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External Quality Assurance - the new ISO/IEC 17043

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Overview

Introduction to PT

- What is PT?
- PT – ensuring the validity of results
- Eurachem PT Guide
- Quality of PT Provision

ISO/IEC 17043

- Key changes to the 2nd edition published 2023
- Scope and structure
- As a participant what can I expect from a PT provider operating in compliance with the standard?

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 the competence of proficiency testing providers

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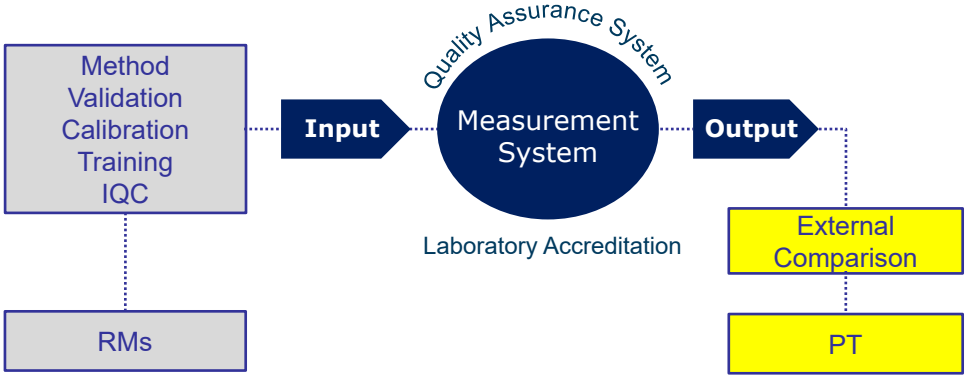
PT – ensuring the validity of results



ISO/IEC 17025 – 7.7.1
ISO 15189 – 7.3.7.2

ISO/IEC 17025 – 7.7.2
ISO 15189 – 7.3.7.3

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PT and accreditation

ISO/IEC 17025 - 7.7 Ensuring the validity of results

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:
a) **participation in proficiency testing**;
b) participation in interlaboratory comparisons other than proficiency testing.

ISO 15189 - 7.3.7 Ensuring the validity of examination results

7.3.7.3 External quality assessment (EQA)
a) The laboratory shall monitor its performance of examination methods, by comparison with results of other laboratories. This includes **participation in EQA programmes** appropriate to the examinations and interpretation of examination results, including POCT examination methods.

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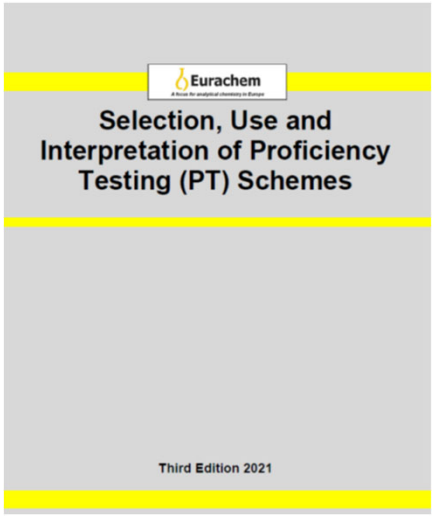
Eurachem PT Guide



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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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 the competence of proficiency testing providers'
- Many PT providers will be accredited to ISO/IEC 17043 – revised 2023
- 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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The revised ISO/IEC 17043

- Second edition, published May 2023
- Changes in application and structure:
  - Broadened use of terms beyond just laboratory testing and calibration
  - Updated management system requirements to reflect current practice and mandatory ISO/CASCO requirements
  - Harmonised requirements to ISO/IEC 17025:2017 for shared elements
  - Clarified or re-phased requirements with known confusion from the 2010 version
  - Restructured the standard to better reflect the PT activities being undertaken by the PT provider
- New normative references:
  - ISO/IEC 17025 for essential testing and calibration activities
  - ISO 17034 for production of (most) PT items,
  - with references to ISO 15189 and ISO 15194 for medical applications

