

Basic Rules

- PTB Ex Proficiency Testing Scheme -

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Ex-PTS - Ex Proficiency Testing Scheme

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1. Introduction

The definition of proficiency testing (PT) is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons [1].

Participation in an Ex proficiency testing scheme (Ex PTS) is essential for the compliance of the requirements of ISO/IEC 17025 [3] and IECEx regarding the need of the Ex laboratories to perform interlaboratory comparisons. In addition, the results of Ex PT programs will contribute considerably to the development of the "peer concept" within the global community of Ex laboratories. With the practical experience gained in its performance, the PTB Ex Proficiency Testing Scheme (PTB Ex PTS) shall be further developed and improved (continuous improvement process). The vision is to extend the PT scheme step by step to all fields of conformity assessment (not only testing) within the scope of the IEC/TC31 standards. The results of this Ex PTS will also be of direct use for all participants, among others for:

- ensuring that the testing laboratory has properly demonstrated compliance with relevant Ex standards
- proving the competence to
 - customers,
 - regulators, and
 - end users
- the identification and avoidance of problems in and between the test laboratories and the initiation of measures for improvement
- the establishment of the effectiveness and comparability of the applied testing and measurement methods
- the provision of additional confidence to the customer
- the avoidance of distortions of competition between the manufacturers as the customers of the test laboratories
- the further promotion of the "fair play" culture.

The implementation of this Ex PT scheme will allow to detail test methods (prescribed by the applicable IEC standards) in "Best Practice Papers" providing continuous improvement of the performance of tests within the field of explosion protection.

2. Scope

This document specifies the policy and basic rules for design, organization and performance of the PTB Ex Proficiency Testing Scheme.

3. Normative references

The following referenced documents are essential for the application of this document:

- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
- ISO/IEC 17043:2010, Conformity assessment – General requirements for proficiency testing
- ISO 13528:2015, Statistical methods for use in proficiency testing for interlaboratory comparisons

4. Competence and qualification

The Physikalisch-Technische Bundesanstalt (PTB) is the national metrology institute and the supreme technical authority of the Federal Republic of Germany for metrology. It comes under auspices of the Federal Ministry of Economics and Technology. PTB providing scientific and technical services and measures with the highest accuracy and reliability – metrology as the core competence.

PTB staff has accrued since foundation of the field of work “Explosion Protection” in 1949 a great treasure trove of experience in testing explosion protected devices. PTB carries out a wide spectrum of basic research and applied research in the field of explosion protection. PTB is member of the IECEx System with a wide scope of the relevant standards in the field of explosion protection.

The PTB Ex PTS exists since 2009 and is organized under the umbrella of the comprehensive PTB Quality Management System. The PTB Ex PTS meets the requirements of standard ISO/IEC 17043:2010 - „Conformity assessment - General requirements for proficiency testing”.

5. Terms and definitions

For the purposes of this document, the terms and definitions given in the following apply.

assigned value:

value attributed to a particular property of a proficiency test item

coordinator:

one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme

interlaboratory comparison:

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

outlier:

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

participant:

laboratory, organization or individual that receives test samples and submits results for review by the proficiency testing coordinator

proficiency testing (PT):

evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

PTB Ex 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

PTB Ex Proficiency Testing Scheme (PTB Ex PTS):

overall design of one or more programs

test round:

single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to the participants

test sample:

sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing

6. Scheme organization

6.1. Organizational structure

PTB is the proficiency testing provider of the PTB Ex Proficiency Testing Scheme. The coordinator is Working Group 3.54 "International Harmonization in Explosion Protection". The coordinator provides the managing staff. Each program has a person who is responsible for development, organization, performance and reporting. A group of PTB experts is assigned to each program depending on the field of testing to assure the provision of the full range of relevant knowledge and expertise needed to operate the program effectively.

The organizational structure is described by an organigram in **Annex A**.

6.2. Scheme design

The PTB Ex Proficiency Testing Scheme consists of different PTB Ex Proficiency Testing Programs with regard to different areas of testing in the field of explosion protection. For conducting the programs, the individual routine procedure of each test laboratory needs to 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. 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:

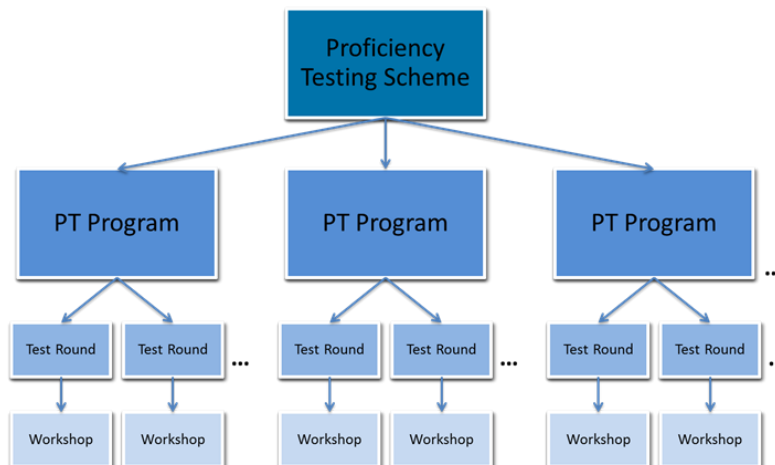


Figure 1: Design of the PTB Ex Proficiency Testing Scheme

6.3. Program design

The individual steps of the typical program design are shown in the following program flowchart. The general structure is usually the same. In any case of deviation from this structure this will be addressed in the respective rollout/procedure instruction. Detailed explanations of each step are mentioned in the tables (Table 1 and Table 2) below.

