



## STEERING COMMITTEE IEC-ILAC-IAF

**SUBJECT:**  
IECEE CTL Operational Procedure Proficiency Testing Program

**BACKGROUND:**  
**Excerpt from the IECEE CMC Minutes Tel Aviv 2010**

**Item 20.3 To review and approve the revised Operational Procedure CTL-OP 103 pertaining to the Proficiency Testing Program IECEE-CMC/1077/INF**

The CTL Chairman gave the summary of the changes included in Draft CTL-OP 103 “Proficiency Testing Program” Ed. 9 (2010-05-22) versus CTL-OP 103 “Proficiency Testing Program” Ed. 8 (2007-11-14) and explained that the revision was particularly focused on integrating quality assurance principles defined in ISO/IEC 17025:2005 as well as changing the process related to the PTP provider’s post PTP actions, the reporting and appeal procedure and the corrective actions procedure.

He explained that the rationale behind the changes was based on the objective of improving the process based on 10 years collective PTP experience, the publication of ISO/IEC 17043:2010 that has modified some requirements for PTP providers, which should be reflected in CTL-OP 103 and the integration and reinforcement of quality assurance principles defined in ISO/IEC 17025:2005

**ACTION:**  
**The Steering Committee to advise on whether the IECEE CTL Proficiency Testing Operational Procedure also matches the practice as agreed by the ILAC MLA Members.**

## **SUMMARY OF MODIFICATIONS COMPARED TO Ed.8 of CTL-OP 103**

### **MODIFICATIONS TO TECHNICAL REQUIREMENTS**

PTP Participation shall include greater attention to clauses 4.10, 4.11, 4.12, 5.4.7 and 5.10 in ISO/IEC 17025:2005 (see next page).

### **MODIFICATIONS TO REPORTING AND APPEAL PROCEDURE**

The PTP Provider is required to issue one (final) report only on completion of the relevant test round. No interim reports will be issued in future.

Participants may appeal their performance assessment within 30 days of issue of the final report. Any appeal made will only be considered if it has a technical basis.

### **MODIFICATIONS TO CORRECTIVE ACTION PROCEDURE**

All non-compliances, whether due to technical, typographical or other errors shall be subject to appropriate investigations followed by remedial and preventive action. All non-compliances will be reported to the IECEE secretariat at the time the report is issued.

The PTP Provider may request clarification of information provided by participants. Such clarifications will be recorded using the same "follow-up" system as the registry of non-compliances.

Participants carrying out corrective actions shall follow the procedures outlined in ISO/IEC 17025:2005; 4.11 and 4.12. Corrective actions shall be reported in a defined format. Completed corrective action reports shall be sent to the PTP Provider, who will record the status of actions.

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

The PTP provider can only take responsibility for monitoring corrective action status, but not for the technical validity of actions undertaken. However, any actions deemed to be inappropriate by the PTP Provider will be forwarded to the relevant technical panel for review. Feedback shall be provided to the participants when available.

Failure to resolve all elements of the corrective action process within 3 months of issue of the PTP report will be reported to the IECEE secretariat for further handling. Laboratories requiring more time shall make a request in writing to the PTP Provider, who will log this information in the follow-up register. Never-the-less, at the conclusion of 3 months all open action items will be referred to the IECEE secretariat and will no longer be followed by the PTP Provider.

## **ISO/IEC 17025:2005**

### **4.10 Improvement**

The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

## **ISO/IEC 17025:2005**

### **4.11.2 Cause analysis**

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

### **4.11.3 Selection and implementation of corrective actions**

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

### **4.11.4 Monitoring of corrective actions**

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

### **4.11.5 Additional audits**

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

## **ISO/IEC 17025:2005**

### **4.12 Preventive action**

**4.12.1** Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

**4.12.2** Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

NOTE 1 Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

## **ISO/IEC 17025:2005**

### **5.4.7 Control of data**

**5.4.7.1** Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

### **5.10 Reporting the results**

#### **5.10.1 General**

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.



**OPERATIONAL PROCEDURE**

**CTL-OP 103**

**Rules of Operation  
for CTL Proficiency Test Programs**

Previous document IECEE-CTL/321/INF, approved at the 47<sup>th</sup> CTL Meeting



## PREAMBLE

The IECEE expects that laboratories maintain a high standard of testing work and aim for continuous quality improvement.

Revision of CTL-OP 103 was recommended in order to improve the principle procedures based on 10 years collective PTP experience. Further, the publication of ISO/IEC 17043:2010 has modified some requirements for PTP providers, which should be reflected in this CTL operational procedure.

This revision implies the application of quality assurance principles defined in ISO/IEC 17025:2005, as most laboratories in the IECEE CB-Scheme are accredited to ISO/IEC 17025:2005.

The philosophical basis of the IECEE CTL Proficiency Testing Scheme is to promote mutual confidence between laboratories operating under the IECEE CB-Scheme.

The demand for the IECEE CTL Proficiency Testing Scheme is defined in Clause 5.9.1 b) of ISO/IEC 17025:2005.

