

**ExTAG/425/R**

**August 2016**

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

**TITLE: Report of the Surveillance Assessment of PTB in Germany as the IECEx Proficiency Testing Program Provider for compliance with ISO/IEC 17043 and OD 202.**

**Circulated to: ExTAG – IECEx Testing and Assessment Group**

**INTRODUCTION**

Following publication of the new IECEx Operational Document, OD 202 during September 2015, the Secretariat arranged for a site assessment to be performed on PTB in their role as the IECEx Proficiency Testing Program Provider.

Mr Munro, as an IECEx Lead Assessor conducted the site assessment visit on 17 June 2016.

This document contains the full report of Mr Munro in which it is recommended that PTB continue as the IECEx PTP Provider.

In line with both ISO/IEC 17043 and OD 202, PTB will provide a separate report of the Program activities since the 2015 Christchurch meetings.

This report is submitted to ExTAG for discussion during the 2016 ExTAG Umhlanga meeting.

Chris Agius, For

***Julien Gauthier***

**Julien Gauthier**

**ExTAG Secretary**

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

Site Assessment Report for Assessment of IECEx Proficiency Testing Body

**Proficiency Testing Body assessed: PTB**

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# Assessment information

## Type of Body covered by this assessment: <retain appropriate marks>

|  |  |
| --- | --- |
| Proficiency Testing provider | ✓ |

## Type of assessment: <retain appropriate marks>

|  |  |
| --- | --- |
| Pre-assessment for candidate body |  |
| Surveillance | ✓ |

## Details of body

### Country

Germany

### Name of body

Physikalisch-Technische Bundesanstalt (PTB)

### Name and title of nominated principal contact

|  |  |  |
| --- | --- | --- |
| Name | Title | E-mail address |
| Tim Krause | Head of Working Group 3.54 | Tim.Krause@ptb.de |

## Assessment information

### Members of the assessment team

|  |  |
| --- | --- |
| Name | Role |
| Jim Munro | IECEx Lead Assessor |

### Place(s) of assessment

|  |  |
| --- | --- |
| Bundesallee 100  38116 Braunschweig, Germany |  |

### Assessment date(s)

17 June 2016

# Recommendation by IECEx Assessor(s) at conclusion of site visit

|  |  |
| --- | --- |
| That acceptance be granted |  |
| That acceptance be granted conditional on <add conditions> |  |
| That acceptance be suspended |  |
| That acceptance continues | ✓ |
| That acceptance continues conditional on <add conditions> |  |

# Summary of findings

## Introduction

This report provides the results of a one-day surveillance visit of PTB as a proficiency testing provider for IECEx. Acceptance of PTB as a proficiency provider had previously occurred by a decision at ExMC.

## Applicable documents

* ISO/IEC 17043:2010, Conformity assessment — General requirements for proficiency testing
* IEC OD 202 Edition 1.0, 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
* ISO 13528:2005, Statistical methods for use in proficiency testing by interlaboratory comparisons

## Background to assessment

In 2007 ExTAGWG10 "Proficiency Testing" received a mandate from ExTAG to check the possibilities of performing inter-laboratory comparisons in the field of explosion protection. In 2009 PTB created a project team to provide proficiency tests in compliance with the requirements of standard ISO/IEC 17043. After a successful pilot project, the program was continued by PTB, establishing itself as a proficiency testing provider. In August 2014 IECEx decided that participation in the PTB Ex PT Scheme would be mandatory for all "IECEx Ex Testing Laboratories" and "ExTL Applicants" (Decision 2014/53; IECEx meeting in The Hague).

The following programs have now been implemented:

|  |  |
| --- | --- |
| IECEx Proficiency Testing program | Program years |
| Program 1 "Explosion pressure" | 2011-2012 |
| Program 2 "Spark ignition" | 2011-2012 |
| Program 3 "Flame Transmission" | 2013-2014 |
| Program 4 "Temperature Classification" | 2013-2014 |
| Program 5 "Electrostatic Charge" | 2015-2016 |
| Program 6 "Intrinsic Safety" | 2015-2016 |

As PTB do not hold accreditation for ISO/IEC 17043, IECEx has implemented a surveillance program with this being the first surveillance visit to check compliance of PTB with ISO/IEC 17043 and IEC OD 202.

The assessor for this visit is a lead assessor in IECEx, Chairman of the Panel of Assessors, convenor of ExMCWG4 and a member of ExTAGWG10. He has been an attendee at all three workshops run by the PTB PT provider.