Program design for programs within the regular two-year-cycle:

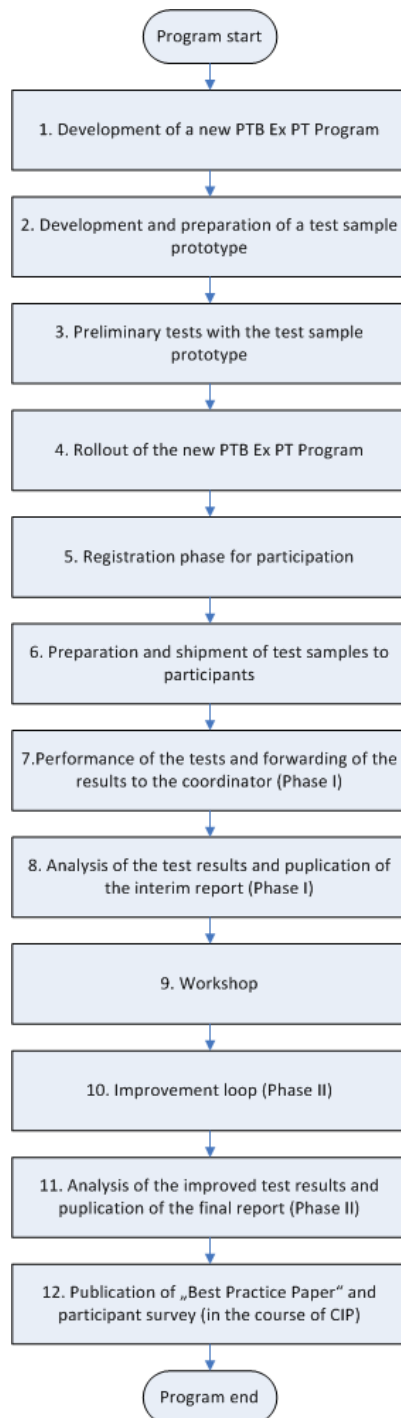


Figure 2: Program design as a flowchart

Table 1: Detailed explanations for the program flowchart

Step	Explanation
1	<p>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. After decision about the topic of the program the coordinator builds an expert group consisting of PTB experts (includes staff, expertise and documents from other PTB working groups) or other experts of the Ex community with the necessary expertise relating to the respective field of explosions protection. Design, procedure instruction, statistical design and design of analyzing are developed by the coordinator in close cooperation with the expert group. The general policy is to develop a program which is as simple as possible and as complex as necessary.</p>
2	<p>A test sample prototype which meets the requirements of ISO/IEC 17043 [1] is developed by the coordinator in close cooperation with the expert group. Special attention is given to the question of homogeneity, stability and practicability.</p>
3	<p>A test phase for the test sample prototype regarding ability for the program is made in the respective laboratories of the coordinator. The results of this test phase are discussed with the expert group and incorporate the program design.</p>
4	<p>A rollout paper with first necessary information about program design, time schedule, design of test sample and all information about participation is send out to all interested parties. Simultaneously the rollout paper is released on the PTB Ex PTS website.</p>
5	<p>The participants apply for the provided program as described in the rollout paper sent out before.</p>
6	<p>The test samples are built in the workshop of the coordinator or by external manufacturers in accordance to the requirements of the coordinator. The test samples are prepared by the coordinator and tested to meet the requirements of ISO/IEC 17043 [1] regarding homogeneity and stability. After the successful quality check each test sample is assigned to a participant with a unique identification number to assure traceability.</p>
7	<p>The participants perform the tests in accordance to the procedure instruction which is provided on the PTB Ex PTS website. This first performance of tests is named phase I. After performing the tests, the results are forwarded to the coordinator in form of completed test records via PTB Ex PTS website.</p>
8	<p>The analysis of the results as well as the preparation of the interim report by the coordinator are in accordance to ISO/IEC 17043 [1] and ISO 13528 [2]. The interim report provides a summary of all uploaded results and (hidden to other laboratories) the specific results of each individual participant. Furthermore, it includes first aspects for discussion and interpretation.</p>
9	<p>The workshops are an essential element of the programs operated by the coordinator and are especially addressed to the laboratory technicians in order to start an experience exchange for further alignment of procedures and technologies, by the opportunity to meet face to face. The venue of the workshops is at PTB. To attend the workshops the participants shall apply separately to the program participation. All participants of the programs get all necessary information regarding the workshops before.</p>
10	<p>After interim report and workshops the improvement loop allows the participant to repeat the tests after improvement of their procedures and instrumentation, if they are</p>

not happy with their position regarding the difference with the assigned value. During this phase the participants are invited to individual and confidential discussion of their results with PTB experts. As far as the coordinator could already identify any inconsistencies, this is addressed in direct contact to the respective participants.

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Similar to step 8. The analysis of the updated results as well as the preparation of the final report by the coordinator are in accordance to ISO/IEC 17043 [1] and ISO 13528 [2]. The final report provides a summary of all uploaded results and (hidden to other laboratories) the specific results of each individual participant. Furthermore, the final report provides an overview about the development of the results from phase I to phase II.

