IECEE OD-2005

Edition 3.2 2016-06-01

IECEE
OPERATIONAL DOCUMENT

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

Testing Laboratory Assessment Report

Confidential to the Members

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.

IECEE OD-2005:2016(EN)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE ZZ

FOREWORD

Scope

To be determined.

Document Owner

PAC

History of changes

Date	Brief summary of changes
2016-06-01	Most changes made cover the change from “MTL” to “CTF”, as well as the discontinuation of SATLs. The following subclauses were modified: 1.5, 2.2 & 10.

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

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)	☐	☐		

NOTE: 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.

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

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.

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

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	Organisation	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
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

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

2 Organisation

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 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.

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

2.4 Organisation of the Testing Laboratory

Include information relevant to the organisation 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

Name	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.

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, sub-clause 5.3?	☐	☐

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 CTL OP-110.	☐	☐
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.

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

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

Control of non-conforming work
Corrective action
Preventive action
Control of records
Internal audits
Management reviews
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 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

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.

	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 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	☐	☐
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.

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 organisation for the scope(s) as reported in Annex 1A /Annex 1B Initial Assessment / Scope extension Assessment Scope of this Assessment Report as appropriate.	☐
2. The Assessment Team recommends **acceptance** of the assessed organisation for the scope(s) as reported in Annex 1A /Annex 1B Initial Assessment / Scope extension Assessment Scope of this Assessment Report **subject to clearance** of the outstanding Non-conformity Reports as appropriate.	☐
3. The Assessment Team recommends that the acceptance of the assessed organisation 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

16 Signatures of the Assessment Team

Date: yyyy-mm-dd

	Printed name	Signature
Lead Assessor		
Assessor		

	Printed name	Signature
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:

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 section.
Lists the corresponding Product Category for each standard selected for this assessment.

Standard:
The assessment team completes this section with the standards selected for this reassessment.
Lists the standards in the Testing Laboratory scope including the editions and amendments.

Number of Test Reports issued during the last three years:
The Testing Laboratory 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 section based upon the on-site assessment.
Where insufficient experience is demonstrated 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.
.

Product Category	Standard	Number of Test Reports issued during the last three years	Assessment Team acceptance	
			Yes	No
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Note: For the organisation's full scope please see the IECEE Website

Annex 1B Initial Assessment / Scope extension Assessment Scope

Product Category:
The assessment team completes this section.
Lists the corresponding Product Category for each standard selected for this assessment.

Standard:
The assessment team completes this section with the standards selected for this reassessment.
Lists the standards in the Testing Laboratory scope including the editions and amendments.

Number of Test Reports issued during the last three years:
The Testing Laboratory 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 section based upon the on-site assessment.
Where insufficient experience is demonstrated 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.

Product Category	Standard	Number of Test Reports issued during the last three years	Assessment Team acceptance	
			Yes	No
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Annex 1C Assessment Scope for Associated Satellite Laboratory

Product Category	Standard	Number of Test Reports completed	Tests not carried out by the Satellite but carried out by the Main CBTL		Assessment Team acceptance	
			Clause of the Standard	Name of the test	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 Organisation 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 organisation to draft a dedicated Organisation 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 <u>all</u> 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"

This Annex to OD-2005 (Annex 5) applies to all Testing Laboratories not already assessed against it.

1. General Operating Procedure	Yes	No
Does the Body 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	☐	☐
Document title: Document number:		

2. Reference Document	Yes	No
Does the Body 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)?	☐	☐

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

4. Documentation and Implementation	Yes	No
Does the Body have documented and implemented (on an on-going basis) sufficient procedures to ensure the independence and impartiality of all staff?	☐	☐
Does the Body 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 Body is its customers paying for its services and that this is a potential threat to independence and impartiality.	☐	☐

Does the Body 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 Body keep records of such reviews and decisions?	☐	☐

5. Marketing and advertising materials	**Yes**	**No**	**N/A**
Do the Body’s marketing materials give the impression that “commercial consultancy” activities are offered?	☐	☐	
Is the Body 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 Body’s certification staff participate in “commercial consultancy”?	☐	☐	☐

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

7. Compliance	**Yes**	**No**
Does the Body comply with all the above independence and impartiality principles on an ongoing basis? Note: If the answer 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?	☐	☐

Non-Conformity Reports

Non-conformity Report No	**/**	**Date**	YYYY-MM-DD
Categories concerned			
Clause / Sub-clause of Non-Conformity			
Non-conformity description			
Lead Assessor		Management representative	
Signature and printed name		Signature, printed name and title	
Root cause of non-conformity			
Proposed Corrective action(s)			

Implementation date	Management representative
YYYY-MM-DD	Signature, printed name, title and date
Proposed Corrective Action(s) acceptance	
Acceptance, no further verification required	☐
Acceptance, further verification of implementation is required, without on-site follow-up assessment	☐
Acceptance, further verification of implementation is required, with on-site follow-up assessment	☐
Lead Assessor (Signature, printed name and date)	
Implementation verified and final clearance provided by Lead Assessor	
Lead Assessor signature, printed name and date	

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IEC SYSTEM OF CONFORMITY ASSESSMENT SCHEMES FOR ELECTROTECHNICAL EQUIPMENT AND COMPONENTS (IECEE)

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