



IECEE OD-5004

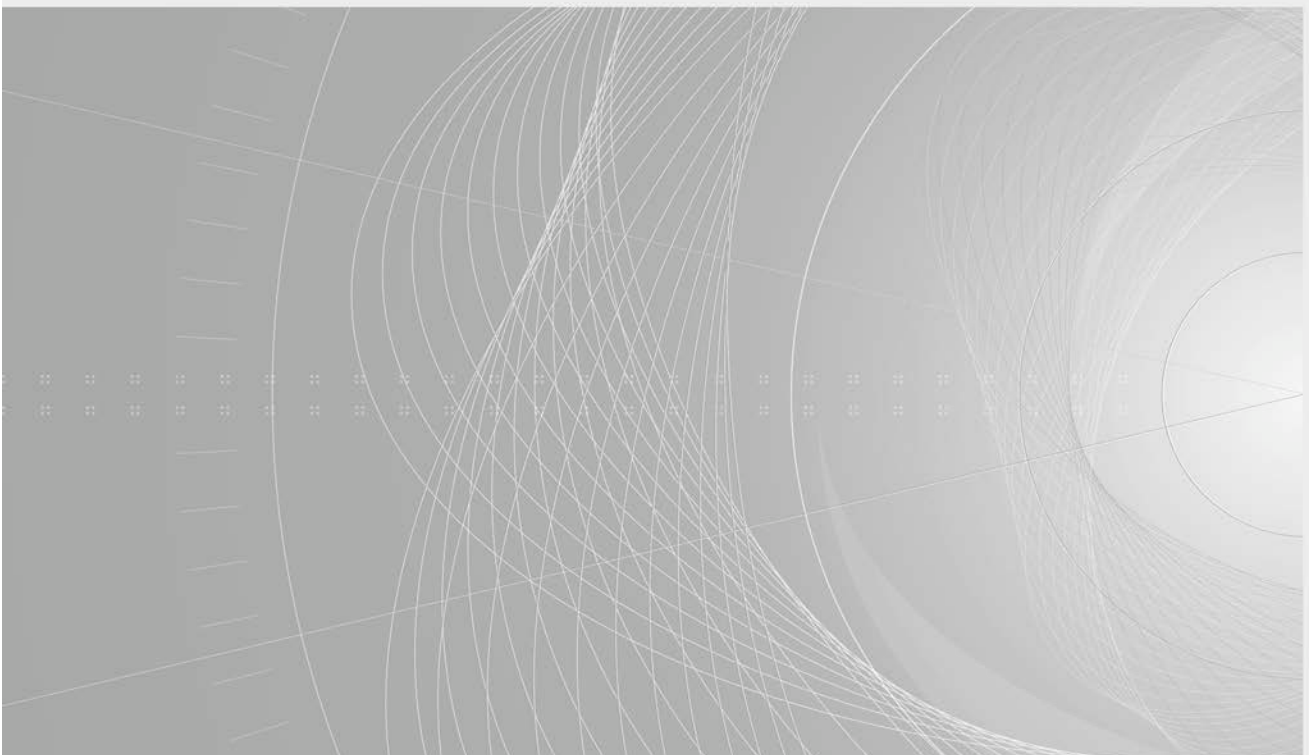
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IECEE OPERATIONAL DOCUMENT

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

Committee of Testing Laboratories (CTL)

Proficiency Testing Programs





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FOREWORD

Document Owner

CTL

History of changes

<u>Revision</u> Date	Brief summary of changes
2017-02-24	Added disclaimer Added foreword Updated content Updated clauses 9. 12. 14 and 15 based on CMC Decision 18/2016
2017-03-13	Update to clause 6 as per CTL decision 73/2010 & CMC decision 19/2016 adding that “the starting time period to start the three years period for PTPs starts with issuing the final PTP report”
2018-xx-xx 04-24	<u>Updated clause 9 Program Management based on CTL decision 26:54/17 and CMC decision 25/2017</u> <u>Added clause 10 PTP on demand based on CTL decision 07:54/17 and CMC decision 25/2017</u>

Effective date	Target revision <u>Next maintenance due</u> date
201 87-03xx-13xx03-24 <u>06-05</u>	2020 <u>2021-02</u> 03-24 <u>06-05</u>

Background

The CTL decided in 2014 to convert the CTL Operational Procedure (OP) into the IECEE Operational Document (OD) structure. The content of the former OP's has not been changed. Editorial adjustments have been made where necessary. The forms have been separated into independent documents for better handling.

