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Maximizing the Use of Proficiency Testing

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Overview

- PT to meet established requirements
- PT participation strategy
- PT to demonstrate personal qualification
- PT to verify methods
- PT to verify measurement uncertainty
- PT as a risk management tool

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PT as a requirement

ISO/IEC 17025	ISO 15189
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.	**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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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?

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

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
• 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?	• 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?	• 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?	• 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?	• 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?	• 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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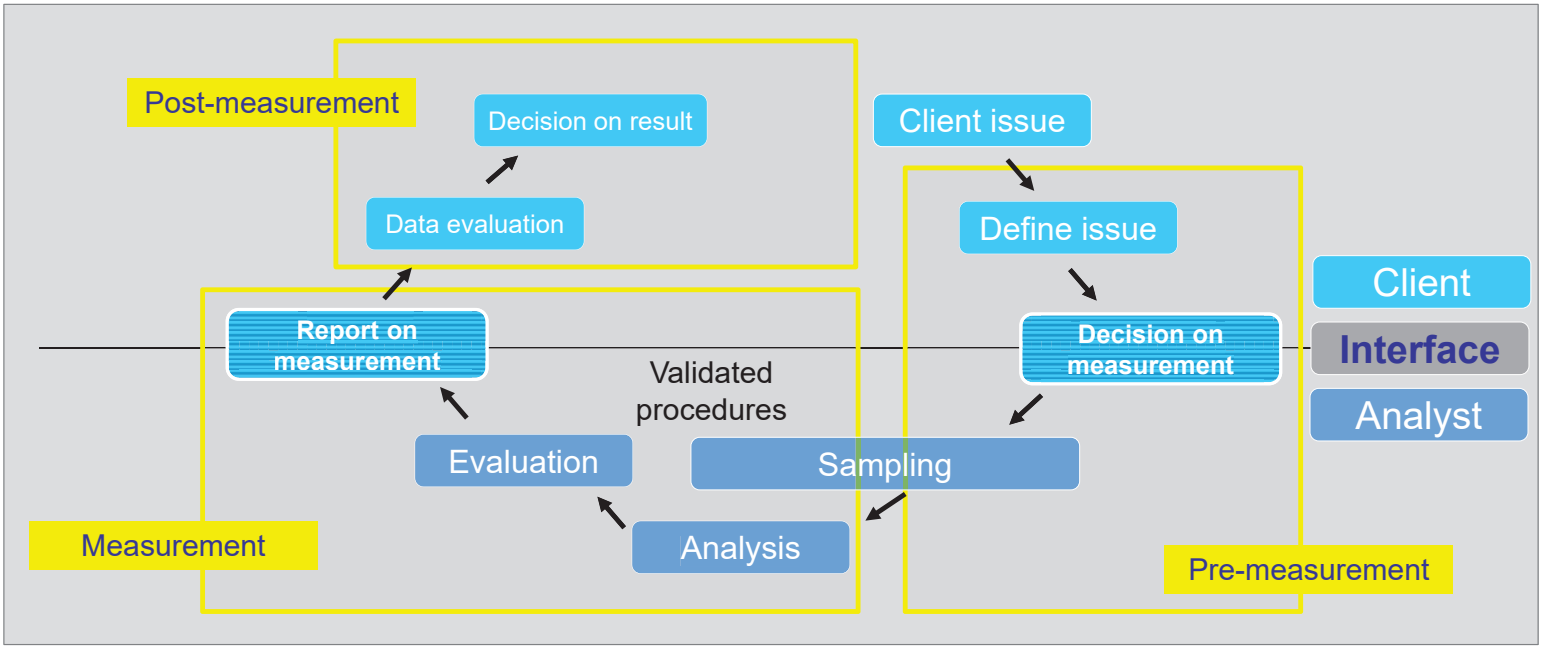
The measurement cycle



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Trends in PT performance

- Trends are valuable in preventive and corrective actions, and root cause analysis
- Trending can serve as an early warning system

Performance over time	Performance of analysts / sites	Performance of methods	Assigned value analysis	Common groups of characteristics

