



IECEX OD-202

Edition 2.0 2017-11

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



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Readline Version



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's (ExTAG)

IECEx Proficiency Testing Program

INTERNATIONAL
ELECTROTECHNICAL
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CONTENTS

<u>CONTENTS</u>	<u>2</u>
<u>Background</u>	<u>4</u>
<u>1 Purpose</u>	<u>5</u>
<u>2 Scope</u>	<u>5</u>
<u>3 Normative References</u>	<u>5</u>
<u>4 Definitions</u>	<u>5</u>
<u>5 Abbreviations</u>	<u>5</u>
<u>6 Participation</u>	<u>6</u>
<u>7 Ex PTP Provider</u>	<u>7</u>
<u>8 Selection of Ex PT Programs</u>	<u>8</u>
<u>9 Program Management</u>	<u>8</u>
<u>10 Ex PTP Results</u>	<u>9</u>
<u>11 Ex PTP Reports</u>	<u>9</u>
<u>12 Unsatisfactory performance / results</u>	<u>10</u>
<u>13 Outliers</u>	<u>11</u>
<u>14 Appeal by the laboratory</u>	<u>11</u>
<u>15 Completion of corrective actions</u>	<u>11</u>
<u>16 Workshops and “Best practice papers” or decision sheets at the end of each Ex PT program</u>	<u>12</u>
CONTENTS	2
Background	3
1	4
2 Scope	4
3 Normative References	4
4 Definitions	4
5 Abbreviations	4
6 Participation	4
7 Topics	5
8 Ex PTP Provider	5
9 Selection of Ex PT Programs	6
10 Program Management	6
11 Ex PTP Results	7
12 Ex PTP Reports	7
13 PTP Outliers	7
14 Appeal by the laboratory	8
15 Completion of corrective actions	8
16 Workshops and “Best practice papers” at the end of each Ex PT program	9

Redline Version

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX Operational Document

IECEX OD 202 Edition 2.0
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 original 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
November 2017	Issue 2.0 as circulated to 2017 ExMC Meeting as ExMC/1292/DV and subsequently approved for publication via Decision 2017/82

This REDLINE VERSION displays changes as compared to Edition 1.0 with side bars and added text shown as text and deleted text shown as ~~text~~

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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
<u>ISO 13528</u>	<u>Statistical methods for use in proficiency testing by interlaboratory comparison</u>
<u>IECEX OD 024</u>	<u>IECEX rules of procedure covering testing, or witnessing testing at a manufacturer's or user's facility</u>

4 Definitions

For the purpose of this publication, the following definitions apply:

proficiency testing program

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

proficiency testing provider

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

outlier

observation in a set of data that appears to be inconsistent with the remainder of that set

Note: An outlier can originate from a different population or be the result of an incorrect recording or other gross error.

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

<u>ExMC</u>	<u>IECEX Management Committee</u>
ExTAG	IECEX Testing and Assessment Group
ExTAG/WG	EXTAG Working Group
ExCB	IECEX Certification Body
ExTL	IECEX Testing Laboratory
MB	Member Body
<u>Ex PTP</u>	<u>IECEX Proficiency Testing Program</u>

56 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.

Note: The term 'Additional Testing Location' is intended to cover laboratories which are additional to an ExTL and generally part of a different legal entity. A current proposal under consideration is to change the name to 'Additional Testing Facility' with the following definition: "A testing laboratory located remotely from an accepted ExTL which is accepted according to the IECEX Rules and which is under the complete control of, or belongs to or works under a written agreement with a single Ex Testing Laboratory (ExTL)."

Applicant ExTLs shall, prior to completion of the assessment process
– complete the programs relevant to the scope of their application; or
– demonstrate satisfactory compliance by other means with past programs, for example by demonstrating tests on program artefacts as part of the assessment process.

NOTE It is anticipated the bodies will have prior/current involvement in IECEX or similar proficiency testing programs to satisfy the requirements of ISO/IEC 17025.

