must be completed and provided in advance with other documentation for the assessment. Use the completed checklist as reference for the assessment of the management system.

Briefly describe the structure of the ~~quality~~ management system, its documentation and degree of implementation, and how it is checked for compliance with ISO/IEC 17025:2017.
State whether reports from external/internal audits, management reviews and corrective action processes have been reviewed and other relevant items from ISO/IEC 17025:2017.

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?	☐	☐	
Does the accreditation include the product categories covered by this assessment?	☐	☐	☐

Structure of the ~~Quality~~ Management System (Cl. 8.1.2, 8.1.3)
Only Option A (compliance with ISO/IEC 17025:2017) may be used. ☐ Option A only: (Cl. 8.2 to 8.9) Brief description
Document control (Cl. 8.3)
Review of requests, tenders and contracts (Cl.7.1)
~~Sub-contracting of tests~~
Deleted
Purchasing services and supplies – Externally provided products and services (Cl. 6.6)
~~Service to the client~~
Deleted
Complaints (Cl. 7.9)

Control of non-conforming work (Cl. 7.10)
Corrective action (Cl.8.7)
Preventive action – Actions to address risks and opportunities (Cl. 8.5)
Control of records (Cl.8.4)
Internal audits (Cl.8.8)
Management reviews (Cl.8.9)
IECEE Rules of Procedure and Guidance

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 7 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 (Cl. 8.3)

Test methods and method validation (Cl. 7.2)
Equipment (6.4)
Measurement traceability (Cl. 6.5)
Sampling (Cl. 7.3)
Handling of test items (Cl. 7.4)

Assuring the ~~quality~~ validity of ~~test~~ results (Cl. 7.7.1)
List the activities implemented by the laboratory related to monitoring of the validity of test results, relevant to the scope of the laboratory, other than Proficiency Testing.

Category/standard	Type of Monitoring Implemented	
	Examples from Cl. 7.7.1: Use of alternative instrumentation that has been calibrated to provide traceable results;	
	Functional checks of measuring and testing equipment	
	Retesting or recalibration of retained items;	
	Testing of blind sample(s)	
	Review of reported results	

Reporting the results (7.8)

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?	☐	☐	
Is the subcontracting allowed by the CTL list?	☐	☐	
Does the practice comply with OD-2012?	☐	☐	☐

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?	☐	☐	
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?	☐	☐	☐

10 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	☐	☐
CTF Stage 2	☐	☐
CTF Stage 3	☐	☐
CTF Stage 4	☐	☐

Does the Testing Laboratory carry out assessment according to ISO/IEC 17025 upon the request of the NCB?	Yes	No
CTF Stage 1	☐	☐
CTF Stage 2	☐	☐
CTF Stage 3	☐	☐
CTF Stage 4	☐	☐

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".

No.	PT Program Year	PTP Title	Remarks

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	

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:

1. The Assessment Team recommends **acceptance** of the assessed organization as reported in Annex 1A/B/C	☐
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 Reports as appropriate.	☐

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.	☐
4. Other, please specify using similar terminology	☐

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

16 Signatures of the Assessment Team

Date: yyyy-mm-dd

☐ 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	☒	☐
MED	IEC 60601-2-11:1997	9	☒	☐

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	☒	☐
OFF	IEC 60950-1:2005/AMD1:2009	333	☒	☐

* 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
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

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	☒	☐
MED	IEC 60601-2-11:1997	9	☒	☐

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	☒	☐
OFF	IEC 60950-1:2005/AMD1:2009	333	☒	☐

* 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
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Annex 1C Assessment Scope for Specialized Facility

Name of the Test	Standard	Clause of the Standard	Assessment Team acceptance	
			Yes	No
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

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.

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?	☐	☐
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?	☐	☐
Does the Body have access to the IEC Guide 115, "Application of Uncertainty of Measurement to Conformity Assessment Activities in the Electrotechnical Sector"?	☐	☐

3. Competency of Laboratory staff in uncertainty of measurement concepts	**Yes**	**No**
Does all the laboratory staff have knowledge of the basic concepts of uncertainty of measurement?	☐	☐
Can the Laboratory staff select instrumentation and make pass/fail decisions taking uncertainty of measurement into account?	☐	☐
Are selected laboratory staff sufficiently expert in uncertainty of measurement to calculate measurement uncertainties associated with test equipment and testing performed?	☐	☐
Names of person(s):		
Were the training records of the selected laboratory staff checked?	☐	☐
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?	☐	☐
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?	☐	☐