A transfer table which CTL/OP has been transferred into which OD is given in OD 5000.

1 Purpose

The purpose of this document is to describe the rules of Operation of the CTL PTP's.

2 Scope

One primary goal of the Committee of Testing Laboratories (CTL) is to increase the mutual confidence among the CB Testing Laboratories operating within the IECEE System.

In order to achieve this, the CTL operates Proficiency Testing Programs (PTPs), designed to improve the consistency and reproducibility of test results.

3 Normative References

The following publication contain provisions which, through reference in this text, constitute modification or additions of this Operational Document.

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17043	Conformity assessment - General requirements for proficiency testing

4 Definitions

For the purpose of this publication, the definitions of *IECEE Definitions* apply with the following additions:

CTL	IECEE Committee of Testing Laboratories
CTL/ETF	CTL Expert Task Force
CTL/WG	CTL Working Group
NCB	National Certification Body
MB	Member Body
TA	Technical Advisor

5 Abbreviations

None	
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6 Participation

All Testing Laboratories accepted by the CB Scheme are generally required to participate in all CTL Proficiency Testing Programs within their scope of recognition within the IECEE System, but not more than three per year, with the priority being given to new topics. The starting time period to start the three years period for PTPs starts with issuing the final PTP report.

Exception: A laboratory may be required to participate in more than 3 programs per year if required to repeat a test as a result of "outliers" in previous programs.

Laboratories participating in a program with satisfactory results will not be required to repeat participation in that particular program topic for 3 years.

Each PTP will identify the relevant IEC standards within the scope of the IECEE System to which it applies.

All NCBs shall ensure that each laboratory, for which the NCB is responsible, participates in the applicable PTPs that fall within the testing scope of the laboratory. The participation of a laboratory shall be monitored by the responsible NCB. An NCB responsible for several laboratories may choose to co-ordinate the PTP arrangements for its corporate family of laboratories.

The number of Proficiency Testing Programs to take place each year shall be decided by the CTL and ratified by the CMC. The maximum number of new programs, e.g. new topics, initiated each year shall be limited to three. Repeated programs also require CTL approval and CMC ratification.

7 Topics

Suggestions for program topics may be made by a CTL Expert Task Force (ETF), IECEE System Member Body (MB), National Certification Body (NCB), or a recognized CB Testing Laboratory (CBTL) - through its responsible NCB.

Based on such suggestions CTL Working Group 2 (Proficiency Testing Programs) makes recommendations for new Proficiency Testing Programs for approval by the CMC on a recommendation by the CTL.

8 PTP Provider

The programs are coordinated and processed by a PTP Provider independent of the participating testing organisations and working in coordination with CTL-WG2.

The PTP Provider shall be selected by the CTL Chairman in consultation with the IECEE Executive Secretary, endorsed at the CTL Plenary session and formally appointed by the CMC.

The PTP Provider shall have a proven capability in the design and management of programs related to electrical safety testing either directly or with the help of the relevant CTL Expert Group.

The PTP Provider shall be formally recognised according to ISO/IEC 17043 by a reputable Accreditation Body.

9 Program Management

The topics decided by the CTL are developed into programs by the PTP provider in cooperation with CTL-WG 2 and the Technical advisors (TAs).

Two or more Technical Advisers (TAs), typically from among the CTL-WG and ETF members, should be appointed for each Proficiency Testing Program by the WG-2 Convenor, based on a call for volunteers throughout the proposers, the CTL-plenary, and via WG2 to all ETFs and WGs, taking adequate care to avoid a potential conflict of interest.

Proficiency Testing Programs may include equipment-audits that may be requested upfront the Proficiency Testing program. Equipment-audits are intended to check test apparatus and procedures used for the Proficiency Testing Programs against the requirements in the relevant standard. These audits are completed by the participating laboratories. The responses to the audit questions are reviewed by the PTP Provider as part of the PTP analysis. In case where equipment-audits are required upfront and when a deficiency is revealed the laboratory is notified and given the opportunity to take corrective actions prior to performing the proficiency testing. Nevertheless this will be shown in the PTP report and all reported actions shall be recorded in a follow-up register by the PTP Provider.

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~~The PTP provider prepares the test samples and first subjects them to a round of homogeneity tests at a competent testing laboratory, preferably a CBTL. The homogeneity test laboratory is chosen by the Provider, if necessary in consultation with CTL-WG2. The Technical Advisers (TAs) are involved in evaluation of the homogeneity test results and assist in the development of the test instructions.~~

The PTP Provider announces Proficiency Testing Programs' enrollment after the groups of programs are ready.