The value of trending

Performance scores provide guidance to a laboratory as to when to take action

Laboratories are advised to take action following :

An unsatisfactory result

Consecutive questionable results (for the same measurement)

Consecutive results with the same bias against the assigned value

The cause of such results should be investigated

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Benefits of PT

Identifying measurement problems	Comparing measurement procedures	Comparing operator capabilities	Comparing analytical systems
Improving performance	Educating staff	Exchange of information with the PT provider	Instilling confidence
Supporting measurement uncertainty estimation	Provision of IQC materials	Determining measurement precision and/or trueness	Satisfying regulators and accreditation bodies

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Requirements for staff competency

ISO/IEC 17025	
6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. **6.2.3** The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.	**6.2.5** The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring competence of personnel.

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PT to demonstrate competency and effectiveness of training

When

- After new-hire training
- Periodic rechecks
- After method or procedure modifications
- After any new or re-training
- After any issue (e.g., inaccurate result is identified)

How

- ✓ Rotating PT through all analysts
- ✓✓ All analysts receive their own PT item to test each round
- Considerations: PT frequency; number of results that can be reported; cost of additional PT items

Making it work on your schedule

- New hire training may not align with PT schedule:
  - Use repeat/troubleshooting or surplus PT items – known sample
  - Then enrol in next available PT round – unknown sample
- Similar steps can be followed for as needed for retraining, issue identification, new methods/instruments, etc.

Requirements for method verification

ISO/IEC 17025

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

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PT for method verification

When

- Implementation of a new method
- To ensure method performance is comparable, fit-for-purpose
- Verification of any method modifications
- Verification of a new instrument, component, etc.

How

- ✓ Rotating PT through all methods
- ✓✓ PT for every method, every round
- ✓✓✓ PT for every method and each instrument, every round
- Considerations: PT frequency; number of results that can be reported; cost of additional PT items

Making it work on your schedule

- New method/instrument installation may not align with PT schedule
  - Use repeat/troubleshooting or surplus PT items – known sample
  - Then enrol in next available PT round – unknown sample
- Similar steps can be followed for recalibrations, method modifications, troubleshooting, etc.

Requirements regarding measurement uncertainty

ISO/IEC 17025
7.6 Evaluation of measurement uncertainty **7.6.1** Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis. **7.6.3** A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

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PT & Measurement Uncertainty

- Data from PT participation can assist in two ways:
  - To check the laboratory's estimated measurement uncertainty
  - To assist in estimating the laboratory's measurement uncertainty

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PT & Measurement Uncertainty

Advantages of using PT data

- Will cover a wide range of well characterized materials
- Specific to the relevant field of measurement
- Often more similar to routine test samples than a CRM

Disadvantage of using PT data

- Lack of traceable reference values similar to those for CRMs

Key conditions of PT data use

- PT items representative of routine test samples
  - Matrix/Concentration
- Assigned values have an appropriate uncertainty
- Minimum of 6 rounds over appropriate time period
- Number of participants sufficient for a consensus value

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Using PT to Check Uncertainty Estimates

- Use of the zeta (ζ) score

$$\zeta = (x_i - x_{pt}) / \sqrt{u(x_i)^2 + u(x_{pt})^2}$$

Where:

x_i is the individual result
x_{pt} is the assigned value
$u(x_i)$ is the laboratory's estimate of the standard uncertainty of its result
$u(x_{pt})$ is the standard uncertainty of the assigned value

$\lvert\zeta\rvert \le 2$	Satisfactory
$2 < \lvert\zeta\rvert < 3$	Questionable
$\lvert\zeta\rvert \ge 3$	Unsatisfactory

If *zeta* scores are outside the acceptable range, this shows that the laboratory is not able to fulfil its own requirements

- Measurement uncertainty is underestimated

Using PT to Check Uncertainty Estimates

- Direct comparison - the standard measurement uncertainty of a laboratory result:
  - Can be expected to be lower than the reproducibility observed in the proficiency test
  - Would be expected to be comparable with the spread of results obtain by the laboratory over a number of PT rounds
  - If it is much lower, the uncertainty estimate should be reviewed