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As the last step of a program cycle the experience gained in the whole program is summarized in a "Best Practice Paper" which provides steps that can be taken to improve the consistency of results obtained when doing tests in the field of explosion protection. In the course of the "Continuous Improvement Process" the coordinator conducts a participant survey to get direct feedback about the quality of the program and to get information about potential for improvement.

Program design for individual participation in previous open programs:

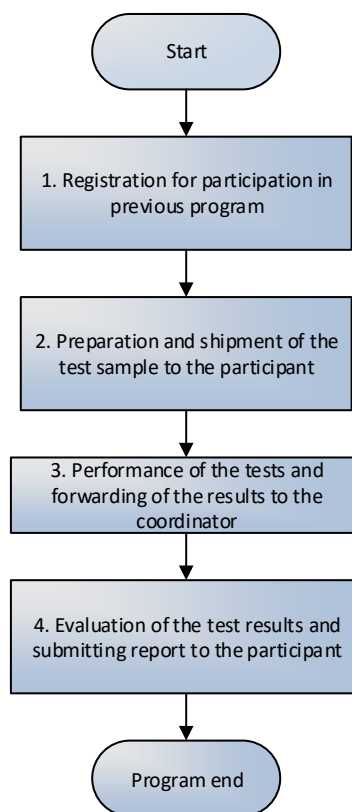


Figure 3: Program design for previous program as a flowchart

Table 2: Detailed explanations for the flowchart for previous programs

Step	Explanation
1	The participant contacts the coordinator informs about his interest in participation in an open previous program. The participant then receives an application form, which is to be sent to the coordinator.
2	After payment the coordinator prepares and ships the test sample to the participant. The test samples are built in the workshop of the coordinator or by external manufacturers in accordance to the requirements of the coordinator. The test samples are prepared by the coordinator and tested to meet the requirements of ISO/IEC 17043 [1] regarding homogeneity and stability. After the successful quality check the test sample is assigned to the participant with a unique identification number to assure traceability.
3	The participants perform the tests in accordance to the procedure instruction which is provided on the PTB Ex PTS website. After performing the tests the results are forwarded to the coordinator in form of completed test records via PTB Ex PTS website.
4	The participant receives an individual report with the respective evaluation of the participant’s results as well as the final report of the program including a summary of all uploaded results and (hidden to other laboratories) the specific results of each individual participant. The analysis of the results is in accordance to ISO/IEC 17043 [1] and ISO 13528 [2].

6.4. Confidentiality

The coordinator ensures compliance with all requirements of the standard ISO/IEC 17043 [1] regarding the confidentiality of all data and information related to the performance of the PT programs. The access to all data, especially to results of participants and information is strictly regulated. The used server is subjected to central PTB safety regulations. The anonymization of all data is guaranteed. Only authorized persons have access to the anonymization code. To increase data security the anonymization code changes in each program or if necessary, in each phase of a program. The confidentiality of results of individual laboratories is essential. The results will be communicated only to the individual laboratory and to the IECEx Secretariat. Only the individual participant 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.

6.5. Access to participation

A rollout paper is available at the beginning of a new program which includes general information about the program e.g. design of the test sample, time schedule, application form and so on. In order to join the program, the interested Ex laboratory (e.g. ExTLs, ExTL applicants, ATFs, applicant ATFs, manufacturer and other parties interested) shall complete the respective application form enclosed as annex in the rollout paper and send it back to the coordinator. Once a completed application form is received, an order confirmation – “Declaration of participation” is sent out to the participant. Simultaneously the new registered participant will be listed on the participants list at the PTB Ex PTS website.

To perform a previous program the interested laboratory needs to contact the coordinator directly to get the application form and further information regarding the individual time schedule and report.

General information about the provided PTB Ex PT Programs (previous and new programs) can be found on the PTB Ex PT website all the time.

6.6. Costs

The basic costs of the PTB Ex Proficiency Testing Scheme (e.g. concept development of the programs and related test samples, manufacturing of the samples, evaluation procedures of the results) are covered by PTB. Nevertheless, PTB cannot cover all expenses caused by the various programs, offered every two years. The PTB Ex PT Scheme is not organized like a commercial provider; it is using instead the non-profit approach in cooperating with the non-profit registered association (e.V.) "Ex Network e.V." in order to process financial transactions. The association works under financial supervision of the local tax authority of the City of Braunschweig. PTB as governmental organization is allowed to receive financial resources from the Ex Network e.V. under the umbrella of a cooperation contract with the scope of offering and conducting Ex proficiency testing programs. The costs for the PT programs within the PTB Ex PT Scheme are as follows:

- Participation in the PTB Ex PT Scheme is considered as a subscription with annual costs of 3000 € (value added tax excluded) for each participant.

To avoid a high level of bureaucracy every laboratory which is requested to participate in the PTB Ex PT Scheme (IECEX ExTLs, ExTL Applicants, ATFs and applicant ATFs) will receive an invoice at the beginning of each two-year cycle (6000 € each two years) after registration, which allows the participating laboratory to perform all new PTB Ex PT program test rounds provided by the coordinator (two new program test rounds every two years). It also allows to perform previous open PTB Ex PT program test rounds at any time. The chosen program test rounds shall be completed within the respective two-year cycle, otherwise the participant has to apply and make the payment for the next two-year-cycle.

The costs of registering individual programs not within the subscription cycle is 3500 € per program (value added tax excluded).

