IECEx OPERATIONAL DOCUMENT

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

IECEx Certified Equipment Scheme

IECEx Proficiency Testing Scheme
Introduction

Following the successful application of the first global Ex proficiency testing scheme, the “IECEx PTS”, IECEx ExTAG and the IECEx Secretariat prepared this IECEx Operational Document as guidance to IECEx test laboratories 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 and then adopted in the IECEx 02 Rules Edition 6.1 October, 2017 as a mandatory requirement.

Document History

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1. **Purpose**
The purpose of this document is to describe the rules of operation of the IECEx Proficiency Testing Scheme (IECEx PTS), which has been developed in line with International Standard ISO/IEC 17043.

2. **Scope**
The primary goal of the IECEx PTS is to increase the mutual confidence among the IECEx test laboratories operating within the IECEx System.
In support of this goal the IECEx PTS 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.

<table>
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<tr>
<td>ISO/IEC 17025</td>
<td>General requirements for the competence of testing and calibration laboratories</td>
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<td>ISO 13528</td>
<td>Statistical methods for use in proficiency testing by interlaboratory comparison</td>
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<td>IECEx 02</td>
<td>IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System) IECEx Certified Equipment Scheme covering equipment for use in explosive atmospheres – Rules of Procedure</td>
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<tr>
<td>IECEx OD 024</td>
<td>IECEx rules of procedure covering testing, or witnessing testing at a manufacturer’s or user’s facility</td>
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4. **Definitions**
For the purpose of this publication, the definitions contained in ISO/IEC 17043 and the following apply:

**Proficiency testing program**
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions, see also ISO/IEC 17043

**IECEx test laboratory**
Includes all IECEx ExTLs, IECEx Applicant ExTLs, IECEx Additional Testing Facilities (ATFs) and IECEx Applicant ATFs, as defined in IECEx 02

*Note: This does not include laboratories operating under the provisions of IECEx OD 024.*

**Desktop Review Report**
Secretariat report provided to the Assessors which includes a summary of participation in the IECEx PTS and if the assessor should review the IECEx test laboratory’s internal management system which may provide further information on the IECEx test laboratory taking corrective actions on unsatisfactory results. The secretariat report must not disclose confidential information

5. **Abbreviations**

<table>
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ATF</td>
<td>Additional Testing Facility</td>
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<tr>
<td>ExMC</td>
<td>IECEx Management Committee</td>
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<td>ExTAG</td>
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6. **Participation**
In accordance with IECEx ExMC Decision 2014/53 and IECEx 02 participation in the IECEx PTS is mandatory for all the IECEx test laboratories, as defined in Clause 4 of this Operational Document.
Laboratory participation is according to their scope of application and/or of acceptance in the IECEx System and is a condition for continued acceptance.

Applicant ExTLs and applicant ATFs 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 schemes to satisfy the requirements of ISO/IEC 17025.

IECEx test laboratories are required to participate in all programs which are relevant to their scope.

In the event of unsatisfactory results in previous programs, it may be required for an IECEx test laboratory to repeat a test round of a previous program in addition to the current test rounds of the current programs.

IECEx test 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 programs to take place each year shall be decided by the ExTAG. The maximum number of new programs shall be limited to two for a two-year cycle. Repeated programs also require ExTAG approval.

During the regular program cycle (two-year cycle), the IECEx test laboratories shall complete the programs. If a laboratory performs previous programs, the programs must be completed within three months of receiving the test samples.

A program is considered to be completed when the tests have been performed by the IECEx test laboratory, the results have been transmitted to the IECEx PTS Provider, and the report has been issued by the IECEx PTS Provider.

Each program will identify the relevant IEC standards within the scope of the IECEx Certified Equipment Scheme to which it applies.

The IECEx Secretariat shall ensure that each accepted IECEx Test Laboratory participates in the applicable programs that fall within the testing scope of the laboratory.

The participation of all IECEx test laboratories shall be monitored by the IECEx Secretariat with the support of the IECEx PTS Provider.

Evidence of participation in the IECEx PTS, completion of all applicable programs and summary of the findings, shall form part of the input for the initial, a mid-term or re-assessment audit.

**NOTE:** Although the purpose of a mid-term surveillance assessment is to carry out a technical review of IECEx Certification files and the related ExTRs and QARs for technical integrity, completeness and compliance with IECEx Rules and Operational Documents, it should also be used to discuss any concerns with the IECEx test laboratory, such as unsatisfactory program results.

### 7. IECEx PTS Provider

The programs are coordinated and processed by an IECEx PTS Provider, independent of the participating testing organisations and working in coordination with ExTAG WG10 “Proficiency Testing”.

IECEx PTS Providers will be determined by the IECEx ExMC on recommendations from ExTAG WG10 via ExTAG.

The competence of the IECEx PTS 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 IECEx PTS Provider. Assessors with prior experience in the field of proficiency testing and whose knowledge of standards is current should be used. The IECEx PTS Provider shall be given the opportunity to agree on the assessors chosen to carry out an assessment. The IECEx PTS 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 IECEx PTS Provider in advance and agreed by the IECEx PTS 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 PTS Providers shall be capable of developing and operating programs for all IEC 60079 series standards and selected standards from the ISO 80079 series.