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Using PT to Evaluate Uncertainty Estimates

- Use in calculating bias component of uncertainty estimate
  - Calculate the bias of results from assigned value over at least 6 rounds of the PT for a specific method in a reasonable time interval
  - Combined uncertainty then calculated from this bias component and the within laboratory reproducibility
  - Converted to expanded uncertainty
- Directly use the reproducibility standard deviation from at least 6 rounds of a PT based on a specific method
  - Uses the value, converted to an expanded uncertainty as an estimate of the combined uncertainty

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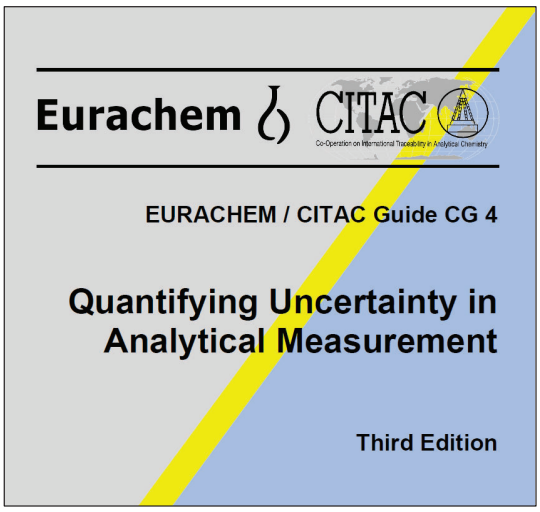
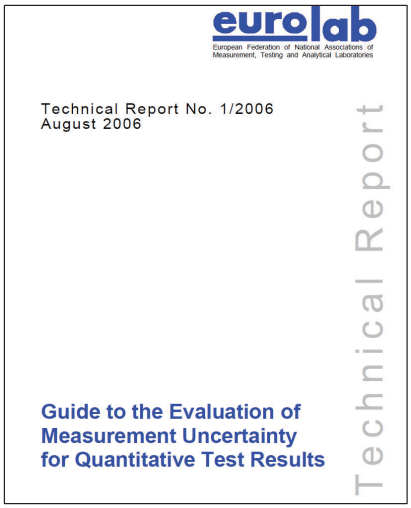
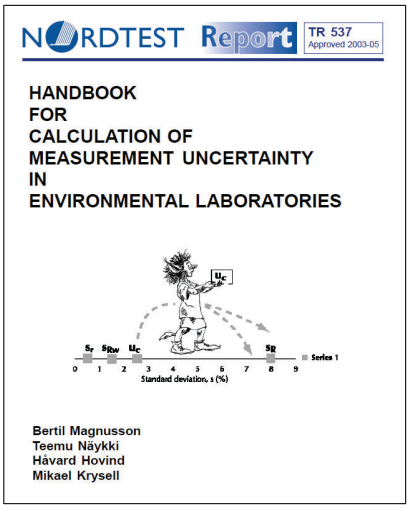
Using PT to Evaluate Uncertainty Estimates

Key References







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Requirements Regarding Risk Management

ISO/IEC 17025

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:
a) give assurance that the management system achieves its intended results;
b) enhance opportunities to achieve the purpose and objectives of the laboratory;
c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
d) achieve improvement.

8.5.2 The laboratory shall plan:
a) actions to address these risks and opportunities;
b) how to integrate and implement these actions into its management system;
c) How to evaluate the effectiveness of these actions

PT as a Risk Management Tool

- Thus, in planning to take account of risks and opportunities of its activities, a laboratory needs to evaluate its use of PT:
  - How Much?
  - How Often?
- Links to the PT participation strategy