Laboratories which are not required to participate in the PTB Ex PT Scheme with a limited scope shall contact the coordinator directly to find an individual solution.

Every financial transaction will be confirmed by the coordinator. Payment deadlines are announced with the invoice or in direct contact with the participant. Non-payment or late payment may result in test samples and/or reports not being distributed.

6.7. Extent of participation

Participants are advised to participate in the programs that are most appropriate to their scope. Where necessary, the coordinator can advise which program(s) are most suitable for the participant. The program cycle of new programs is biennial. That means every two years two new programs or program test rounds are provided in the PTB Ex PT Scheme. Respective the individual scope of the Ex laboratories it is recommended to perform these two new programs / program test rounds. Additionally, it could be fruitful to perform one or more older programs in between (if the laboratory wasn't a participant in the "original" program test round).

IECEX test laboratories which are requested to participate in the PTB Ex PT Scheme (all IECEX ExTLs, ExTL Applicants, ATFs and applicant ATFs) are required to participate in all programs which are relevant to their scope.

In case previous programs have to be closed (e.g. due to instability of test samples, new program versions, etc.), this information will be reported to the IECEx test laboratories, ExTAG and the IECEx Secretariat.

7. Test item

7.1. Developing, manufacturing and preparation

The developed test items are in direct connection to a certain PT program and therefore to a standard of the applicable type of protection. This is considered in the naming of the respective test item, so called Test Sample "XY*" (* XY stands for the abbreviation of the respective program). The test samples are developed as similar as possible to those samples routinely tested by participating laboratories in daily work. The development of the test samples based on the same principle as the development of a program, the test sample should be as simple as possible and as complex as necessary, and it should reflect the properties of a real sample.

Manufacturing and preparation of the test samples is made by PTB or (if this is not possible) by most reliable manufacturers. The selection criteria for manufacturers depends on the program or rather on the type of test sample and based on highest quality in questions of homogeneity and stability (see Section 7.2). Details of individual test samples like construction drawings and parameters, further handling and preparation instructions and so on are described in the procedure instruction for each PT program.

7.2. Homogeneity and stability

To ensure that every participant receives comparable test samples, and that these test samples remain stable throughout the whole PT program, homogeneity- and stability tests are conducted by the coordinator on every single test sample. To do so the coordinator uses an excellent infrastructure in terms of the PTB scientific instrumentation workshop and different expert laboratories. Every phase of homogeneity- and stability tests is documented and follows a defined procedure optimally adapted to the particular PT program. The defined tolerances of the parameters to assure homogeneity have been determined related to preliminary tests performed at PTB.

Please notice that the tests for homogeneity and stability only ensures the comparability of the test samples during the PT program test rounds and aren't valid for further tests the participant may do on his own. Further details regarding homogeneity- and stability testing are included in the procedure instruction of the respective PT program.

7.3. Storage, packaging and shipping

The test samples are stored in appropriate locations at the area of PTB with strictly regulated access. The test samples are packed and sent out by the PTB shipping department under conditions intended to maintain the integrity of the test samples during shipment. Special shipping requirements of the respective participant or of customs should be addressed before shipment of the test sample by direct contact to the coordinator. A brief email will be sent to the participant after the test sample leaves PTB. The costs required for shipping of the test samples to the participants are included in the program fees. No extra costs will be incurred.

Once the package has been delivered, the participant should contact the coordinator about the receiving. The participants don't need to send back the test samples to the coordinator after performing the tests. The test samples are to be considered to stay permanently at the participants' laboratories. This procedure gives the opportunity to make further test rounds or programs with the

test samples if the participant is interested. Furthermore, it is important for discussion related to the performance of the tests, for possible troubleshooting and additional tests.

7.4. Condition of use of test samples

In the scope of the PTB Ex Proficiency Testing Scheme test samples will be shipped to the participants of the scheme in order to perform interlaboratory comparisons. The test objects were developed and prepared at PTB for the PT programs and are made available at the own risk of the participating test laboratories.

PTB assumes no responsibility whatsoever for the use of the test samples by the participants and makes no guarantees, expressed or implied, about its quality, reliability, safety, suitability or any other characteristic. As far as legally permitted PTB refuses any liability for any direct, indirect or consequential damage arising in connection with the use of the test samples. The participants shall bear the risk of the use of test samples and of their internal work. German law shall apply.

By handling the test samples after receipt the participant agrees to these conditions of use. If a participant does not agree, the test laboratory shall not be authorized to work with the test samples. In this case the test samples have to be returned to PTB immediately.

Please notice that test samples are provided for the use within the PTB Ex PT Scheme. It is not intended to use the test samples for other purposes.

7.5. Loss or damage

Once the shipped test sample has been delivered, the participant should check the condition immediately. For the case of loss, 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 lost or 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. If a test sample is damaged or lost due to incorrect behavior of the participant, additional costs may be incurred to provide a new test sample.

8. Performance of tests and reporting of results

8.1. Time schedule and deadlines

Every two years the coordinator provides two new parallel PT programs or rather PT program test rounds. The time schedules of the programs are normally structured identically and have the same or similar milestones and deadlines. For previous programs the time schedules are different and will be provided by the coordinator directly. The time schedules for the new programs are published with the roll out paper and on the PTS website at the respective program section (where it will be updated in case of any changes). For a smooth procedure it is important that the participants meet the deadlines in question e.g. of application for a program or for uploading the test results. Applications received after the deadline of the registration phase cannot be considered. Results received after the reporting deadline cannot be included in the report. The deadlines are included in the published time schedules and additionally every participant will be informed directly via email.