In order to assure continuity of the effectiveness of operation of the IECEx PTS, IECEx PTS Providers shall provide annual reports to the ExTAG and the IECEx Secretariat on activities, program results and any issues arising that may have an impact on the effectiveness of the IECEx PTS.

8. Selection of Programs

Suggestions for programs can be made by the IECEx PTS Provider based on questionnaires circulated under all the IECEx test laboratories, by proposals of the ExTAG WG 10 “Proficiency Testing” or by other experts. The IECEx PTS Provider shall then take a decision on the programs to provide, taking those suggestions and any recommendations by ExTAG into account.

All related costs (IECEx PTS Provider costs, in-house costs for the test laboratory staff etc.) shall be estimated and compiled for consideration. After agreement by ExTAG the IECEx PTS Provider shall implement the programs and request IECEx test laboratories for participation. The IECEx PTS Provider shall ensure that all available programs can be performed by any IECEx test laboratory at any time. In case previous programs must be closed (e.g. due to instability of test samples, new program versions, etc.), the IECEx PTS Provider shall report this information to the IECEx test laboratories, ExTAG and the IECEx Secretariat.

9. Program Management

The IECEx Secretariat role is to assist the IECEx PTS including the activities of the IECEx PTS Provider ensuring that all IECEx test laboratories participate in the IECEx PTS.

The IECEx PTS Provider sends out the details for each program to the IECEx test laboratories in advance.

Each IECEx test laboratory shall acknowledge its willingness to participate in individual programs to the IECEx PTS Provider. This acknowledgement shall be made directly to the IECEx PTS Provider in writing prior to the sample shipping date provided with the program details.

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

Given that this Operational Document is intended to fulfil part of the IECEx Certified Equipment Scheme Rules, the IECEx Secretariat shall follow up with IECEx test laboratories that are required to participate but have not registered.

The IECEx PTS 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 IECEx PTS Provider, if necessary, in consultation with ExTAG WG10.

The IECEx PTS Provider sends out the detailed instructions and samples, then collects and analyses the results.
The data analysis and evaluation of the results from the IECEx test laboratories shall be performed by the IECEx PTS Provider in accordance to ISO/IEC 17043 and ISO 13528.

Based on this, the IECEx PTS Provider completes the reports (identity of participants is anonymous), circulates them to ExTAG WG10 for information, and issues the reports to the participating laboratories. Only the participants and the IECEx Secretariat shall be provided with the anonymization codes by the IECEx PTS Provider.

A test round consists of two phases (Phase I and Phase II). In Phase I, the IECEx test laboratories perform the tests and transmit the results to the IECEx PTS Provider. The IECEx PTS Provider evaluates the results and publishes the interim report. In addition to the evaluated results, the interim report contains initial aspects for discussion and interpretation.

Phase I is followed by the workshops (see clause 16) assigned to the programs.

Phase I and the workshops are followed by Phase II (Improvement loop). In this phase the IECEx test laboratories can repeat their tests if they are not satisfied with their results from Phase I. The new results are then used to create the final report. If the IECEx test laboratories are satisfied with their Phase I results, they do not need repeat the Phase II tests. In this case, the results obtained in Phase I are used for the final report.

The final report is the decisive report for the assessment of the performance of the laboratories (unsatisfactory performance/results) and is the basis for the List of Laboratories with warning/action signals.

An overview and description of the IECEx PTS structure and the program design can be found in Annex A.

10. Program Results
The confidentiality of results of individual laboratories is essential.

The IECEx PTS Provider communicates the results only to the individual IECEx test laboratories and to the IECEx Secretariat. If requested by the IECEx Secretariat the IECEx PTS Provider provides a summary report about the performance of IECEx test laboratories to the IECEx Secretariat (see clause 11). In preparation of an initial, mid-term or re-assessment the IECEx Secretariat provides the following information to assessment teams:

1) that individual IECEx test laboratories 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 IECEx test laboratory suggests that they are in line with results obtained from other IECEx test laboratories in the programs; or

3) the results of an individual IECEx test laboratory suggests that there may be issues that the assessment team should look at closely during their assessment.

The individual IECEx test laboratory 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 detailed program results. Only general information about results of programs may be published.

11. Program Reports
The program reports shall be prepared and distributed by the IECEx PTS Provider according to the requirements of ISO/IEC 17043. The program reports include the following:

- Status of Participants Report
- Participants Results Summary Report (Interim & Final Report)
- List of Laboratories with warning/action signals (if used in the program)
- Additional information/report regarding an IECEx test laboratory’s performance for a certain program (if requested by the IECEx Secretariat);
In addition to program reports, a separate report shall be prepared on an individual IECEx test laboratory about the overall performance of all programs performed by the laboratory. This would be for the purposes of an initial, mid-term or re-assessment.

- The Secretariat shall prepare a Desktop Review Report (DTR) as per clause 10 for the assessment team in time for them to take it into account when preparing their assessment plan.