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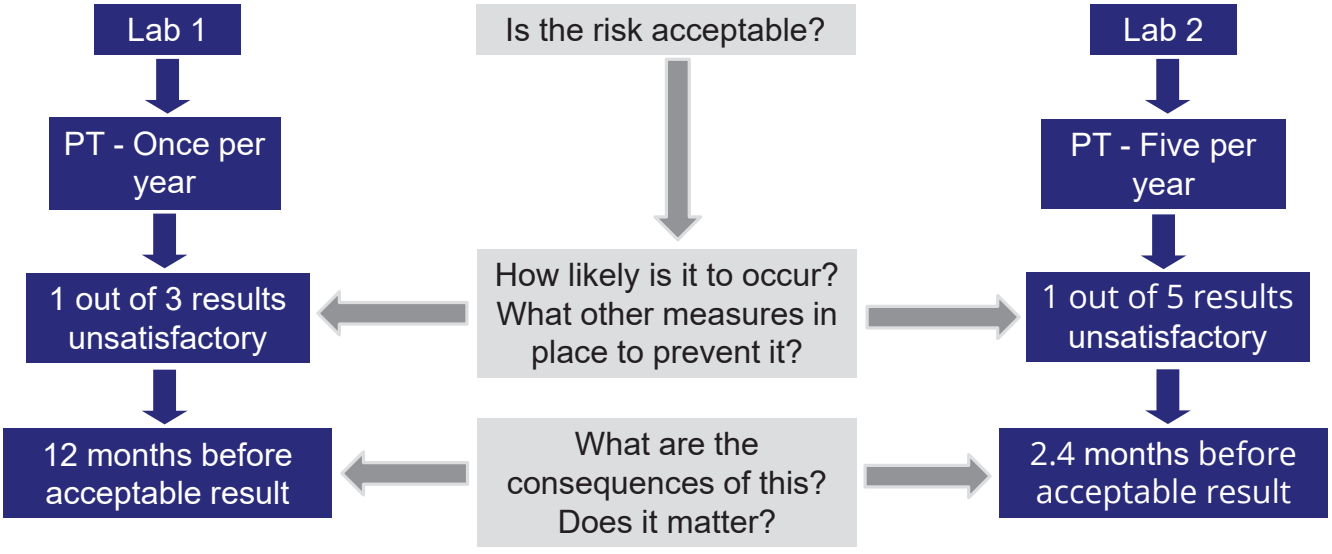
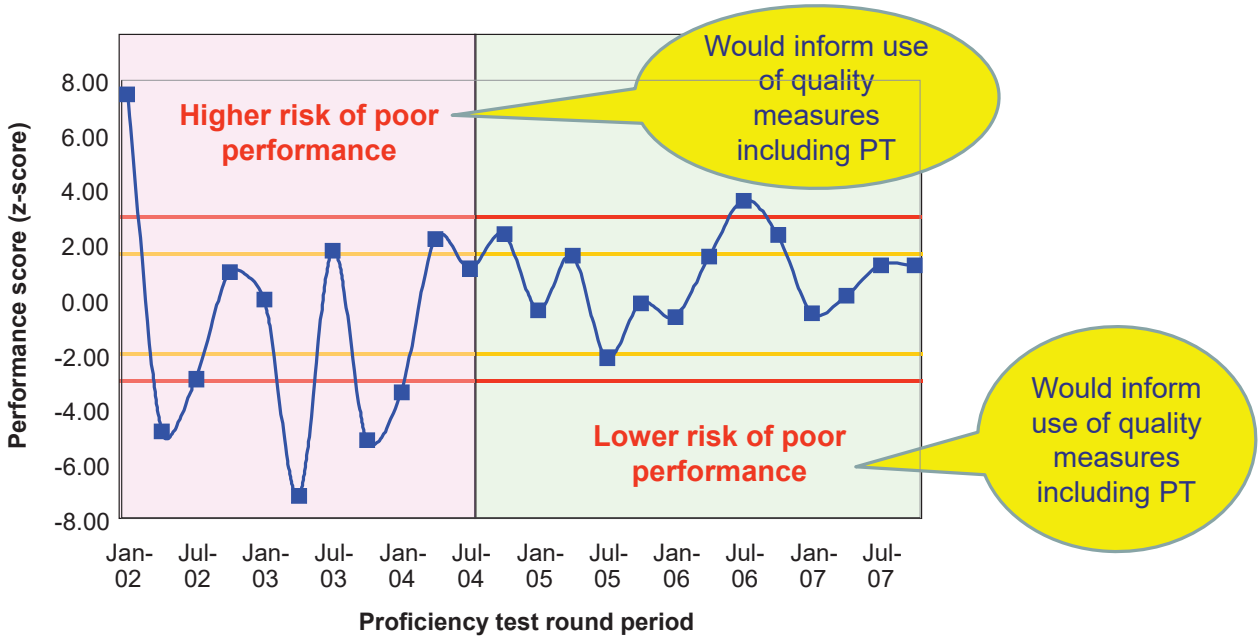
Analysis of Risk