The PTP Provider sends out the details for each program to the NCBs and laboratories in advance. **The PTP Provider provides sufficient time with a minimum of 6 weeks for laboratories to study the instructions, determine the applicability of the PTP within the scope, handle internal approval processes, communicate with their NCB(s) for agreement and enroll the PTP.** The NCBs shall inform the PTP Provider which of their laboratories are in scope and shall update any contact details as necessary.

Each laboratory shall acknowledge its willingness to participate in individual PTPs to the PTP provider. This acknowledgement shall be made directly to the PTP Provider in writing prior to the sample shipping date provided with the program details.

The PTP Provider supplies to the IECEE Secretariat the list of laboratories that have registered for each program to enable a check, if all laboratories in scope of the relevant PTP have registered.

The PTP provider shall send an automatic alert to the registered laboratories and corresponding NCBs when the program status is changed, revised or modified.

The IECEE Secretariat should follow up with the NCBs and their laboratories that are required to participate but have not registered.

~~The PTP provider prepares the test samples and first subjects them to a round of homogeneity tests at a competent testing laboratory, preferably a CBTL. The homogeneity test laboratory is chosen by the Provider, if necessary in consultation with CTL-WG2. The Technical Advisers (TAs) are involved in evaluation of the homogeneity test results and assist in the development of the test instructions.~~

The PTP Provider sends out the detailed instructions and samples, then collects and analyses the results.

At the completion of a program, the PTP Provider circulates a draft report to the Technical Advisers (TAs) and CTL-WG2 for comment. This is not a ballot, however, a lack of comments will be considered as approval.

For each program, CTL-WG 2 and the Technical Advisers (TAs) in cooperation with the PTP Provider shall analyse the statistical presentation of the results of the Proficiency Testing and decide data that are considered outliers. The outlier criteria and any suggested improvements shall be accommodated as best as possible in the report.

Based on this, the PTP provider completes the report, including comments from Technical Advisers (TAs) and/or CTL-WG2 where appropriate, and issues the report to the participating laboratories and their NCBs.

Responsibilities in cases where corrective action is required are described in Section **12-13** of this document.

The PTP provider will be responsible for following up on the clearance of technical related GNCRs that are issued due to non compliances with this OD.

10 PTP on demand

The PTP provider may offer PTP on demand when laboratories may need to engage in certain PTP topics at times other than the timeframes of the planned PTP rounds.

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PTPs on demand are operated using samples from previous programs. The statistically acceptable range of the relevant prior PTPs will apply to the assessment of the laboratory engaging in the on-demand PTP.

Participation by the laboratory in a PTP on demand is voluntary and does not replace the mandatory participation as required in Section 6 of this document.

In some cases the laboratory may demand a PTP out of the regular timeframes, for example after relocation of laboratory, in preparation for a scope extension or if a PTP was not offered for a longer period. In those cases, especially if the PTP results were positive, the laboratory shall not be forced to repeat the PTP shorter than three years period.

The IECEE Secretariat exercises discretion regarding GNCRs that may be issued as a result of failure to follow up outliers from a PTP on demand.

4011 PTP Results

The confidentiality of results from individual laboratories is important to the operation of the PTPs.

Because of their responsibility for laboratories within the IECEE System, NCBs shall make appropriate arrangements with their testing laboratories (CBTLs and ACTLs) concerning access to laboratory results and the maintenance of confidentiality. Except as mentioned in clause c) below, individual and consolidated testing laboratory results shall be maintained confidential by the PTP Provider.

PTP results are made available as follows:

- a) individual results – to the relevant laboratory and its responsible NCB.
- b) complete consolidated (anonymous) results – to the participating labs, the CTL Chairman and Secretary, and also presented at the CTL Plenary meeting.
- c) All individual and complete consolidated results – provided to the IECEE Secretariat.

4112 PTP Reports

The PTP Reports shall be prepared and distributed by the PTP Provider and shall include the contents detailed in ISO/IEC 17043:2010 as relevant to the program topic.

4213 PTP Outliers

In parallel to the issuance of the report the PTP provider shall compile a complete list of individual participants that have either produced “outlier results” and/or other non-compliances (e.g. equipment related). This list is provided to the IECEE secretariat.

Individual laboratories are notified regarding PTP outliers, when applicable.

