



Demonstrating the validity of measurement results through reliable proficiency testing

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Overview

Introduction to PT

The Eurachem PT Guide

- Key principles, aims and audience
- Strategy of PT participation
- Selecting the most relevant PT schemes
- Benefits of PT to a laboratory

Quality of PT provision

Concluding remarks

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What is PT?

The definition of proficiency testing (ISO/IEC 17043*) is:

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

The primary aim of proficiency testing is:

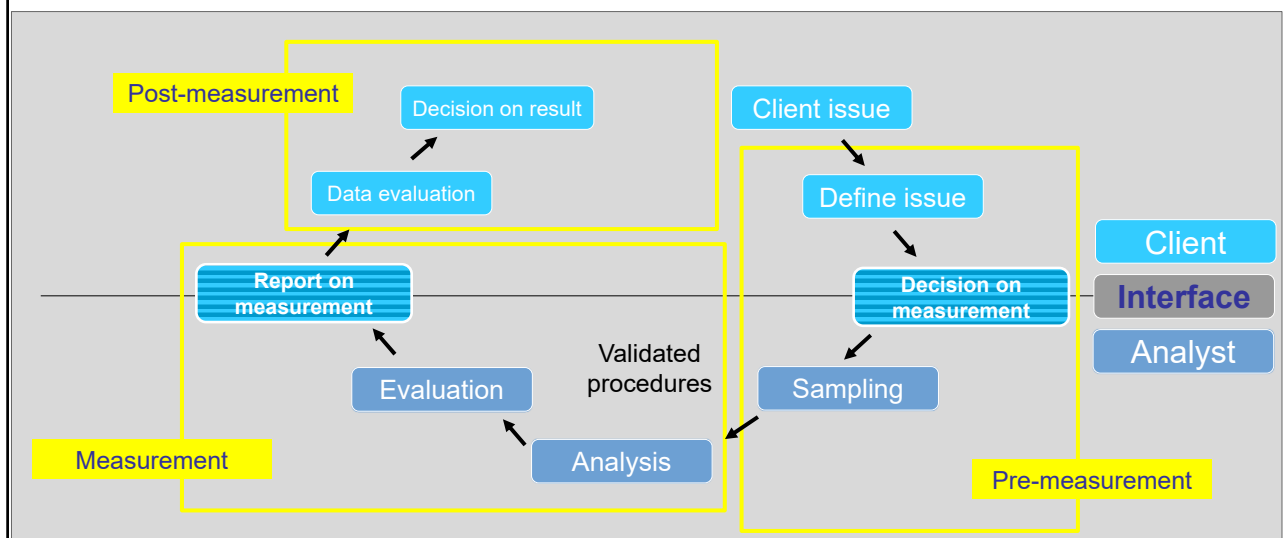
To provide the infrastructure for a laboratory to monitor and improve the quality of its routine analytical measurements

A proficiency testing scheme provides laboratories with a framework for obtaining a regular external & independent assessment of their performance

*ISO/IEC 17043 Conformity assessment – General requirements for Proficiency Testing

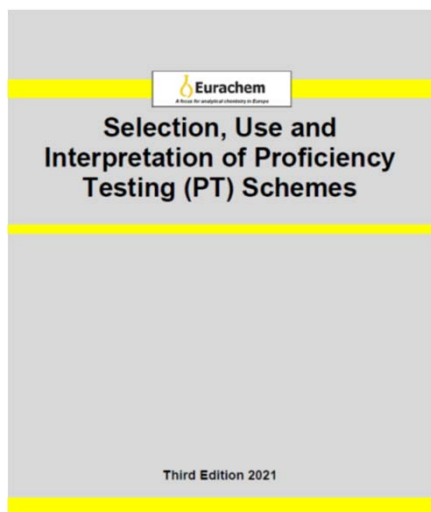
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The Measurement Cycle



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Eurachem PT Guide



Contents

- Introduction, scope and definitions
- Introduction to proficiency testing
- Selection of appropriate PT schemes ★
- Use of PT by laboratories ★
- How a PT provider evaluates the laboratory's performance
- Laboratory interpretation of PT results
- Annex A – Selection the most relevant PT scheme
- Annex B - Investigating unsatisfactory or questionable PT results
- Annex C - Interpretation of PT data by end users
- Annex D - Statistical aspects of PT
- Bibliography

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The Eurachem PT Guide – the scope

Aim of the guide

- aims and benefits of participation in PT schemes;
- selecting the most appropriate PT scheme;
- understanding the basic statistics and performance scoring used by the PT providers;
- using and interpreting the PT results in order to improve the overall performance of the laboratory.

Audience for the guide

- all organizations performing:
 - Sampling
 - Testing
 - Calibrations
 - Examinations
- E.g. testing laboratories, calibration laboratories, inspection bodies, biobanks, etc.
- covers measurements, examinations and interpretations.