Annex C includes a presentation from the last PTB workshop, held in May/June 2016 which contains a useful overview of the PTB proficiency testing scheme.

## Findings from the assessment

PTB was found to be implementing an effective proficiency testing scheme in compliance with ISO/IEC 17043 and OD 202.

The assessment visit particularly concentrated on the technical requirements of ISO/IEC 17043 in Section 4, as follows:

* General
* Personnel
* Equipment, accommodation and environment
* Design of proficiency testing schemes:
  + Planning
  + Preparation of proficiency test items
  + Homogeneity and stability
  + Statistical design
  + Assigned values
* Choice of method or procedure
* Operation of proficiency testing schemes
  + Instructions for participants
  + Proficiency test items handling and storage
  + Packaging, labelling and distribution of proficiency test items
* Data analysis and evaluation of proficiency testing scheme results
  + Data analysis and records
  + Evaluation of performance
* Reports
* Communication with participants
* Confidentiality

The assessment confirmed PTB PT Scheme is operating in accordance with the standard and OD 202 with only some documentation issues that have been resolved to the satisfaction of the assessor.

A checklist demonstrating compliance with ISO/IEC 17043 was completed for all clauses for ISO/IEC 17043 by PTB prior to the assessment visit. This checklist was reviewed during the assessment visit with particular emphasis on Section 4 "Technical Requirements". A copy of the completed checklist has been provided to the IECEx Secretariat.

## Issues

Issues raised during the assessment and how they were resolved are contained in Annex A.

## Observations raised during the assessment

1. It would be useful to clearly indicate results for accepted and applicant ExTLs in the report
2. In work instructions the term 'issued by' is misleading - perhaps use of the term 'drafted' would be clearer.
3. In 3.54mmb-01 it would be helpful to add a bullet point regarding ensuring testing has properly demonstrated compliance with relevant Ex standards.

## Target date for resolution of issues

The following was agreed as the target date for resolution of outstanding issues: 15 July 2016.

# Actions after visit

Actions on the issues raised were received on 12 July 2016.

# Recommendation by IECEx Assessor(s) after all issues resolved

Based on the assessment performed above, PTB is recommended for continued acceptance in the IECEx scheme as:

* A Proficiency Testing (PT) Provider in the IECEx System

|  |
| --- |
| Jim Munro |
| IECEx Lead Assessor |

Date: 23 July 2016

# Annexes

See Contents.

1. Issues and subsequent responses

The following shows issues raised at the assessment and shown in the first draft of the ExCB assessment report, together with subsequent actions.