Analysis of Risk



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In Conclusion

- Proficiency Testing is a very beneficial quality assurance tool
- Fundamentally in provides an independent comparison of the performance of a laboratory with other laboratories
  - As required by ISO/IEC 17025 and ISO 15189
- However, PT participation brings many other benefits, many of which can assist laboratories in implementing other requirements of ISO/IEC 17025 and ISO 15189
- To maximise the use and benefits of PT, it is important to establish an appropriate participation strategy and select the most appropriate PT schemes in which to participate

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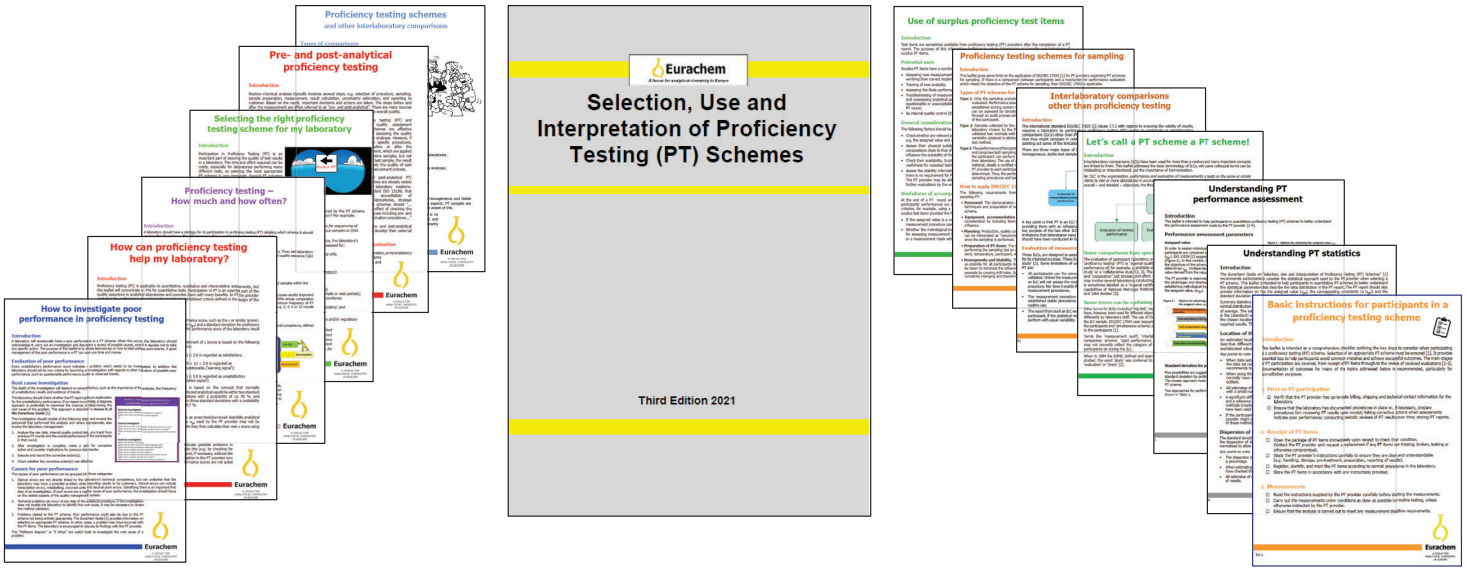
Eurachem PT Publications



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Thank you for your attention