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.	☐	☐

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 and impartiality, so as to increase the amount of trust, confidence and value that those activities have in the market place	☐	☐
Document title: Document number:		

2. Reference Document	**Yes**	**No**
Does the Laboratory have access to ISO/IEC 17025:2017 and in particular Sub-clause 4.1 ~~4.1.4 (including Note 2, 4.1.5 B) and 4.1.5 d)~~?	☐	☐

3. Knowledge, training and decision making	**Yes**	**No**
Does the Laboratory staff have knowledge of the basic concepts of independence and impartiality?	☐	☐
Were the training records of the Laboratory's staff checked?	☐	☐
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?	☐	☐
Names of person(s):		
Were examples of training programs of the Laboratory's staff reviewed and found to be sufficient?	☐	☐
Does the Laboratory's staff select and make pass/fail decisions taking the principles of independence and impartiality into account?	☐	☐
Are the Laboratory's decisions based on objective evidence of conformity (or nonconformity) obtained by the Laboratory's staff?	☐	☐
Are the Laboratory's decisions influenced by other interests or parties?	☐	☐

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?	☐	☐

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? 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.	☐	☐
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?	☐	☐

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

6. Staff declarations	**Yes**	**No**
Does the Laboratory require all staff acting on its behalf to declare any potential conflict of interest?	☐	☐

7. Compliance	**Yes**	**No**
Does the Laboratory comply with all the above independence and impartiality principles on an ongoing basis? Note: If the answer to this item is NO a Non-Conformity Report must be issued	☐	☐

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?	☐	☐
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?	☐	☐
Does the CBTL 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?	☐	☐

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

This is informative for PAC data collection.

0. Internal Calibration Laboratory	Yes	No
Does the laboratory perform internal calibration?	☐	☐
1. Scope of calibrations performed by the internal calibration laboratory	**Yes**	**No**
Does the internal calibration laboratory have a controlled calibration list identify all test equipment which is internally calibrated?	☐	☐
Were examples of calibration records available?	☐	☐

Sampling of internal calibrated test equipment

Description	Equipment Identification (i.e. Asset Number)	-	-

2. Dedicated calibration standards	Yes	No
Does the calibration laboratory have controlled calibration methods, i.e. procedures, for each item of test equipment which is internally calibrated?	☐	☐
Does the laboratory have documented procedure for the validation of the internal calibration methods?	☐	☐
Does the laboratory have a documented operating procedure for the calibration and maintenance of equipment used for calibration?	☐	☐
Document title: Document number:		
Does the laboratory have a dedicated and secure storage location for the calibration standards and related equipment.	☐	☐

3. Uncertainty of measurement in calibration	Yes	No
Does the laboratory have access to and working knowledge of the ISO/IEC Guide 98-3, Guide to the Expression of Uncertainty in Measurement?	☐	☐
Do internal calibration certificates/reports fulfill the requirements of IECEE?	☐	☐
Do internal calibration certificates/reports include the measurement results and the measurement uncertainty statements for the calibrations?	☐	☐

4. Assurance of quality of internal calibrations	Yes	No
Does the laboratory have participation in proficiency or comparison testing related to calibration?		
Does the laboratory established a traceability chains for equipment calibrated internally?	☐	☐

5. Control of internally calibrated equipment?	Yes	No
Does the internal calibration laboratory have a procedure to distinguish internally calibrated test equipment from other test equipment?	☐	☐
Document title: Document number:		

6. Laboratory compliance with IECEE requirements for internal calibration	Yes	No
Does the internal calibration laboratory undergo annual audits by a qualified auditor or a metrologist (refer to OD 5011)?	☐	☐

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.

Testing Laboratory Assessment Report	IECEE-PAC/ /

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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 (if required) and printed name		Signature (if required) and printed name	
Root cause of non-conformity			
Proposed Corrective action(s)			
Implementation date		Management representative	
YYYY-MM-DD		Signature (if required), 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 (if required), printed name and date Signature: ☐ The Secretariat has received an email confirmation from the Lead Assessor in lieu of a signature accepting the content of this NCR.	
Implementation verified and final clearance provided by Lead Assessor	
Lead Assessor signature (if required), printed name and date Signature: ☐The Secretariat has received an email confirmation from the Lead Assessor in lieu of a signature accepting the content of this NCR.	

Testing Laboratory Assessment Report	IECEE-PAC/ /

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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.

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

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