8.2. Transfer of results

The templates for all data, information and documentation to be recorded are made available in an electronic form on the PTB Ex PT Scheme website: “<http://www.Ex-Proficiency-Testing.ptb.de>”. Detailed information about how to complete the templates are described in the procedure instruction of the respective program. The completed templates are to be uploaded on the PTS website in the upload area. By this, the documents are forwarded to the coordinator.

Once completed test data are received, an incoming control (plausibility check) of the data will be conducted by the coordinator to ensure no significant mistake in completion of the templates has been made. In the case of no conspicuous data the participant gets reply about the successful transfer of the results and the start of analysis and evaluation. If there are any issues with the uploaded data, the coordinator will contact the participant immediately.

8.3. Test method

Participants are generally requested to follow an individual test method which is specified in the procedure instruction of the respective PT program. This test method is intended to be either as similar as possible to the test method described in the specific standard or it supplements the standard method. If there are no further information regarding certain questions of the test method neither in the standard nor in the procedure instruction, participants may carry out the tests using any method that they feel is technically appropriate. In that case appropriate means that the required tests should be carried out in accordance with routine test methods of the participating test laboratory.

8.4. Cheating and falsification

The objectives of taking part in proficiency testing programs will be destroyed if participants are not returning truthful results. It is generally assumed that participants of the PTB Ex PT Scheme perform the programs in a professional, responsible and honest manner. Nevertheless, the statistical design for analyzing and the evaluation of the results and data by experts shall allow to identify possible cheating or falsification. In cases of possible suspected irregularity or cheating the coordinator contacts the participant to clarify this situation. If the suspicion is confirmed the participation of the test laboratory will be canceled.

9. Data analysis and evaluation of results

The statistical methods being used to analyze and evaluate the participants’ results are developed and documented in accordance to ISO/IEC 17043 [1] and ISO 13528 [2]. An overview about the structure of data analysis and evaluation of results is shown in **Annex B**.

9.1. Measurand or characteristic of interest

The measurand or characteristic of interest is the quantity selected which is to be compared in a PT program. The provided PT programs have a wide range of different topics within the field of explosion protection and therefore the measurands and characteristics of interest are manifold, too. The measurand or characteristic of interest is defined in the roll out paper and procedure instruction of each program. The PTB Ex PT Scheme is not limited to physical measurands as usually used for quantitative programs. There are also qualitative programs with relation to conformity assessment or safety characteristic data for the field of explosion protection.

9.2. Participants' result

The participants' result is in direct connection to the measurand or characteristic of interest. This value is the main parameter and therefore the "result" of the participant. The statistical method to determine this value differs depending on the program and is described in detail in the procedure instruction of the respective programs. Usually for quantitative programs this value is a mean value of a number of measurements or a direct result of an observation. For qualitative programs this value could also be a safety assessment e.g. in the field of conformity assessment.

9.3. Assigned value

The assigned value is a value attributed to a particular property of a proficiency test item [1]. It is the best estimate of the "true value" for the measurand or characteristic of interest and it is the value (reference value) which is to be compared with the participants' results. The method used to determine the assigned value may vary depending on the particular program and measurand or characteristic of interest and is described in the respective program documents in detail. Usually for quantitative based programs the approach to calculate the assigned value is the robust average of the results reported by all participants in the round in accordance to ISO 13528 [2]. The general calculation of the robust average and the robust standard deviation is described in **Annex C**. For qualitative programs e.g. related to conformity assessment the assigned value can also be influenced by PTB experts.

9.4. Outliers

Possible outliers in the participants' results are treated in accordance with ISO/IEC 17043 [1].

- Obvious blunders, such as those with incorrect units, decimal point errors, and results for a different proficiency test item will be indicated in the incoming control of the coordinator. They will be corrected after discussion with the participant. These results aren't subject to outlier tests or robust statistical methods.
- When participants' results are used to determine assigned values, the statistical methods used in the program minimize the influence of outliers due to robust algorithms.
- If results are removed as outliers, they will be removed only for calculation of summary statistics. These results will still be evaluated within the proficiency testing scheme and be given the appropriate performance evaluation.

9.5. Evaluation of participants' performance

For quantitative data, participants are assessed on the difference between their result and the assigned value (see Section 9.2 and 9.3); with this difference being represented by performance statistics called laboratory bias D , percentage difference $D\%$ and z-score. Usually the laboratory bias, percentage difference and z-score are interpreted in accordance with ISO 13528 [2] described in detail in **Annex D**. The specified methods for the evaluation of participants' performance are described in the respective report of each program.

The evaluation of participants' performance depends on the statistical description of the measurand or characteristic of interest. It may be possible that the methods of performance statistics described

in **Annex D** can't be used for the evaluation of participants' performance (e.g. due to the statistical distribution form, small sample size, etc.). For that case the evaluation shall be limited to a graphical presentation of the results focused on the location parameter. This procedure allows getting an impression about the trend of the participant if the test results tend to be higher, lower or equal to other participants and the assigned value.

In addition to the statistical evaluation a qualitative evaluation will be made by the coordinator. To do so every participants' performance (test results, test setup, used measurement devices, testing method, ambient conditions, data graphs and trend curves, etc.) will be discussed by the PTB expert group of the respective program.