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Further changes

- Other major general changes:
  - Changed the title to align with other CASCO documents
    - "Conformity assessment – General requirements for the competence of proficiency testing providers"
  - Requires a risk-based approach for appropriate technical requirements, in addition to management requirements - to allow the use of experience from previous rounds of PT
  - Aligned statistical terms and symbols with ISO 13528:2022 Statistical methods for proficiency testing by interlaboratory comparison
- Changes to the annexes include:
  - Updated Bibliography
  - Revised Annex A on types of proficiency testing to update types
  - Revised Annex B on statistical methods for PT with references to ISO 13528
  - Removed Annex C on the selection and use of PT schemes

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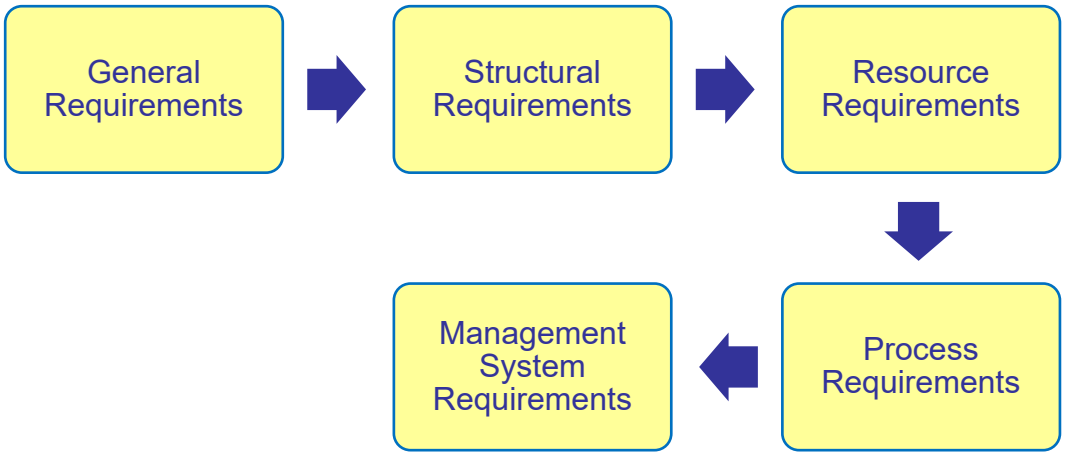
Requirements of ISO/IEC 17043



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As a laboratory what does a PT provider complying with ISO/IEC 17043 mean to me?

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General requirements

Impartiality	Confidentiality
• All PT activities untaken impartially • Activities and relationships are monitored to identify threats to impartiality • Threats to impartiality are eliminated or minimized • Top management is committed to impartiality	• All information obtained or created whilst undertaking PT activities manged through legally enforceable agreements • All proprietary information regarded as confidential • Identity of participants confidential kept confidential; only known to persons involved in the operation of the PT scheme

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Structural requirements

- PT provider is a legal identity or defined part of a legal identity with clear management responsibility for the PT activities
  - Defined organizational and management structure
  - Its place in any parent organization
  - Relationships between the management, technical operations and support services
  - Personnel with the necessary authority and resources to undertakes their duties
  - Specified responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of the PT activities
  - Documented procedures to ensure consistent application and validity of PT activities
- Maintained documented list of PT schemes conforming to the Standard
- PT activities meet the requirements of the Standard as well as requirements of participants, customers, regulatory authorities, and organizations providing recognition
- Integrity and effectiveness of the management system maintained at all times

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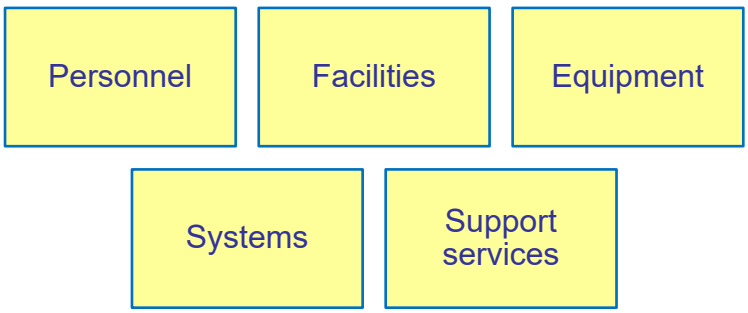
Resource requirements

