



ExMC/1292/DV
August 2017

**INTERNATIONAL ELECTROTECHNICAL COMMISSION SYSTEM FOR
CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE
IN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

**Title: Proposed Revised Edition of IECEx Operational Document OD 202 – IECEx
Proficiency Testing Program (Ex PTP)**

To: Members of the IECEx Management Committee, ExMC

Introduction

This document contains a proposed Revised Edition to IECEx Operational Document OD 202 – IECEx Proficiency Testing Program (Ex PTP) as prepared by ExTAG WG10.

This document will be reported at the 2017 ExTAG Washington meeting for ExTAG review but is also submitted to ExMC for approval at the 2017 Washington meeting.

To assist the meetings, the ExTAG WG10 Convener, Tim Krause has prepared this document in two parts with Part 1 as the clean text and Part 2 showing the changes to the current edition.

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IECEX OD 202

DRAFT Edition 2.0 2017-XX

IECEX OPERATIONAL DOCUMENT

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

IECEX Certified Equipment Scheme –

IECEX Operations Manual – IECEx Proficiency Testing Program



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEX Operational Document

IECEX OD 202 Edition 2.0

**IECEX Certified Equipment Scheme – IECEX Operations Manual –
IECEX Proficiency Testing Program**

Background

Following the successful application of the first global Ex proficiency testing program formerly named as Ex proficiency testing scheme “Ex PTS”, IECEX ExTAG and the IECEX Secretariat prepared this IECEX Operational Document as guidance to all accepted and applicant IECEX ExTLs on satisfying the requirements of ISO/IEC 17025 with respect to participation in proficiency testing programs as conducted for interlaboratory 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

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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 provide a high level of confidence in the competence of the IECEx Testing Laboratories (ExTLs) operating within the IECEx Certified Equipment Scheme.

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

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 program provider

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

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.

5 Abbreviations

ExMC	IECEX Management Committee
ExTAG	IECEX Testing and Assessment Group
ExTAG WG	ExTAG Working Group
ExTL	IECEX Testing Laboratory
MB	IECEX Member Body
Ex PTP	IECEX Proficiency Testing Program

6 Participation

In accordance with IECEx ExMC Decision 2014/53, participation in the Ex PTP is mandatory for all accepted and applicant 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 Certified Equipment Scheme 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.

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

ExTLs 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, e.g. new topics, initiated each year shall be limited to one. Repeated programs also require ExTAG approval.

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 ExTL and applicant ExTL participates in the applicable programs that fall within the testing scope of the laboratory.

The participation of an ExTL shall be scheduled and monitored by the IECEx Secretariat.

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".

Ex PTP 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.

Ex PTP Providers shall be capable of developing and operating programs for all relevant IEC 60079 series standards and selected standards from the ISO 80079 series.

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

8 Selection of programs

Suggestions for programs may be made by the Ex PTP Provider based on questionnaires circulated under the participating laboratories, by proposals of the ExTAG WG10 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. After agreement by the ExTAG the Ex PTP Provider can implement the programs and request ExTLs for participation. The Ex PTP Provider shall ensure that all available programs can be performed by any accepted ExTL or applicant ExTL 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 are developed into programs by the Ex PTP Provider in cooperation with ExTAG WG10.

Ex PTP 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 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 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 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 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 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 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.

Based on this, the Ex PTP 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 Ex PTP Provider.

10 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.

11 Program 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

12 Unsatisfactory performance/results

In parallel with the issue of the reports, the Ex PTP Provider shall compile a complete list of individual participants that have either produced “unsatisfactory results” and/or other non-compliances (e.g. equipment related). This list is provided to the IECEx Secretariat.

In the event of the IECEx Secretariat or the IECEx assessment team identifying unsatisfactory results from a program that may be due to the poor performance of an individual ExTL, the IECEx Secretariat may take action, in cooperation with the 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 whose test results are identified as unsatisfactory, 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. However, the identity of the ExTL shall remain confidential for the duration of such consultation. ExTAG WG10 members shall respond within 15 working days upon receipt of the request.

15 Completion of corrective actions

All “unsatisfactory 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 ExTLs 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 applicant ExTLs failing to overcome the unsatisfactory results 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 program

The Ex PTP Provider shall offer workshops in order to promote 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 Ex PTP 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.

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2 Scope

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

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

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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.

5 Abbreviations

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ExTAG_WG	<u>ExTAG Working Group</u>
ExTL	IECEX Testing Laboratory
MB	<u>IECEX Member Body</u>
<u>Ex PTP</u>	<u>IECEX Proficiency Testing Program</u>

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Commented [TK2]: Comment from Otto Walch: "As you added the abbreviation Ex PTP this abbreviation should be used in the whole document instead of the word program / programs"

There is a difference between "Ex PTP" and "program / programs". Ex PTP describes the whole Proficiency Testing Program which covers many different single programs related to certain standards. For example:

Ex PTP → General IECEx Proficiency Testing Program
 program → Program Explosion Pressure

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ExTLs 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, e.g. new topics, initiated each year shall be limited to one. Repeated programs also require ExTAG approval.

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

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

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The participation of an ExTL shall be scheduled and monitored by the IECEx Secretariat.

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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".

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

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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

- Deleted: <#>Topics¶
- Deleted: 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).¶
- Deleted: 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.¶
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shall be given the documentation that supports the findings of the assessment and how any issues have been resolved.

Ex PTP Providers shall be capable of developing and operating programs for all relevant IEC 60079 series standards and selected standards from the ISO 80079 series.

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

8 Selection of programs

Suggestions for programs may be made by the Ex PTP Provider based on questionnaires circulated under the participating laboratories, by proposals of the ExTAG WG10 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. After agreement by the ExTAG the Ex PTP Provider can implement the programs and request ExTLs for participation. The Ex PTP Provider shall ensure that all available programs can be performed by any accepted ExTL or applicant ExTL 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 are developed into programs by the Ex PTP Provider in cooperation with ExTAG WG10.

Ex PTP 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 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 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 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 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 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 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.

- ~~Deleted: Ex PTP Providers shall be submitted to the peer assessment procedure of IECEX and the relevant principles and requirements of ISO/IEC 17043. Where the Ex PTP Provider is formally accredited by an IAF/ILAC Accreditation Body according to ISO/IEC 17043, "Conformity assessment - General requirements for proficiency testing", the period of IECEX assessment visits may be reduced.¶ 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~~
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~~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. Based on this, the Ex PTP 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 Ex PTP Provider.~~

10 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.~~

11 Program 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~~

~~Deleted:~~ 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.¶

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~~Deleted:~~ 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.

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

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- 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

12 Unsatisfactory performance/results

In parallel with the issue of the reports, the Ex PTP Provider shall compile a complete list of individual participants that have either produced "unsatisfactory results" and/or other non-compliances (e.g. equipment related). This list is provided to the IECEx Secretariat.

In the event of the IECEx Secretariat or the IECEx assessment team identifying unsatisfactory results from a program that may be due to the poor performance of an individual ExTL, the IECEx Secretariat may take action, in cooperation with the 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 whose test results are identified as unsatisfactory, 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. However, the identity of the ExTL shall remain confidential for the duration of such consultation. ExTAG WG10 members shall respond within 15 working days upon receipt of the request.

15 Completion of corrective actions

All "unsatisfactory" 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.

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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 ExTLs 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.

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ExTLs and applicant ExTLs failing to overcome the unsatisfactory results with effective proposed corrective action within three months will be notified by the IECEX Secretariat with a formal General Non-Conformity Report.

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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 program

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The Ex PTP Provider shall offer workshops in order to promote 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 Ex PTP 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.

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