If participant(s) fail to resolve outliers of the PTP within the given time frame:

- A technical related GNCRs will be issued by the IECEE Secretariat, of which the PTP provider will follow up on corrective actions related to the outlier. The PTP provider is entitled to invoice the CBTL for this additional activity. See section [4516](#).
- A quality-system-related GNCR will be issued by the IECEE Secretariat to the responsible NCB for not ensuring that the PTP “outliers” are resolved in the time provided by this OD. This GNCR is to be resolved by a special administrative assessment carried out by an assessment team appointed by the Executive Secretary when the GNCR is issued. The assessment team is entitled to invoice the NCB for the time spent. See section [4516](#).

4314 Appeal by the laboratory

A testing laboratory whose test results are sorted as outlier has the right to appeal.

Appeals shall be made in writing to the Executive Secretary of the IEC EE, with a copy to the PTP Provider, within two month from the report issue date, and shall clearly indicate the reasons for appealing. These two months for appeal do not extend the three month period allowed for completion of corrective actions.

For appeals that require technical input CTL-WG2 and/or the Technical Advisors (TAs) may be consulted, however the identity of the testing laboratory shall be kept undisclosed at all time. CTL-WG2 and /or the Technical Advisors (TAs) shall respond within 15 working days upon receipt of the request.

4415 Completion of corrective actions

All “outlier results” and non-compliances, whether due to technical, typographical or other errors, shall be subject to appropriate investigation, followed by remedial and preventive actions. All reported actions shall be recorded in a follow-up register by the PTP Provider.

The PTP Provider may request clarification of information provided by participants to assist in determining whether a non-compliance exists. Such clarifications shall also be recorded using the follow-up register.

Participants carrying out corrective actions shall follow the procedures outlined in ISO/IEC 17025:2005; 4.11 and 4.12. Completed corrective action reports shall be sent to the IEC EE Secretariat with a copy to the PTP Provider, who will record the status of actions in the follow-up register.

Copies of completed corrective action forms shall be held by the laboratory for review during the next on-site assessment.

The IEC EE Secretariat takes responsibility for monitoring the corrective action status, but is not responsible for the technical validity of the actions undertaken. However, any actions deemed to be inappropriate will be forwarded to the relevant technical panel for review. Feedback shall be provided to the participants when available.

Laboratories requiring more time shall make a request in writing to the IEC EE Secretariat with a copy to the PTP Provider, who will log this information in the follow-up register.

Laboratories failing to overcome the outlier with effective proposed corrective action within three months will be notified by the IEC EE Secretariat with a formal General Non-Conformity Report. The GNCR should be issued within one week after IEC EE Secretariat is informed by the PTP provider of the failure to complete corrective action within the set time frame.

The PTP provider will subsequently follow-up on corrective actions for the technical related GNCRs in accordance with this OD, and report the status to the IEC EE Secretariat. If corrective actions provided are considered to be acceptable and complete, the PTP provider will issue a recommendation of acceptance to the IEC EE Secretariat to resolve the issued GNCR. The Secretariat will inform the infringing organization and the PTP provider when the GNCR is cleared.

4516 Financial matters

An estimate of the cost of a new program including a monitoring service, which is limited to three month after issue of the report, shall be provided in advance to the CTL Chairman and Secretary.

Programs are advertised well in advance with the details of a proposed date and the costs for participation posted on the website of the PTP Provider.

After enrolment to a specific PTP more details are sent by the PTP Provider to the NCBs and individual participants for their final confirmation, with an invoice and instructions for payment that is to be made directly to the PTP Provider. Acceptable payment options are described on the PTP Provider's website.

Laboratories can pay individually or via their NCB, depending on arrangements made with the PTP Provider.

Cost related to follow up on corrective actions for technical related GNCRs issued by the Secretariat due to failure to clear outliers in due time is detailed in OD-2026 in the section for CTL Proficiency Test Program.

For cost related to follow up on corrective actions for quality-system-related GNCRs issued by the Secretariat due to failure to clear outliers in due time, the appointed assessment team is entitled to invoice the NCB for the time spent, based on the daily assessment fee for Assessors detailed in OD-2026. The minimum chargeable fee is half of the daily rate.

Payment is required prior to the laboratory being accepted to participate in a particular program. Unpaid invoices will result in deletion of participation records and subsequent reporting to IECEE secretariat that will undertake due actions in accordance with the IECEE Rules. Payment for follow up on corrective actions for both the technical and quality-system related GNCRs is required prior to clearance of the issued GNCRs.

4617 Workshop

Based on CTL membership interest, the CTL will hold workshops on conducted PTPs.

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