- The PT provider will have access to the necessary resources to manage and perform its PT activities:



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Resources – Link to other Standards

ISO/IEC 17025	ISO 17034
• Relevant requirements apply to measurements or tests related to: – PT item characterization – Assessing homogeneity and stability • Only applies to requirements that relate to the validity of the measurement or test results, which can impact the validity of PT activities – e.g., metrological traceability • In the medical area ISO 15189 applies	• Relevant requirements apply to the production of PT items where such materials meet the definition of a "reference material" (RM) – Includes RMs with or without certified property values • Only applies to requirements that relate to the validity of operations to produce a RM that directly impacts the PT activities – e.g., mixing, or handling and storage • In the medical area ISO 15194 can apply if applicable

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Resource requirements

Personnel	Facilities and environmental conditions
• Sufficient and competent personnel to perform PT activities and evaluate the significance of deviations – Process in place to manage and demonstrate the personnel competence – All internal or external personnel that can influence the PT activities to act impartially • Personnel with communicated responsibilities and authority to perform specific activities	• Appropriate facilities and environmental conditions ensuring validity of PT activities – All sites and locations, including external service providers – Appropriate access controls in place – Appropriate separation between neighbouring areas in which there are incompatible PT activities • Environmental conditions impacting the validity of PT activities documented, controlled, monitored/recorded and periodically reviewed

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Resource requirements - externally provided products and services

- Three activities that will not be undertaken by an external service provider
  - Design and planning of PT schemes
  - Evaluation of performance
  - Authorization of reports
- Procedures in place to ensure experience and technical competence of external providers of products and services
- PT participants will be informed in advance and in writing of products and services that are/can be provided externally if they can impact validity of the PT services
- Procedures and retained records for managing external product and service providers
- Responsible to the participants for the externally provided products and services

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Process requirements

- The PT provider will have process procedures in place to manage:

Establishing, contracting and communicating the PT scheme objectives	Design and planning of a PT scheme	Production and distribution of PT items
Evaluation and reporting of PT scheme results	Control of the PT scheme process	Handling of complaints and appeals

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Establishing, contracting and communicating the PT scheme objectives

Review of requests, tenders and contracts

- Review procedure will have addressed the following questions:
  - Are the objectives defined and do they meet the customer needs?
  - Are the requirements defined, documented and understood?
  - Is sufficient capability and resources to meet the requirements?
  - Is the PT scheme technically appropriate?
- Simplified when the PT scheme is fully described in documentation for routine PT rounds

PT scheme communication

- Detailed information will be available:
  - Objectives and relevant details of the PT scheme
  - Criteria to be met for participation
  - Confidentiality arrangements
  - Critical timelines
  - Any fees for participation
  - Details of how to apply
- Any changes to PT scheme design or operation will be communicated to the participants

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Design & planning

- All activities which directly affect the validity of the PT scheme will have been identified, designed and planed
  - A documented plan will have been developed addressing the objectives, purpose and design
  - Risks to the validity of the PT scheme will be identified and manged whenever significant changes to activities are introduced
- Statistical designs will have been developed to meet the objectives of the PT scheme
  - Statistical design and data analysis methods used to determine the assigned value and evaluate participant results will be documented
  - The statistical assumptions will be demonstrated to be reasonable
- Will have a documented procedure for determining the assigned values taking account of the required metrological traceability and uncertainty

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Statistical design considerations

- Accuracy, as well as the uncertainty, required or expected for the assigned values
- Minimum number of participants needed to meet the objectives
- Number of significant figures or decimal places to be reported
- Number of PT items to be measured/tested and the number of repeat measurements/tests
- Procedures to establish the evaluation criteria
- How to treat results from non-technically equivalent methods
- Whether the measurement uncertainty of participant results to be reported and how it will be used to evaluate the participant's performance
- How to identify or handle outliers, or both
- Procedures for the evaluation of values excluded from statistical analysis
- Objectives to be met for the design and the frequency of PT rounds

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Production and distribution of PT items