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The Eurachem PT Guide – Key principles

PT scheme selected should resemble as closely as possible the laboratory's routine work

Laboratories should treat PT items as routine samples

PT scheme documentation, must provide clear information in order for all parties to understand how the PT scheme operates

Poor performance must be thoroughly investigated so that the laboratory can understand the reasons for poor performance and correct as necessary

Evaluation and interpretation of the performance in a PT scheme should take into account the risk associated with the measurement

Performance of a laboratory over several rounds of a PT scheme and analysis of trends is paramount to determining the successfulness of participation

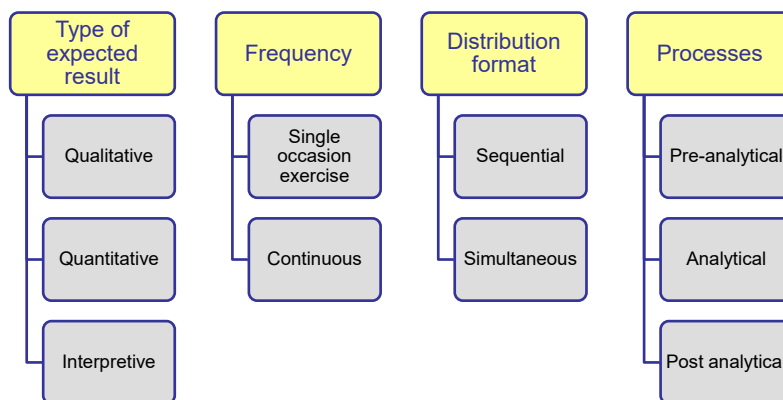
PT provider should be open to discussion amongst interested parties in order to gain a more accurate understanding of the PT scheme and its operation

Laboratories should view PT participation as an educational tool, using the PT scheme results in the improvement process and to give feedback to staff

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Types of PT schemes



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Strategy of PT participation

- All laboratories need to develop an appropriate PT participation strategy
- The aim is to participate in relevant PT schemes, at an appropriate frequency for the laboratory's circumstances
- Before selecting an appropriate PT scheme, the level and frequency of participation should be evaluated
- This is the first of five key questions that a laboratory needs to address in order to select the most appropriate PT scheme

What level of PT and frequency do I need?

Do any PT schemes exist for the technical competence required?

Is the PT scheme relevant?

Is the PT provider competent i.e., do they operate to ISO/IEC 17043?

Is the PT scheme independent of any manufacturing or marketing interests in equipment, test kits, or calibrators?

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Level of PT participation

- Level
 - The number of specific activities that an organisation identifies within its scope of accreditation, and therefore the number of specific proficiency tests that should be considered for participation
- Consider areas of technical competence based on:

Measurement procedure
e.g., ICP-MS, Rockwell hardness, PCR, microscopy, force measurement

Characteristic to be measured
e.g., arsenic, fat, creatinine, length, hardness, force

Product to be analysed
e.g., soil, vegetables, serum, polystyrene, concrete

- An area of technical competence may encompass several products, properties and/or measurement techniques
- The laboratory must be able to demonstrate equivalence within each area of technical competence

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Frequency of PT participation

- Frequency
 - The number of proficiency tests per unit of time, in which a laboratory participates for an activity as specified in their scope of accreditation
- Consider the level of risk affecting the laboratory, the sector in which it operates or the measurement procedures being used

Level of Risk

- No. measurements undertaken
- Turnover of technical staff
- Experience and knowledge of technical staff
- Source of metrological traceability (e.g. CRMS, national standards)
- Known stability/instability of measurement procedure
- Significance and final use of data

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Other QA Measures

- The laboratory should define its level and frequency of participation after careful analysis of its other QA measures
- For example
 - regular use of (certified) reference materials ((C)RMs);
 - comparison of analysis by independent measurement procedures;
 - participation in method development/validation and/or RM characterisation studies;
 - use of IQC measures;
 - other interlaboratory or intralaboratory comparisons, e.g. analysis of blind samples within the laboratory.

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Selecting the most relevant PT Schemes

PT Item	Participants	PT item distribution	Results	PT Reports	PT Providers
<ul style="list-style-type: none"> • What is the matrix? • Is the PT item real or simulated? • Are all the characteristics routinely tested available? • Are the characteristic values (e.g. concentrations) appropriate? • Are standard reporting units used? 	<ul style="list-style-type: none"> • Is the participant base national or international? • Is the number of participants or the size of the peer group appropriate? • What measurement procedures are being used by participants? • What type of laboratories are participating? 	<ul style="list-style-type: none"> • Are the distribution dates available and appropriate? • Does the frequency of distributions meet the needs of the laboratory? • Does the PT provider allow flexible participation? 	<ul style="list-style-type: none"> • Are result deadlines available and appropriate? • How are results to be reported? • Can participants use their choice of measurement procedure? • Can measurement uncertainties be reported and will they be assessed? • Is the statistical approach used available and appropriate? 	<ul style="list-style-type: none"> • How quickly are PT reports provided? • What information is provided in the PT reports? • Are the evaluation criteria fit for the laboratory's purpose? • What format is the PT report? • Does the report include interpretable graphical summaries? • Is the language is used in the PT reports understood by the relevant staff? 	<ul style="list-style-type: none"> • What is the scope of PT schemes offered? • Is appropriate feedback and assistance provided? • Are "surplus/repeat PT items" provided for further investigations? • Do they comply with the requirements of ISO/IEC 17043? • Are they accredited to ISO/IEC 17043 by an accreditation body?