The method used to determine the standard deviation for the evaluation of participants' performance may vary depending on the particular program and measurand or characteristic of interest. The standard deviation derived in accordance with ISO 13528 [2] on the basis of robust statistical methods (see **Annex C**).

For qualitative programs, participant results will be compared against the intended result, also called the assigned value, based on formulation or assessment by the PTB expert group of the respective program.

9.6. 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. After completion of the respective program phase, the coordinator will elaborate an interim report or a final report in compliance with the requirements of ISO/IEC 17043 [1]. The reports are made available electronically using the PTB Ex PTS website. The contents of reports vary from program to program but include details of the test sample, the assigned value, tabular and graphical representations of participants' results and performance in an anonymous way. Furthermore, general aspects for discussion and interpretation are commented in the reports. All participants 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 Secretariat.

10. Information distribution

10.1. Communication

A personnel, continuous and confidential communication with the participating parties is essential for the success of the whole PTB Ex PT scheme. Therefore, the coordinator uses several different ways to stay in contact with the participating laboratories like the PTS website, email correspondence, telephone and direct contacts on meetings and workshops. In accordance to ISO/IEC 17043 [1] the coordinator makes all necessary information available like relevant details of the scope of a proficiency testing program, any fees for participation, documented eligibility criteria for participation, confidentiality arrangements, details of how to apply and information about published reports. Participants will be advised promptly by the coordinator of any changes in proficiency testing program design or operation. Participants are welcome to contact the coordinator at any time, if they have questions or concerns in any matter.

All news, information, reports and documents which are necessary to conduct the different PT programs can be found on the PTB Ex PT website under:

<https://www.Ex-Proficiency-Testing.ptb.de>

For individual personal support please contact one the following persons:

- **Head coordinator:**

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10.2. Contradictions, appeals and complaints

In the event of complaints or appeals, these will be fully examined according to the quality system of the provider PTB, to determine the underlying reason and to decide about the way of proceeding. Appeals and complaints by participating laboratories are addressed to the coordinator in direct contact or by the IECEx Secretariat and shall clearly indicate the basis for the appeal.

Another possibility to lodge a complaint is to contact the IECEx ExTAG Working Group 10 “Proficiency Testing” which act as an advisory group for the PTB Ex PT Scheme. The complaints will be discussed at the annual IECEx ExTAG WG 10 meeting or if necessary, in a short-term meeting.

However, the way of proceeding together with the results of any examination carried out will be communicated, as appropriate, to the participant.

11. Corrective actions and continuous improvement process

With the practical experience gained day by day in the performance and organization of PT programs, the PTB Ex Proficiency Testing Scheme shall be further developed and improved (continuous improvement process). After each PT program cycle a critical review of the whole performance is done to highlight the potential of improvement. As a result of this critical review process a package of measures will be adopted to eliminate weak points of the PT scheme. Helpful for this process is a survey at the end of each program cycle to get feedback from the participants concerning the organization and performance of the tests. The results of that survey are evaluated by the coordinator and will be published for all participating laboratories. The feedback will be used and analyzed to improve the management system, PT programs, and customer service.

12. Annex

12.1. Annex A- Organigram of the PTB Ex Proficiency Testing Scheme

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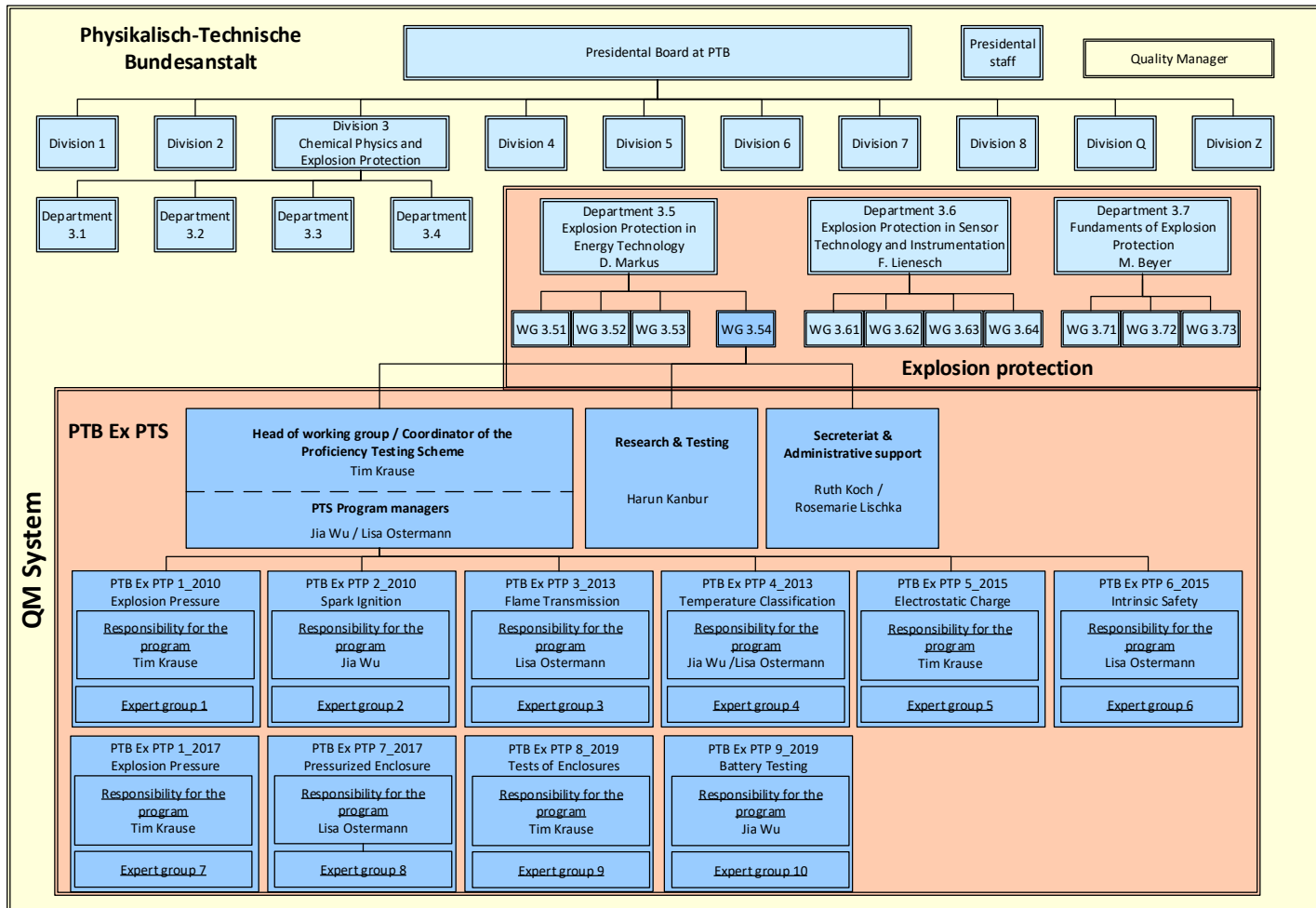