- Procedures in place to ensure PT items are produced in accordance with the plan and fit for purpose
  - PT items should usually match laboratory routine samples
  - Both real or simulated PT items might be used
- Criteria for suitable homogeneity and stability will have been established based on the risks to impact the evaluation of participant performance
- Appropriate handling, storage and shipment of PT items will be in place from production to distribution
  - Prevent contamination, damage or deterioration
  - Meet national, regional, or international safety and transport requirements
- Participants will be given sufficient notice when they will receive the PT items
- Participants will receive detailed documented instructions on handling and treating PT items, and the reporting of results

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Evaluation and reporting of PT scheme results

- Participant results will be recorded and analysed by appropriate methods
  - Summary statistics and performance statistics and associated information consistent with the statistical design will be generated
  - Procedures to handle outliers, results from different methods and results inappropriate for statistical evaluation will be in place
- Valid documented methods of performance evaluation will be used that meet the objectives of the PT scheme
  - Examples of valid methods of evaluation are described in ISO 13528, also summarised in Annex B of ISO/IEC 17043
  - Expert commentary to be provided, where applicable, on participant performance
- The PT provider needs to provide clear, accurate, objective, comprehensive and controlled PT reports to the participants within planned timescales
  - ISO/IEC 17043 lists a long list of information that must be included

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Control of the PT scheme process

- The PT provider will maintain controlled technical records
  - Results, reports and other necessary information
  - Date and the identity of personnel responsible for each PT activity and for checking data and results
  - Data used to verify the PT items, instructions to participants, the original responses of participants and any other information included in reports
- The PT software and other information systems will have been validated for functionality and maintained to ensure integrity of the data and information
- A procedure will be in place to ensure sufficient surveillance of the processes to ensure the validity of the PT scheme
- A documented procedure to address nonconforming work will be in place
- A documented procedure for the handling of complaints and appeals will be in place and available to participants

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Management system requirements

- Documented management system will have been implemented to fulfil requirements of ISO/IEC 17043 and scope of PT activities
- The PT provider may have met the management system requirements by establishing, implementing and maintaining a quality management system
  - e.g., in accordance with the requirements of ISO 9001.
  - Needs to support and demonstrate the consistent fulfilment of the requirements of ISO/IEC 17043
- To include:
  - Policies
  - Responsibilities
  - Management system documentation
  - Control of management system documents
  - Control of records
  - Actions to address risks and opportunities
  - Improvement
  - Corrective actions
  - Internal audits
  - Management reviews

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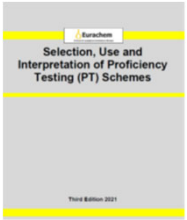
Concluding remarks



- PT is a powerful and essential quality assurance tool for laboratories
  - Reflects the laboratory's actual quality
- Enables a laboratory to monitor and improve the quality of its measurements
  - A key requirement of ISO/IEC 17025 and ISO 15189
- Participating in PT schemes is an essential requirement for any laboratory wishing to ensure and demonstrate the validity of their measurements
- The Eurachem PT Guide provides valuable advice to laboratories on the use, selection and interpretation of PT schemes
- The international standard ISO/IEC 17043 provides the framework for assessing the competency of the providers of the PT schemes
- Accreditation to ISO/IEC 17043 gives confidence to laboratories that the PT scheme conforms to the standard

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Concluding remarks

- By participating in a PT scheme managed and operated by a PT provider in compliance with ISO/IEC 17043, a participating laboratory can be confident that:
  - The PT scheme is operated impartially with all information kept confidential
  - The PT provider is appropriately structured with sufficient and competent personnel and other resources to undertake the necessary PT activities
  - All activities that directly affect the validity of the PT scheme will have been identified, designed and planned
  - All PT items distributed will be fit for purpose to meet the objectives of the PT scheme
  - The evaluation of all participant results will be undertaken using appropriate statistical approaches using validated software and other information systems
  - The PT reports produced by the PT provider will be clear, accurate and objective, providing the necessary information to understand the performance evaluation
  - All processes will be controlled and kept under surveillance
  - The PT provider will have a comprehensive and documented management system in place

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Thank you for your attention