### **5.9 Assuring the quality of test and calibration results**

**5.9.1** *The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:*

- a) regular use of certified reference materials and/or internal quality control using secondary reference materials;*
- b) participation in inter-laboratory comparison or proficiency-testing programmes;***
- c) replicate tests or calibrations using the same or different methods;*
- d) retesting or recalibration of retained items;*
- e) correlation of results for different characteristics of an item.*

*NOTE The selected methods should be appropriate for the type and volume of the work undertaken.*



## ***RULES OF OPERATION FOR CTL PROFICIENCY TESTING PROGRAMS (PTPs)***

### **PURPOSE**

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

### **1. PARTICIPATION**

All Testing Laboratories accepted by the CB Scheme, including CB Testing Laboratories (CBTLs) and manufacturers' SMT and RMT Laboratories (MTLs), are required to participate in CTL Proficiency Testing Programs within their scope of recognition for the CB Scheme.

Each PTP will identify the relevant IEC standards within the scope of the CB-Scheme to which it applies.

Based on the identified applicable standards for each PTP, the IECEE Secretariat will provide to the PTP Provider a list of all relevant CBTLs and MTLs being recognised for these standards.

All NCBs shall ensure that each CBTL, SMT and RMT 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 family of laboratories.

A laboratory is not required to participate in more than 3 programs per year, with the priority being given to new topics.

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 for 3 years.



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

## **2. TOPICS**

Suggestions for program topics may be made by a CTL Expert Task Force (ETF), CB-Scheme Member Body (CB-MB), CB National Certification Body (CB-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 PT programs for approval at the CTL Plenary Meeting.

## **3. PTP PROVIDER**

The programs are managed 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 members of CTL WG2 and WG4, accepted at the CTL Plenary session and confirmed by the CMC. The PTP Provider shall have a proven capability in the design and management of programs related to electrical safety testing. The PTP Provider shall be formally recognised according to:

- (a) ILAC G13:2000, "Guidelines for the requirements for the competence of providers of proficiency testing schemes"

and/or

- (b) ISO/IEC 17043:2010, "Conformity assessment - General requirements for proficiency testing"



#### **4. PROGRAM MANAGEMENT**

The topics decided by the CTL are developed into programs by the PTP provider in cooperation with CTL WG2 and the Technical advisors (TAs).

The TAs are appointed for each PT programme by the WG2-Convenor, typically from among the CTL WG and ETF members, taking adequate care to avoid a potential conflict of interest.

PTPs may include equipment-audits or such equipment-audits may be requested upfront the proficiency testing. Equipment-audits are intended to check test apparatus and/or procedures used for the PTP. 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 according Section 6.

In accordance with Section 1, the PTP Provider sends out the details for each program to the NCBs and laboratories in advance. 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.

The IECEE Secretariat follows 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 in consultation with CTL WG2.

The PTP Provider sends out the detailed instructions and samples 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 PT program CTL WG2 and the TAs in cooperation with the PTP Provider shall analyse the statistical presentation of the results of the proficiency testing and decide what data 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 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 7 of this document.

## **5. 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 CB-Scheme, NCBs shall make appropriate arrangements with their laboratories concerning access to laboratory results and the maintenance of confidentiality. Except as described in this section 5, individual laboratory results shall be maintained on a confidential basis by the PTP Provider.

PTP results are made available as follows:

- (a) individual results – to the relevant laboratory and its responsible NCB.
- (b) overall consolidated (anonymous) results – to the CTL Chairman and Secretary and to the IECEE Secretariat, and are presented at the CTL Plenary meeting.
- (c) All individual results – retained on file by the PTP Provider for reference and provided to the IECEE Executive Secretary on request.

## **6. 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.



## **7. 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.

## **8. APPEAL BY LABORATORY**

A testing laboratory whose test results are classified as outliers has the right to appeal this classification on technical reasons, or if their result has been misrepresented by the PTP Provider. Appeals shall be made in writing to the IECEE Secretariat and to the PTP Provider within 30 days from the report issue date, and shall clearly indicate the reasons for appealing.

For appeals that require technical input CTL WG2 and/or the TAs may be consulted, if it can be done without revealing the identity of the testing laboratory. CTL WG2 and /or the TAs will be expected to respond within 15 days of receiving a request from PTP Provider.

## **9. 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. The corrective actions shall be reported in a defined format provided on the IECEE website.

Completed corrective action reports shall be sent 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.



## OPERATIONAL PROCEDURE

CTL-OP 103

The PTP Provider can only take responsibility for monitoring corrective action status, but not for the technical validity of actions undertaken. However, any actions deemed to be inappropriate by the PTP Provider 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 PTP Provider, who will log this information in the follow-up register.

Three months after issue of the report, all open items shall be referred to the IECEE Secretariat and will no longer be followed by the PTP Provider. Failure to resolve **all** elements of the corrective action process may result in issue of a formal General Non-Conformity Report (GNCR).

The IECEE Secretariat will subsequently follow-up on corrective actions in accordance with the IECEE procedures.

### 10. FINANCIAL MATTERS

An estimate of the cost of a new program including the 3 month monitoring service after issue of the report shall be provided in advance to the CTL Chairman and CTL WG2 Convenor.

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.

Payment is required before a laboratory is accepted for participation in the particular program. Unpaid invoices will result in deletion of participation records and subsequent reporting to IECEE Secretariat with issue of GNCR.

### 11. WORKSHOP

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