Figure 3: Organizational structure of the PTB Ex Proficiency Testing Scheme

12.2. Annex B - Method of data analysis

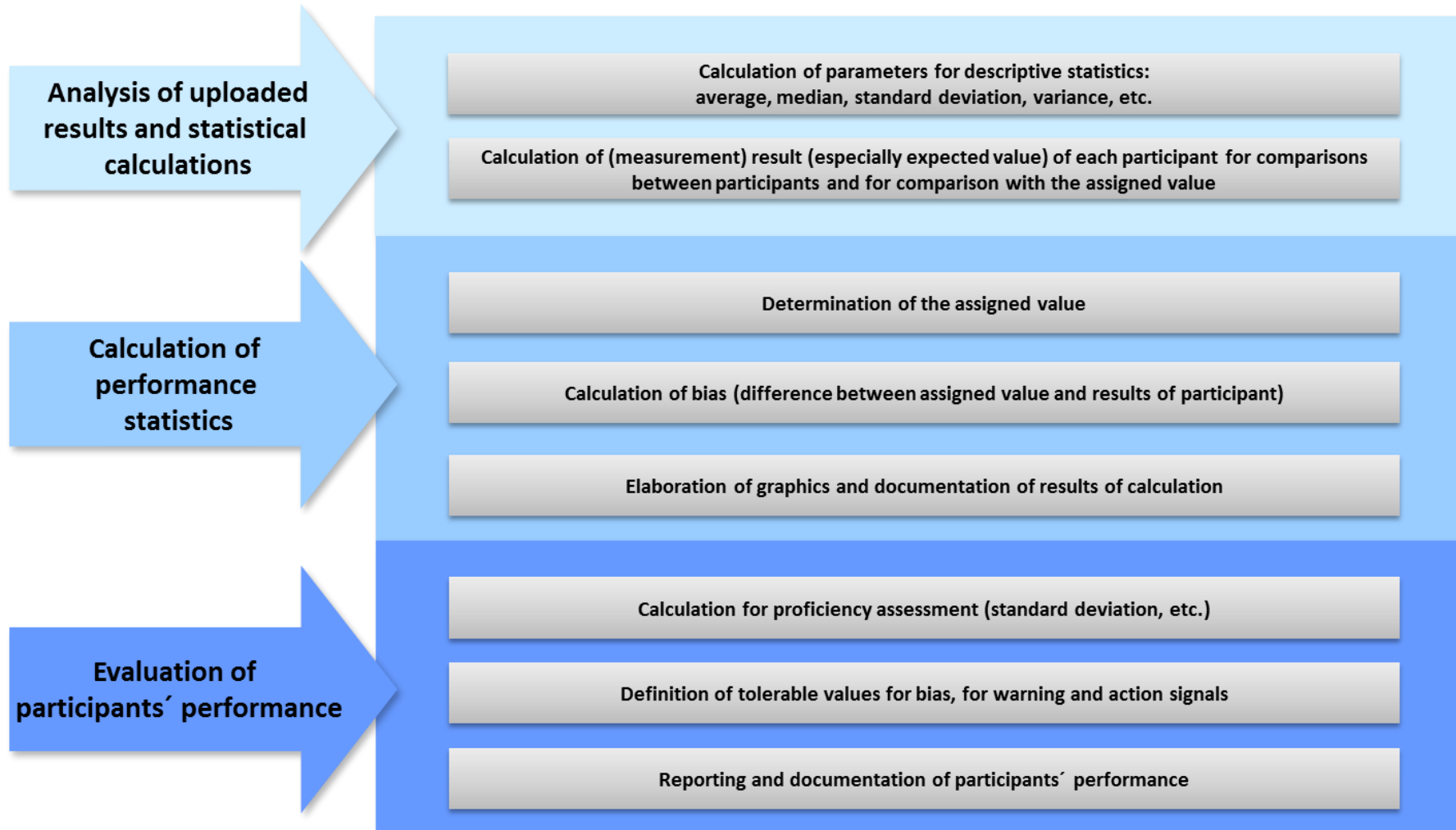


Figure 4: Overview about the structure of data analysis

12.3. Annex C - Robust analysis algorithm for the determination of the assigned value and its standard deviation (for quantitative programs) [2]

This algorithm yields robust values of the average and standard deviation of the data to which it is applied.