|  |  |  |
| --- | --- | --- |
| Issues raised in assessment and first draft of report | Response from PTB on 12/7/16 and as shown | Assessor comments |
| 1. In 3.54-AA-08 - the decision path for recommendation and approval of programs needs clearer definition, eg in accordance with OD 202. | Working instruction 3.54-AA-08 has been updated and reflects the requirements of OD 202 better now. The following information has been added:  “*Suggestions for programs may be made by the coordinator based on questionnaires circulated under the participating laboratories (e.g. IECEx System Member Bodies, IECEx Testing laboratories, etc.), by proposals of the IECEX ExTAG Working Group 10 “Proficiency Testing” or by other experts. The decision which program suggestions becomes official suggestions for IECEx is made by the coordinator (preselection based on what the coordinator is able to develop and organize). Based on such suggestions ExTAG WG 10 makes recommendations for new PT programs for approval by the ExMC on a recommendation by the EXTAG.”* | **Jim Munro 19/7/16**  The decision path for recommendations is now clearer.  **Resolved. No further action required.** |
| 1. The complaints and appeals processes need clarification, taking into account OD 202 for appeals. It is recommended that complaints be dealt with 'in house' but perhaps with analysis by ExTAGWG10. Also suggest reference to 'contradictions' be dropped as these are not referred to in ISO/IEC 17043. | Working instruction 3.54-AA-07 has been updated and the following information has been added:  *“For the case of appeals and complaints the coordinator may contact the IECEx ExTAG Working Group 10 “Proficiency Testing” and inform about the action which has been taken to solve the issue. The topic can be discussed at the annual IECEx ExTAG WG 10 meeting or if necessary in a short-term meeting. The way of proceeding together with the results of any examination carried out will be communicated, as appropriate, to the participant.”*  Working instruction 3.54-AA-13 has been drafted which covers the topic of appeals and complaints. | **Jim Munro 19/7/16**  Working instruction 3.54-AA-07 and new Working instruction 3.54-AA-13 now provide clarity on an appropriate complaints and appeals approach.  **Resolved. No further action required** |
| 1. 3.54-AA-05 should make reference to login and access by ExTAGWG10. | Working instruction 3.54-AA-05 has been updated and the following information has been added:  ***“Login data***  *Username and password of participants, PTS team members and ExTAG WG10 members required to login on the PTS Website, required to access protected areas of the PTS website (and upload test results)”* | **Jim Munro 19/7/16**  The decision path for recommendations is now clearer.  **Resolved. No further action required.** |
| 1. ISO/IEC 17043 4.4.2 - minimum levels of qualification and experience for PT staff are not defined | Working instruction 3.54-AA-04 has been updated and the following information has been added:  ***“Levels of qualification for PTS staff***  *The key positions of the PTB Ex PTS and the minimum levels of qualification are defined as follows:*  *• Main coordinator for the PTB Ex PTS (scheme manager):*  *o Master’s degree in engineering (science)*  *o Five years’ experience in the field of proficiency testing*  *o Five years’ experience in the field of explosion protection*  *o Good command of English, spoken and written*  *o Experience in the IECEx System*  *• Person responsible for a program (program manager):*  *o Bachelor’s degree in engineering (science)*  *o Two years’ experience in the field of proficiency testing*  *o Two years’ experience in the field of explosion protection*  *o Good command of English, spoken and written”* | **Jim Munro 19/7/16**  The levels of qualification are now clearly specified in Working instruction 3.54-AA-04  **Resolved. No further action required.** |
| 1. ISO/IEC 17043 4.7.1.6 - 3.54-AA-06 does not address approach if there is a problem found with a test item after delivery | Working instruction 3.54-AA-06 has been updated and the following information has been added:  ***“Loss or damage of test items***  *Once the shipped test item has been delivered, the participant should check the condition immediately. For the case of a damage or other problems with the condition of the test samples due to shipment or any other reason, the participant should contact the coordinator directly. If it is not possible to solve the issue via correspondence, a replacement will be sent out as soon as possible. Same approach is applied for the case that the test sample is damaged during the performance of tests. The damage of the “old” test sample shall be documented and considered for the identification of the “new” test sample.”* | **Jim Munro 19/7/16**  3.54-AA-06 now identifies the approach to be taken if test items are "found to be unsuitable for performance evaluation", as required by ISO/IEC 17043.  Note: The heading also says 'lost' but there is no information required for this situation. It is recommended that either this be deleted from the headed or reference to 'lost' items be added to the clause.  **Resolved. But it is recommended that the note shown above be addressed.** |
| 1. OD 202 requires ' 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.' This is also reflected in the relevant PTB work instruction. But it is not current practice and does not appear practicable. A plan should be developed to resolve the discrepancy. | We suggest to adjust the wording in OD 202 to reflect the current practice. After that the PTB working instructions will be updated.  We recommend to handle the statistical presentation of the results and outliers in accordance to the used standards ISO/IEC 17043 and ISO 13528. However, this is sometimes not possible due to the special character of the programs in the field of Explosion protection. The role of ExTAG WG 10 could be an advisory function for cases where the standards are difficult to apply for the statistical evaluation. | **Jim Munro 19/7/16**  The way forward suggested by PTB looks appropriate.  Note: It is recommended that they prepare a proposal for consideration by ExTAGWG10.  **Resolved. But it is recommended that the note shown above be addressed.** |
| 1. ISO/IEC 17043 4.8.4 - there is not policy for use of reports by individuals or organisations | Working instruction 3.54-AA-11 has been updated and the following information has been added:  ***“Use of reports***  *All analyzed and evaluated participant-related test results are foreseen to be published within the group of participants after approval from those laboratories being involved in the programs. The results of the participants are in anonymous form. All involved parties are requested to handle all information and data of the reports confidentially. 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 PT programs. It is not permitted to publish detailed PT program results.”* | **Jim Munro 19/7/16**  Working instruction 3.54-AA-11 now includes a policy on use of reports.  **Resolved. No further action required.** |
| 1. ISO/IEC 17043 4.8.5 - there are no procedures for handling new or amended reports. | Working instruction 3.54-AA-11 has been updated and the following information has been added:  *“A new or amended report for a proficiency testing scheme has to include a unique identification, a reference to the original report that it replaces or amends and a statement concerning the reason for the amendment or re-issue. Any action regarding a new or amended report has to be communicated to all participants of the respective program, the members of ExTAG WG10 and the IECEx Secretary.”* | **Jim Munro 19/7/16**  Working instruction 3.54-AA-11 now addresses new or amended reports.  **Resolved. No further action required.** |
| 1. ISO/IEC 17043 4.10.3 - 6.4 OF 3.54-AA-01should address results being provided to IECEx secretary | Basic Rules 3.54-MB-01 has been updated and the following sentence has been added:  *“The results will be communicated only to the individual ExTL and to the IECEx Secretary.”*  Furthermore this topic is considered in Working instruction 3.54-AA-11. | **Jim Munro 19/7/16**  Basic Rules 3.54-MB-01 and Working instruction 3.54-AA-11now make clear that results will be provided to the IECEx Secretary.  **Resolved. No further action required.** |