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Benefits of PT to a laboratory

Identifying measurement problems

- An unsatisfactory performance in a PT should start a process of investigation
- Such errors could remain undetected without PT participation; lead to ongoing provision of poor results to customers
- Undetected errors could lead to loss of reputation for the laboratory or legal action against the laboratory
- PT is thus a risk management and performance improvement tool

Comparing measurement procedures

- Trial new, modified or infrequently conducted measurement
- Compare two or more measurement procedures used in the laboratory

Comparing operator capabilities

- Multi analyst participation, enabling comparison of operators and identification of training needs
- Can contribute to measurement uncertainty estimates
- Evaluate between-operator precision for the laboratory; can compare to that published for the measurements concerned

Comparing analytical systems

- Provides an objective external assessment of the relative performance of analytical system on the same or different sites used within the laboratory

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Benefits of PT to a laboratory

Improving performance

- If a laboratory is not satisfied with its performance in the PT, areas for improvement can be investigated
- E.g. additional staff training, adoption of new or modified measurement procedures, enhancing IQC measures, equipment modifications, re-calibration, replacement etc

Education staff

- Some schemes have a comprehensive educational role for participants and individual analysts
- Some schemes allow multi-analyst reporting of results

Exchange of information with the PT provider

- Following issue of the report many PT providers will be happy to provide additional information
- Many PT providers use an advisory group of experts who may also be able to help
- Some PT providers hold participant meetings

Instilling confidence in staff, management, and external users of laboratory services

- Successful performance in PT provides confidence to:
 - Staff
 - Management with additional confidence
 - Customers
 - Accreditation bodies and other regulators

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Benefits of PT to a laboratory

Measurement uncertainty

- Results from participation in a PT can be used by a laboratory to check their measurement uncertainty evaluation
- In some cases it might be possible to use the participation in a PT scheme to evaluate the uncertainty for a specific measurement

Use of PT items as Internal Quality Control materials

- Unused PT test material, providing it is stable, can be useful for internal quality control monitoring
- Some PT providers make available surplus test material for this purpose

Determining measurement precision and/or trueness

- Some schemes, dependent on design, can be useful in determining the precision or comparative trueness of the measurement procedures used
- Often further information will be required from the PT provider

Satisfying regulators and accreditation bodies

- Successful performance, or effective correction of measurement problems after poor performance, may provide regulators and accreditation bodies with confidence in the laboratories
- However, internal benefits will be of most value if laboratories view PT as an improvement tool irrespective whether they need to participate for accreditation purposes.

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Quality of PT Provision

- Essential that the PT schemes being provided are of a high quality to support the quality assurance system of any laboratory
- The PT provider is critical external service provider to the laboratory, so it is important that that the laboratory can be assured of the quality of the PT schemes provided.
- PT providers should operate to the international standard ISO/IEC 17043 – ‘Conformity assessment – General requirements for proficiency testing’
- Many PT providers will be accredited to ISO/IEC 17043
- Accreditation reassures that:
 - Working to the international standard
 - Aspects of the PT scheme conform to standard including:
 - Test material quality
 - Technical specifications
 - Customer feedback
 - Reporting and reports
 - Statistics

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ISO/IEC 17043 – the requirements



Technical Requirements

- Personnel
- Equipment, accommodation and environment
- Design
- Choice of method or procedures
- Operation of PT schemes
- Data analysis and evaluation of results
- Reports
- Communication with participants
- Confidentiality

Management Requirements

- Organisation
- Management system
- Document control
- Review of requests, tenders and contracts
- Subcontracting services
- Purchasing services and supplies
- Service to the customer
- Complaints and appeals
- Control of nonconforming work
- Improvement
- Corrective actions
- Preventive actions
- Control of records
- Internal audits
- Management reviews

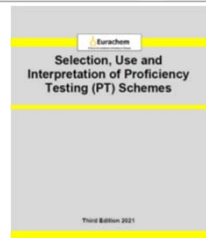
The standard is currently being revised – new version expected to be published mid to late 2022

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Concluding remarks

- PT is a powerful and essential quality assurance tool for laboratories
 - Reflects the laboratory's actual quality
 - Can address all phases of the measurement cycle
- Enables a laboratory to monitor and improve the quality of its measurements
- Participating in PT schemes is an essential requirement for any laboratory wishing to ensure and demonstrate the validity of their measurements
 - Need to establish a participation strategy
 - Need to select the most appropriate PT schemes
- The recently revised Eurachem PT Guide provides valuable advice to laboratories on the use, selection and interpretation of PT schemes
- The international standard ISO/IEC 17043, currently under revision, provides the framework for assessing the competency of the providers of the PT schemes



Thank you for your attention