# IECEx OD-202

Edition 1.0  2015-09

# IECEx
# OPERATIONAL DOCUMENT

**IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System)**

**IECEx Testing and Assessment Group (ExTAG)**

## IECEx Proficiency Testing Program

## About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

## About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

**Useful links:**

IEC publications search - www.iec.ch/searchpub

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,…).
It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.
Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

# IECEx
# OPERATIONAL DOCUMENT

**IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System)**

**IECEx Testing and Assessment Group's (ExTAG)**

## IECEx Proficiency Testing Program

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE **ZZ**

# CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION
_____

**IECEx Operational Document**

# IECEx OD 202 Edition 1.0

# IECEx Operations Manual – IECEx Certified Equipment Scheme - IECEx Proficiency Testing Program

This IECEx Operational Document provides guidance to IECEx ExTLs on satisfying the requirements of ISO/IEC 17025 with respect to participation in proficiency testing programs as conducted for inter-laboratory comparisons.

The principles and requirements of ISO/IEC 17043 have been incorporated in or referenced from this Operational Document.

## Background

Following the successful application of the first global Ex proficiency testing scheme "PTB Ex PTS", IECEx ExTAG and the IECEx Secretariat prepared this IECEx Operational Document as guidance to IECEx ExTLs on satisfying the requirements of ISO/IEC 17025 with respect to participation in proficiency testing programs as conducted for inter-laboratory comparisons.

The principles and requirements of ISO / IEC 17043 have been incorporated in or referenced from this Operational Document.

Decision 2014/53 taken at the 2014 IECEx Management Committee (ExMC) Meeting in The Hague is the basis for the preparation of this IECEx Operational Document.

## Document History

| Date | Summary |
|---|---|
| September 2015 | Original issue (Edition 1.0) as approved for publication via ExMC Decision 2015/40 regarding ExMC/1040/CD and subsequent changes by ExTAG WG10 as detailed in ExMC(Christchurch/ExTAG WG10)05 |

Address:

IECEx Secretariat
Level 33, Australia Square
264 George Street
Sydney NSW 2000
Australia

Contact Details:

Tel: +61 2 4628 4690
e-mail: info@iecex.com
http://www.iecex.com

## 1  Purpose

The purpose of this document is to describe the rules of operation of the IECEx Proficiency Testing Program (Ex PTP).

## 2  Scope

The primary goal of the Ex PTP is to increase the mutual confidence among the IECEx Testing Laboratories (ExTLs) operating within the IECEx System.

In support of this goal the Ex PTP has been designed to improve the consistency and reproducibility of test results.

## 3  Normative References

The following publications 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 following definitions apply:

**proficiency testing provider**
organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme

**proficiency testing scheme**
proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection

## 5  Abbreviations

| | |
|---|---|
| ExTAG | IECEx Testing and Assessment Group |
| ExTAG/WG | EXTAG Working Group |
| ExCB | IECEx Certification Body |
| ExTL | IECEx Testing Laboratory |
| MB | Member Body |

## 6   Participation

In accordance with IECEx ExMC Decision 2014/53, participation in the Proficiency Testing Program is mandatory for all accepted and applicant IECEx ExTLs and any Additional Testing Locations (noting that this does not include laboratories operating under the provisions of IECEx OD 024). Laboratory participation is according to their scope of acceptance in the IECEx System and is a condition for continued acceptance.

Candidate ExTLs shall, prior to acceptance, complete the IECEx Proficiency Testing Programs relevant to the scope of their application prior to acceptance as an ExTL.

ExTLs are required to participate in all programs which are relevant to their scope, with the priority being given to new topics.  A laboratory may be required to conduct more than one program per year in the case of repeating a test as a result of "outliers" in previous programs.

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

The number of Proficiency Testing Programs to take place each year shall be recommended by the IECEx Testing and Assessment Group (ExTAG) and decided by the IECEx Management Committee (ExMC). The maximum number of new programs, e.g. new topics, initiated each year shall be limited to one. Repeated programs also require ExTAG recommendation and subsequent ExMC approval.

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

The IECEx Secretariat shall ensure that each accepted ExTL laboratory and ExTL applicant participates in the applicable Ex PTPs that fall within the testing scope of the laboratory.

The participation of a laboratory shall be scheduled and monitored by the IECEx Secretariat.

The IECEx Secretary shall be responsible for the overall management of the Ex PT Program including the activities of the Ex PT Program provider.

## 7   Topics

Suggestions for program topics may be made by the ExTAG, an IECEx System Member Body (MB), an IECEx Certification Body (EXCB), or an accepted IECEx Testing Laboratory (ExTL).

Based on such suggestions ExTAG Working Group 10 (Proficiency Testing Programs) makes recommendations for new Proficiency Testing Programs for approval by the ExMC on a recommendation by the EXTAG.

## 8   Ex PTP Provider

The programs are coordinated and processed by an Ex PTP Provider independent of the participating testing organisations and working in coordination with ExTAG WG10.

IECEx PT Program Providers will be determined by the IECEx ExMC on recommendations from ExTAG WG10 that have been endorsed by ExTAG.