1. PT Scheme assessment plan and notes

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| --- | --- |
| Action | Assessor Notes |
| Opening meeting, commencing at 9 am unless otherwise agreed. Discuss proposed assessment. |  |
| PTB to provide brief summary of the IECEx PTB PT Proficiency Scheme, taking into account the assessor's existing knowledge of the PT Scheme. | Report does not yet make clear the performance of accepted and applicant ExTLs because of presence of other bodies. Similar issue when looking at number of participants.  ISO13528 Annex C - 'Robust analysis' is used for the analysis of the results. This includes adjustment of significant outliers. However, prior to this analysis PTB do a sensibility check on the results to see if some results are very wrong, for example a pressure reported as negative.  Attach presentation made to workshop as an annex to the site assessment report - done. |
| PTB to provide brief introduction on how the quality aspects of the PT Scheme fit into existing quality systems, including additional quality aspects found necessary to implement. | There is an overall manual for all PTB  The PT staff have no role in the ExTL but ExTL staff are used as part of the program.  ExTL staff doing PT tests for PTB cannot be part of the PT team.  Data is also restricted only to PT program staff.  Working instructions for the PT Scheme are currently only in English and therefore only need control as English documents. All members of PT program are English speaking and some of the documents are used with participants. |
| Compliance with **4.Technical Requirements** of ISO/IEC 17043, as follows:  4.1 General  4.2 Personnel  4.3 Equipment, accommodation and environment  4.4 Design of proficiency testing schemes::  4.4.1 Planning  4.4.2 Preparation of proficiency test items  4.4.3 Homogeneity and stability  4.4.4 Statistical design  4.4.5 Assigned values  4.5 Choice of method or procedure  4.6 Operation of proficiency testing schemes  4.6.1 Instructions for participants  4.6.2 Proficiency test items handling and storage  4.6.3 Packaging, labelling and distribution of proficiency test items  4.7 Data analysis and evaluation of proficiency testing scheme results  4.7.1 Data analysis and records  4.7.2 Evaluation of performance  4.8 Reports  4.9 Communication with participants  4.10 Confidentiality | PTB were found to be in compliance with these requirements, except for the need to make some documentation modifications. These were subsequently done. A checklist to ISO/IEC 17043 was used to check and document compliance with these requirements (see below). |
| Review of other requirements of ISO/IEC 17043, including review of checklist. | PTB provided a completed checklist which included all requirements of ISO/IEC 17043 but only section 4 above was checked in detail. |
| Discussion on matters of specific relevance to IECEx, eg:  Knowledge of performance of ExTLs within the PT Scheme  Communication channels with IECEx Secretariat  Method to accommodate new applicants to the PT Scheme  Relationship between IECEx assessments and the PT Scheme  PTB assistance to participants in the PT Scheme  Role of ExTAGWG10 | Clear reporting will be provided  These seem to be addressed in OD 202  There seem to be some issues with enabling application to all programs.  It was agreed Tim Krause would assist in training at the meetings in South Africa  For difficult issues PTB provides staff to assist, with only reimbursement of costs sought.  PTB have addressed this in a work instruction, but it will need further discussion at the next WG10 meeting |
| Follow up on surveillance and scope extension visit to PTB on 3 June 2016. | This occurred. |
| Drafting of reports and closing meeting | A draft report was discussed at the closing meeting and left with PTB. |

Jim Munro

IECEx Lead Assessor

1. Presentation from PTB Workshop



1. Organisation charts