~~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. ~~An ExTL laboratory~~ may be required to conduct more than one program per year in the case of repeating a test as a result of ~~"outliers"~~ "unsatisfactory results" in previous programs.

~~ExTLs 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 ~~decided by the ExTAG 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 ~~program Ex PTP~~ will identify the relevant IEC standards within the scope of the IECEX ~~Certified Equipment Scheme System~~ to which it applies.

The IECEX Secretariat shall ensure that each accepted ExTL laboratory and applicant 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.~~

~~6~~ **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.~~

7 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 "Proficiency Testing".

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

The competence of the Ex PTP Provider shall be demonstrated by assessment. The general competence, efficiency, experience, familiarity with the relevant standards used for the programs as well as compliance with ISO/IEC 17043 shall be assessed. Accreditation by a recognized national accreditation body, where existing, shall be taken into account. The ExMC shall decide upon the extent of the assessment that is necessary (considering the period of new programs). Assessors approved by the ExMC shall carry out the assessment. The IECEx Executive Secretary appoints the assessment team to conduct the assessment of the Ex PTP Provider. Assessors with prior experience in the field of proficiency testing and whose knowledge of standards is current should be used. The Ex PTP Provider shall be given the opportunity to agree on the assessors chosen to carry out an assessment. The Ex PTP Provider to be assessed shall express its willingness to pay the professional fees of the assessors, the amount to be decided by the ExMC, and the reasonable travelling and living expenses arising from the assessment. An estimate of these expenses shall be provided to the Ex PTP Provider in advance and agreed by the Ex PTP Provider. After the assessment, the IECEx Secretariat shall be given the documentation that supports the findings of the assessment and how any issues have been resolved.

~~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 PTP 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 PTP Program.

8 Selection of Ex PTP Programs

Suggestions for programs may be made by the ~~IECEX PTP Program Provider~~ based on questionnaires circulated ~~under the participating laboratories to ExTLs~~, by proposals of the ExTAG WG 10 “Proficiency Testing” or by other experts. The Ex PTP Provider will then take a decision on the programs to provide, taking those suggestions and any recommendations by ExTAG into account.

All related costs (~~Ex PTP 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 agreement approval by ExTAG WG 10 the ~~Ex PTP Provider~~ can implement the programs and request ExTLs for participation. The ~~Ex PTP Provider~~ shall ensure that all available ~~Ex PTP~~ programs can be performed by any accepted ExTL or applicant ~~ExTL candidate~~ at any time.

9 Program Management

The IECEX Secretariat shall be responsible for the overall management of the Ex PTP including the activities of the Ex PTP provider.

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

~~IECEX PTP 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 ~~Ex 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 program~~ report and all reported actions shall be recorded in a follow-up register by the ~~Ex PTP Provider~~.

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

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

The ~~Ex 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 program ~~PTP~~ have registered.

Given that this Operational Document is intended to fulfil part of the IECEX Certified Equipment Scheme Rules, ~~t~~The IECEX Secretariat shall follow up with ExTLs that are required to participate but have not registered.

The ~~Ex 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 ~~Ex PTP Provider~~, if necessary in consultation with ExTAG WG10.

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

The data analysis and evaluation of the results from the ExTLs shall be performed by the Ex PTP Provider in accordance to ISO/IEC 17043 and ISO 13528.

~~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 Ex PTP Provider completes the report (identity of participants is anonymous), circulates them to, including comments from ExTAG WG10 for information where appropriate, and issues the report to the participating laboratories. Only the participants and the IECEX Secretariat shall be provided with the anonymization codes by the Ex PTP Provider.

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

10 Ex PTP Results

The confidentiality of results of individual laboratories is essential.

The Ex PTP Provider communicates the results only to the individual ExTL and to the IECEX Secretariat. If requested by the IECEX Secretariat the Ex PTP Provider provides a summary report about the performance of accepted or applicant ExTLs to the IECEX Secretariat (see clause 11). In preparation of an initial or re-assessment the IECEX Secretariat provides the following information to assessment teams:

1. that individual accepted or applicant ExTLs have participated in the programs relevant to the scope of their application; and (2 or 3 below as appropriate)

2. the results of an individual accepted or applicant ExTL suggests that they are in line with results obtained from other ExTLs in the programs; or

3. the results of an individual accepted or applicant ExTL suggests that there may be issues that the assessment team should look at closely during their assessment.

The individual ExTL may discuss its results with the IECEX assessment team or national accreditation bodies who may ask separately for the results of the programs. It is not permitted to publish program results. Only general information about results of programs can be published.

IECEX assessors shall be trained accordingly.

~~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.~~

11 Ex PTP Reports

The program reports shall be prepared and distributed by the Ex PTP Provider according to the requirements of ISO/IEC 17043. In addition to the comprehensive reports, it may be necessary to issue summary reports in order to highlight the essential results of a program. The following list provides an overview of the reports to be prepared for a program:

- Full interim report on the program in accordance to ISO/IEC 17043;
- Full final report on the program in accordance to ISO/IEC 17043;
- Summary final report focussing on accepted ExTLs in accordance to ISO/IEC 17043 (to be provided to the IECEX Secretariat and ExTAG WG10);
- Additional information/report regarding an ExTL's performance for a certain program (if requested by the IECEX Secretariat);

In addition to program reports, a summary report may be prepared on an individual accepted or applicant ExTL about the overall performance of all programs performed by the laboratory. This would be for the purposes of an initial assessment or re-assessment. The report would include all programs the body has been, or is, signed up for. For each of those programs that are completed, the report should provide an indication of how the body has performed, including a comparison (for example in a chart) of how it compares with other bodies. It is anticipated that the process for providing this report to the assessment teams would be:

- The Secretariat to provide the Ex PTP Provider with advice as early as possible when an initial or re-assessment for a particular body is expected, with (if possible) an indicative date
- The Ex PTP Provider to provide a report to Secretariat on that body's participation on all programs as early as possible before the indicative date
- Secretariat to provide that report to the assessment team in time for them to take it into account when preparing their assessment plan, noting that the information may affect the tests that the team wish to include for their witness of testing

~~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.~~

12 Unsatisfactory performance / results PTP Outliers

In parallel with the issue of the report, the Ex PTP Pprovider shall compile a complete list of individual participants that have either produced “unsatisfactory 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 Secretariat~~y~~ or the IECEX assessment team identifying unsatisfactory results from a ~~n~~ IECEX-PT-P program that may be due to the poor performance of an individual ExTL, the IECEX Secretariat~~y~~ 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 ~~complete~~ potentially leading to a reduced scope for the ExTL.

On receipt of the “unsatisfactory results” notification from the Ex PTP provider, the individual ExTLs shall assess the possible risk, and may voluntarily suspend their testing activities to the relevant scope of standards until successful completion of their corrective actions.

13 Outliers

The Ex PTP Provider shall give careful consideration to procedures to be used to handle outliers. The influence of outliers on summary statistics shall be minimized by the use of robust statistical methods or appropriate tests to detect statistical outliers in accordance to ISO 13528.

Individual ExTLs are notified regarding PTP outliers, when applicable.

14 Appeal by the laboratory

An ~~ExTL 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 Secretariat, with a copy to the Ex 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 does not extend the three month period allowed for completion of corrective actions.

For appeals that require technical input ExTAG WG10 may be consulted. ~~H,~~ 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 "~~unsatisfactory 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 Ex PTP Provider.

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

ExTLs and ~~ExTL applicants~~ ExTLs 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 ~~shall~~ will offer workshops in order to promote 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 PTP Program provider and published at the end of each ~~Ex-PT~~ program. All participants shall have access to the “Best practice papers”. Laboratories considering becoming applicants may be provided with the papers for which a fee may be charged. Only participants shall have access to the “Best practice papers”.

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