IECEx PT Program Providers shall be formally accredited by an IAF/ILAC Accreditation Body according to:
- ISO/IEC 17043, "Conformity assessment - General requirements for proficiency testing"
OR
- alternatively submitted to the peer assessment procedures of IECEx and the relevant principles and requirements of ISO/IEC 17043.

IECEx PT Program Providers shall be capable of developing and operating PT programs for all IEC 60079 series standards and selected standards from the ISO 80079 series as determined by the IECEx ExMC.

In order to assure continuity of the effectiveness of operation of the IECEx PT Program, IECEx PT Program Providers shall be contracted for a period of at least 10 years. IECEx PT Providers shall provide annual reports to the ExTAG on activities, PT Program results and any issues arising that may have an impact on the effectiveness of the IECEx PT Program.

## 9   Selection of Ex PT Programs

Suggestions for programs may be made by the IECEx PT Program provider based on questionnaires circulated to ExTLs, by proposals of the ExTAG WG 10 "Proficiency Testing" or by other experts. All related costs (provider costs, in-house costs for the test laboratory staff etc.) must be estimated and compiled for consideration and ExTAG WG 10 will be required to approve the programs as presented. After approval by ExTAG WG 10 the provider can implement the programs and request ExTLs for participation. The Ex PT provider shall ensure that all available Ex PT programs can be performed by any accepted ExTL or ExTL candidate at any time.

## 10   Program Management

The topics decided by the ExTAG are developed into programs by the PTP provider in cooperation with ExTAG WG10.

IECEx Proficiency Testing Programs may include equipment audits that may be requested under the Ex PTP. 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 ExTLs. 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 and when a deficiency is revealed the ExTL shall be 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.

The PTP Provider sends out the details for each program to the laboratories in advance.

Each ExTL 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 IECEx Secretariat the list of ExTLs that have registered for each program to enable a check, if all ExTLs in scope of the relevant PTP have registered.

The IECEx Secretariat shall follow up with ExTLs 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. The homogeneity test laboratory is chosen by the Provider, if necessary in consultation with ExTAG WG10.

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 ExTAG WG10 for comment. This is not a ballot, however, a lack of comments will be considered as approval.

For each program, ExTAG WG10 in cooperation with the PTP Provider shall analyse the statistical presentation of the results of the Proficiency Testing and identify data that are considered as 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 ExTAG WG10 where appropriate, and issues the report to the participating laboratories.

Responsibilities in cases where corrective action is required are described in Section 15 of this document.

## 11 Ex PTP Results

The confidentiality of results of individual laboratories is essential.

The results will be communicated only to the individual ExTL and to the IECEx secretary. The individual ExTL may discuss their results with the IECEx assessment team or national accreditation bodies who may ask on its own for the results of Ex PT programs. It is not permitted to publish Ex PT program results. Only general information about results of Ex PT programs can be provided. IECEx assessors shall be trained accordingly.

## 12 Ex PTP Reports

The Ex PT Program Reports shall be prepared and distributed by the IECEx PT Program provider according to the requirements of ISO/IEC 17043. In addition to the comprehensive reports, summary reports are to publish in order to highlight the essential results of a program.

## 13  PTP Outliers

In parallel with the issue 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 IECEx Secretariat.

Individual ExTLs are notified regarding PTP outliers, when applicable.

In the event of the IECEx Secretary or the IECEx assessment team identifying unsatisfactory results from an IECEx PT Program that may be due to the poor performance of an individual ExTL, the IECEx Secretary may take action, in cooperation with the IECEx ExMC Chairman. Such action may include the establishment of a requirement on the ExTL for improvement of competence (e.g. training of staff, investment for better instruments) before a deadline with failure to do potentially leading to a reduced scope for the ExTL.

## 14  Appeal by the laboratory

A testing laboratory (ExTL) whose test results are identified as an outlier has the right to appeal.

Appeals shall be made in writing to the IECEx Secretary, with a copy to the PTP Provider, within two months from the report issue date, and shall clearly indicate the basis for the appeal. This allowance of two months for the preparation of an appeal do not extend the three month period allowed for completion of corrective actions.

For appeals that require technical input ExTAG WG10 may be consulted, however the identity of the ExTL shall remain confidential for the duration of such consultation. ExTAG WG10 shall respond within 15 working days upon receipt of the request.

## 15  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 IECEx Secretariat (with a copy to the PTP Provider) for inclusion and update of 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 IECEx Secretariat is responsible 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.

ExTLs and ExTL candidates requiring more time shall make a request in writing to the IECEx Secretariat with a copy to the PTP Provider, who will log this information in the follow-up register.

ExTLs and ExTL applicants failing to overcome the outlier with effective proposed corrective action within three months will be notified by the IECEx Secretariat with a formal General Non-Conformity Report.

The IECEx Secretariat shall subsequently follow-up on corrective actions in accordance with the IECEx procedures.

## 16  Workshops and "Best practice papers" or decision sheets at the end of each Ex PT program

The IECEx PT Program Provider will offer workshops in order to assure experience exchange among ExTLs. These workshops shall provide scientific background of the objective of a program, daily practice presented by volunteering ExTLs and practical training to be offered in a laboratory. After the workshops, "Best practice papers" and decision sheets may be drafted by the IECEx PT Program provider and published at the end of each Ex PT program. Only participants shall have access to the "Best practice papers".