12. Unsatisfactory performance / results
On receipt of the List of Laboratories with warning/action signals report by the IECEx PTS Provider, the Secretariat will file this for future reference so when the DTR is prepared for the initial, mid-term or re-assessment it will include a comment that the Assessor shall review the ExTLs Quality Management Procedures, which should address any unsatisfactory performance results with corrective action plans.

On receipt of the “unsatisfactory results” notification from the IECEx PTS Provider, the individual IECEx test laboratory shall register this as a matter requiring attention in accordance with their quality management procedures. Action signal reports from the IECEx PTS Provider shall initiate the preparation of a corrective action plan by the IECEx test laboratory. This corrective action plan should consider seeking assistance from the IECEx PTS Provider.

NOTE: Test results can appear in many forms, spanning a wide range of data types and underlying statistical distributions. The statistical methods used to analyse and evaluate the results need to be appropriate for each situation. The analysis and evaluation shall be performed by the IECEx PTS Provider in accordance to ISO/IEC 17043 and ISO 13528. In some cases, due to the test method to be used or the non-physical measured variables, etc., no evaluation in the form of warning/action signals can be performed. In such cases, the IECEx PTS Provider shall define other applicable evaluation criteria. If this is also not possible, the IECEx PTS Provider should identify the reasons for this and offer suggestions for improving the situation (e.g. adaptation/improvement of the applied test methods, improvement measures to increase the comparability of the results, etc.).

13. Outliers
The IECEx PTS Provider shall limit the influence of outliers on summary statistics by the use of robust statistical methods or appropriate tests to detect statistical outliers in accordance to ISO 13528.

Individual IECEx test laboratories may be informed of outliers, e.g. if there are obvious errors in data transmission (number shifts, etc.) or other inadvertent errors.

14. Appeal by the laboratory
An IECEx test laboratory that disagrees with the performance evaluation has the right to appeal.

Appeals shall be made in writing to the IECEx Secretariat, with a copy to the IECEx PTS 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. However, the identity of the IECEx test laboratory 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 warning/action signals reported shall be investigated by the IECEx test laboratory as part of their planning of corrective and preventive actions.
Participants carrying out corrective actions shall follow the procedures outlined in ISO/IEC 17025:2017; 8.6 and 8.7 and the results should be documented in their internal document management system.

Completed corrective action reports shall be sent to the IECEx Secretariat (with a copy to the IECEx PTS 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 and shall perform this through the surveillance assessment program but is not responsible for the technical validity of the actions undertaken.

IECEx test laboratories requiring more time to prepare corrective action plans, shall make a request in writing to the IECEx Secretariat with a copy to the IECEx PTS Provider.

IECEx test laboratories failing to complete the proposed corrective action within three months will be notified by the IECEx Secretariat.

The IECEx Secretariat shall subsequently follow-up on corrective actions in accordance with the IECEx procedures for planning the assessment of IECEx test laboratories – OD 003-2.

16. Workshops and “Best practice papers”/Decision Sheets (DS)
The IECEx PTS Provider shall offer workshops in order to promote experience exchange among IECEx test laboratories. These workshops shall provide scientific background of the objective of a program, daily practice presented by volunteering IECEx test laboratories and practical training to be offered in a laboratory. After the workshops, “Best practice papers” and Decision Sheets may be drafted by the IECEx PTS Provider and published at the end of each 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.
Annex A
Informative

Description and structure of the IECEx PTS

The IECEx PTS consists of different programs with regard to different areas of testing in the field of explosion protection. For conducting the programs, the individual routine procedure of each IECEx test laboratory should be applied (used every day for achieving the test results for real projects). The general routine procedure is described by the standards of the applicable type of protection. This means that the standard of the respective type of protection shall also be used as a basis when the quantities to be compared (measurands or characteristics of interest) are selected by the IECEx PTS Provider.

Each test round is unambiguously assigned to a program and is indicated by the year of the roll-out. Each program can have more than one test round. During each test round there will be a workshop on the corresponding topic. The following figure illustrates the structure:

![Figure A.1 - Overview of the structure of the IECEx PTS](image)
The individual steps of the typical program design are shown in the following program flowchart. In any case of deviation from this structure this shall be addressed in the respective roll-out paper and procedure instruction by the IECEx PTS Provider.

1. Development of a new program
2. Development and preparation of a test sample prototype
3. Roll-out of the program
4. Registration phase for participation
5. Preparation and shipment of the test samples to the participants
6. Performance of the tests by the IECEx test laboratories and transmission of the results to the IECEx PTS Provider (Phase I)
7. Analysis of the test results and publication of the interim report by the IECEx PTS Provider (Phase I)
8. Workshop
9. Repetition of the tests by the IECEx test laboratories and transmission of the results to the IECEx PTS Provider (Phase II)
10. Analysis of the repeat test results and publication of the final report by the IECEx PTS Provider (Phase II)
11. Publication of „Best Practice Paper“, Decision Sheets, etc.

Figure A.2 - Program flowchart
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