Denote the n items of data, sorted into increasing order, by:

$$x_1, x_2, \dots, x_i, \dots, x_n$$

Denote the robust average and robust standard deviation of these data by x^* and s^* . Calculate initial values for x^* and s^* as:

$$x^* = \text{median of } x_i \ (i = 1, 2, \dots, n)$$

$$s^* = 1,483 \text{ median of } |x_i - x^*| \ (i = 1, 2, \dots, n)$$

Update the values of x^* and s^* as follows. Calculate:

$$\delta = 1,5 s^*$$

For each $x_i \ (i = 1, 2, \dots, n)$, calculate:

$$x_i^* = \begin{cases} x^* - \delta, & \text{if } x_i < x^* - \delta \\ x^* + \delta, & \text{if } x_i > x^* + \delta \\ x_i, & \text{otherwise} \end{cases}$$

Calculate the new values of x^* and s^* from:

$$x^* = \frac{\sum x_i^*}{n}$$

$$s^* = 1,134 \sqrt{\frac{\sum (x_i^* - x^*)^2}{(n - 1)}}$$

where the summation is over i .

The robust estimates x^* and s^* may be derived by an iterative calculation, i.e. by updating the values of x^* and s^* several times using the modified data, until the process converges. Convergence may be assumed when there is no change from one iteration to the next in the third significant figure of the robust standard deviation and of the equivalent figure in the robust average.

12.4. Annex D - Procedure for calculating performance statistics of participants' performance [2]

- **Bias**

The estimate of absolute differences between assigned value and result of participant, calculated as:

$$D = x - X$$

X = the assigned value

x = the result of participant

- **Percentage differences**

The estimate of percentage differences between assigned value and results of participant, calculated as:

$$D_{\%} = \frac{100 (x - X)}{X}$$

X = the assigned value

x = is the result of participant

- **z-score**

Standardized measure of laboratory bias, calculated using the assigned value and the standard deviation for proficiency assessment (SDPA):

$$z = \frac{(x - X)}{s^*}$$

s^* = is the standard deviation for proficiency assessment (SDPA).

x = is the result of participant.

X = is the assigned value

Interpretation of laboratory biases and z-scores (for normal distribution)

When a participant reports a result that gives rise to a laboratory bias greater than $3,0 s^*$ or less than $-3,0 s^*$, then the result shall be considered to give an "action signal". Likewise, a laboratory bias above $2,0 s^*$ or below $-2,0 s^*$ shall be considered to give a "warning signal".

Interpretation of percentage differences (for normal distribution)

Percentage differences shall be interpreted using equivalent guidelines to those given for laboratory biases, i.e. when a participant reports a result that gives rise to a percentage difference above $300 s^*/X$ % or below $-300 s^*/X$ %, then the result shall be considered to give an “action signal”. Likewise, a percentage difference above $200 s^*/X$ % or below $-200 s^*/X$ % shall be considered to give a “warning signal”.

Evaluation basis of participant’s results

An “action signal” shall be taken as evidence that an anomaly has occurred that requires investigation. A “warning signal” shall be taken as indication for the laboratory to check the testing process internally. This criterion is equivalent for z-scores in the sense that it will give the same action and warning signals. If X and s^* are good estimates of the mean and standard deviation of the population from which the x values are derived, and the underlying distribution is normal, then the D values will be approximately normally distributed with a mean of zero and a standard deviation s^* . Under these circumstances only about 0,3 % of estimated laboratory biases would be expected to fall outside the range $-3,0 s^* < D < 3,0 s^*$, and only about 5 % would be expected to fall outside the range $-2,0 s^* < D < 2,0 s^*$. Because these probabilities are so low, it is unlikely that action signals will occur by chance when no real issue exists, so there is a reasonable chance of identifying the reason for an anomaly when an action signal is given.

It is important that the used “warning signals” and “action signals” are not interpreted as safety limits.

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, other applicable evaluation criteria are defined. If this is also not possible, the IECEx PTS Provider identifies the reasons for this and offers suggestions for improving the situation (e.g. adaptation/improvement of the applied test methods, improvement measures to increase the comparability of the results, etc.).

Warning and action signals are important criteria for analyzing poor performance or unsatisfactory results of laboratories and normally provide good information and orientation on the laboratory’s overall performance. However, in certain cases it may happen that an unsatisfactory performance of a laboratory is not shown by only focusing on the warning/action signals. Because of this, the PTS Provider provides on top of the statistical evaluation a qualitative and program-based evaluation.

Bibliography

- [1] ISO/IEC 17043:2010, Conformity assessment – General requirements for proficiency testing
- [2] ISO 13528:2015, Statistical methods for use in proficiency testing by interlaboratory comparisons
- [3] ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories