


กระทรวงสาธารณสุข
DEPARTMENT OF MEDICAL SCIENCES

Proficiency Testing Provider

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Outline

- **ISO/IEC 17043: 2010**
- **BDN as Proficiency Testing Provider**
- **PT provider: Procedure**

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Proficiency Testing (PT)

- a form of external assessment of quality assurance system
- a mechanism to evaluate laboratory's performance in comparison to other participants' performance


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Purposes of Proficiency Testing

- To determine the competency of individual laboratories in performing specific tests or measurements
- To monitor laboratories' continuing performance


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**International Standards for
Proficiency Testing Provider (PTP)**

- **ISO/IEC 17043:2010**
Conformity assessment- General requirements for proficiency testing
- **ISO 13528:2015 (E)**
Statistical methods for use in proficiency testing by inter-laboratory comparisons

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ISO/IEC 17043:2010

Conformity assessment-

General requirements for proficiency testing

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Introduction

Interlaboratory comparisons:

Typical purposes involved in PT

- a) Evaluation of the performance of laboratories for specific tests or measurements and monitoring laboratories' continuing performance
- b) Identification of problems in laboratories and initiation of actions for improvements
- c) Establishment of the effectiveness and comparability of test or measurement methods
- d) Provision of additional confidence to laboratory customers

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Introduction

Interlaboratory comparisons:

Typical purposes involved in PT

- e) Identification of interlaboratory differences
- f) Education of participating laboratories based on the outcome of such comparisons
- g) Validation of uncertainty claims

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Terms and definitions

Proficiency testing –

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

Proficiency testing scheme –

PT designed and operated for a specified area of testing

Proficiency testing provider –

organization which takes responsibility for all tasks in the operation of a PT scheme

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Terms and definitions

Coordinator –

One with responsibility for organizing and managing all of the activities involved in the operation of PT scheme

Participant –

laboratory, organization or individual that receives PT items and submits results for review by PT provider

Subcontractor –

organization or individual engaged by PTP to perform activities specified in this ISO and that affect the quality of a PT scheme

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5. Management requirements

- 5.1 Organization
- 5.2 Management system
- 5.3 Document control
- 5.4 Review of requests, tenders and contracts.
- 5.5 Subcontracting services
- 5.6 Purchasing services and suppliers
- 5.7 Service to the customer
- 5.8 Complaints and appeals
- 5.9 Control of nonconforming work
- 5.10 Improvement
- 5.11 Corrective actions
- 5.12 Preventive actions
- 5.13 Control of records
- 5.14 Internal audits
- 5.15 Management reviews

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5.1 Organization

- PTP – organization or part of an organization legally, identifiable and accountable
- if part of an organization, identify the responsibilities of key personnel, in order to identify potential conflicts of interest
 - have policies and procedures to ensure the protection of participants' confidential information
 - define the organization and management structure and the relationships between quality management, technical operations and support services

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5.2 Management system

Quality manual

- quality policy statement
 - * management's commitment to the quality of PT services
 - * management's statement of standard of service
 - * purpose of the management system related to quality
 - * requirement that all personnel familiarize with the quality documentation and implement the policies and procedures in their work
 - * management's commitment to comply with ISO/IEC 17043 and continually improve the effectiveness of the management system

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5.2 Management system

Quality manual

- include the supporting procedure and technical procedure, outline the structure used in management system
- define roles and responsibilities of technical management and quality manager complied with ISO/IEC 17043

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5.3 Document control

Documents

- be reviewed and approved for use by authorized personnel prior to issue.
- be available at all locations where activities of PT schemes are performed
- be reviewed and approved by the same function that performed the original review and approval, if changes to document

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5.4 Review of requests, tenders and contracts

- policies and procedures should be established and maintained.
- review should ensure
 - * the requirements are adequately defined, documented and understood.
 - * PTP has capability and resources to meet the requirements
 - * PT scheme is technically appropriate.

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5.5 Subcontracting services

- PTP shall demonstrate that subcontractors' experiences and technical competence are sufficient for their assigned tasks.
- PTP shall not subcontract
 - * planning of PT scheme
 - * evaluation of performance
 - * authorization of final report
- PTP shall inform participants of services that are subcontracted.

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5.6 Purchasing services and supplies

- PTP shall have a policy and procedure for the selection of services and supplies that affect the quality of PT scheme.
- PTP shall ensure that purchased supplies, equipment and consumable materials are not used until they have been inspected or verified as complying with specifications or requirements.
- PTP shall evaluate suppliers of critical supplies and services which affect the quality of PT scheme.

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5.7 Service to the customer

- PTP shall be willing to cooperate with participants and other customers in clarifying customers' requests and in monitoring PTP's performance.
- PTP shall seek feedback, both positive and negative from customers to improve the management system.

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5.8 Complaints and appeals

- PTP shall have a policy and follow a procedure for the resolution of complaints and appeals received from participant.
- Records shall be maintained of all complaints appeals, investigations and corrective actions taken by PTP.


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5.9 Control of nonconforming work

- The policy and procedure shall ensure that
 - * responsibility and authorities for the management of nonconforming work are designated and actions are defined and taken when nonconforming work is identified.
 - * evaluation of the significance of the nonconforming work is made.
 - * decision on the need for action and timescale is taken immediately.
 - * participants are informed and the nonconforming PT sample or reports already sent to participants are recalled or disregarded.
 - * responsibility for authorization of the resumption of work is defined


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5.10 Improvement

- PTP shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

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5.11 Corrective actions

- PTP shall establish a policy and procedure for implementing corrective actions when nonconforming works have been identified.
- procedure for corrective action shall start with an investigation to determine the root cause of the problem.
- select and implement the actions to eliminate the problem and prevent recurrence
- PTP shall monitor the results to ensure that the corrective actions taken have been effective.

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5.13 Control of records

General :

- PTP shall establish and maintain procedures for control of records.
- all records shall be legible and be stored and retained to prevent damage and loss.
- all records shall be kept secure and confidential.
- records should be protected, electronically back-up and prevented from unauthorized access and amendment

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5.13 Control of records

Technical records :

- PTP shall retain records of all technical data for a defined period.
- Data entry, checking and calculation shall be recorded at the time they are made and shall be identifiable to the specific task and to the personnel responsible.
- Correction of records, action shall be taken to
 - * identify the change and data alteration
 - * avoid loss of original data
 - * identify the person making the alteration

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5.14 Internal audits

- Internal audit program shall address
 - * all elements of the management system
 - * technical procedure
 - * PT sample preparation, storage and distribution
 - * reporting activities for the operation of a PT scheme
- It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.
- Internal audits shall be carried out by trained and qualified personnel.
- Audit findings should be recorded.

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5.15 Management reviews

- PT's top management shall periodically conduct a review of the PTP's management system and PT activities.
- The review shall take account of
 - * suitability of policies and procedure
 - * reports from management and supervisory personnel
 - * outcome of recent internal audits
 - * corrective and preventive action
 - * assessments by external bodies
 - * changes in the volume and type of work
 - * customer, advisory group or participant feedback
 - * complaint and appeals
 - * recommendation for improvement
 - * other relevant factors, such as resources and staff training


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4. Technical requirements

- 4.1 General
- 4.2 Personnel
- 4.3 Equipment, accommodation and environment
- 4.4 Design of proficiency testing schemes
- 4.5 Choice of method or procedure
- 4.6 Operation of proficiency testing schemes
- 4.7 Data analysis and evaluation of proficiency testing scheme results
- 4.8 Reports
- 4.9 Communication with participants
- 4.10 Confidentiality

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4.1 General

PT provider, undertaking the development and operation of PT schemes shall have:

- competence to conduct interlaboratory comparisons
- access to expertise with particular type of PT items

ISO/IEC 17025 can be used to demonstrate the competence of a PTP's laboratory to perform tests related to the PT schemes.

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4.2 Personnel

- PTP shall have managerial and technical personnel with necessary
 - * authority
 - * resources
 - * technical competency to perform duties
- PTP's management shall define the minimum levels of qualification and experience necessary for the key positions within its organization and ensure those qualifications are met.

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4.2 Personnel

The PT provider shall authorize specific personnel to:

- a) select appropriate proficiency test items
- b) plan proficiency testing schemes**
- c) perform particular types of sampling
- d) operate specific equipment
- e) conduct measurements to determine stability and homogeneity, as well as assigned values and associated uncertainties of the measurands of the PT item
- f) prepare, handle and distribute PT items
- g) operate the data processing system
- h) conduct statistical analysis
- i) evaluate the performance of proficiency testing participants**
- j) give opinions and interpretations; and
- k) authorize the issue of proficiency testing reports**

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4.2 Personnel

– The PT provider shall maintain up-to-date records, for all technical personnel, including contracted personnel.

Up-to-date records of relevant:

- authorization (s)
- competence
- educational and professional qualifications
- training, skills and experience

– This information shall be readily available and shall include the date on which competence to perform their assigned tasks was assessed and confirmed.

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4.2 Personnel

- PTP shall have a policy and procedures for
 - * identifying training needs
 - * providing training of personnel

- The PT Provider shall ensure that
 - * staff receive the necessary training to ensure competency in performance of measurements
 - * operation of equipment
 - * any other activities which affect the quality of the PT scheme

The effectiveness of training activities shall be evaluated

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4.3 Equipment, accommodation and environment

- The PT Provider shall ensure appropriate accommodation for the operation of PT scheme including facilities and equipment for
 - * proficiency testing item
 - * manufacturing handling, calibration, testing, storage and dispatch
 - * data processing
 - * communications
 - * retrieval of materials and records

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4.3 Equipment, accommodation and environment

- PTP shall ensure that the environmental conditions do not:
 - * compromise the proficiency testing scheme
 - * the required quality of operation

Particular care shall be taken when:

- * operations are undertaken at sites away from PTP's permanent facilities or operations are undertaken by subcontractors

The technical requirements shall be documented for accommodation & environmental conditions that can affect the PT.

- Access to and use of areas shall be controlled if it affects quality of PT.

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4.3 Equipment, accommodation and environment

- PTP shall identify environmental conditions that can significantly influence the quality of the PT items.
- PTP shall control and monitor these conditions and record all relevant monitoring activities.
- Relevant PT activities shall be stopped when the environmental conditions jeopardize the quality or the operations of the PT scheme.
- Action shall be taken to prevent cross-contamination from incompatible activities.
- PTP shall ensure the performance characteristics of laboratory methods and equipment used to confirm the content, homogeneity and stability of PT items are appropriately validated and maintained.

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4.4 Design of proficiency schemes

Planning

- PTP shall identify and plan those processes which directly affect the quality of PT scheme and ensure that they are carried out in accordance with prescribed procedures.
- PTP shall not subcontract the planning of the PT scheme.*
- PTP shall document a plan before commencement of the PT scheme that address the objectives, purpose and basic design of the PT scheme.

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4.4 Design of proficiency schemes

Plan shall include the following information

- a) name and address of the PTP
- b) name, address and affiliation of the coordinator and other personnel involved in the design and operation of the PT scheme
- c) the activities to be subcontracted and the names and addresses of subcontractors involved in the operation of the PT scheme
- d) criteria to be met for participation

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4.4 Design of proficiency schemes

- e) the number and type of expected participants in the PT scheme
- f) selection of the measurand and or characteristic of interest, including information on what the participants are to identify, measure, or test for in the specific PT round
- g) a description of the range of values or characteristics, or both, to be expected for the PT items
- h) the potential major sources of errors involved in the area of PT offered
- i) requirements for the production, quality control, storage and distribution of PT items

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4.4 Design of proficiency schemes

- j) reasonable precautions to prevent collusion between participants or falsification results, and procedures to be employed if collusion or falsification of results is suspected
- k) a description of the information which is to be supplied to participants and the time schedule for the various phases of the PT scheme
- l) for continuous PT schemes, the frequency or dates upon which PT items are to be distributed to participants, the deadlines for the return of results by participants and , where appropriate, the dates on which testing or measurement is to be carried out by participants

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4.4 Design of proficiency schemes

- m) any information on methods or procedures which participants need to use to prepare the test material and perform the tests or measurements
- n) procedures for the test or measurement methods to be used for the homogeneity and stability testing of PT items and, where applicable, to determine their biological viability
- o) preparation of any standardized reporting formats to be used by participants
- p) a detailed description of the statistical analysis to be used
- q) the origin, metrological traceability and measurement uncertainty of any assigned values

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4.4 Design of proficiency schemes

- r) criteria for the evaluation of performance of participants
- s) a description of the data, interim reports or information to be returned to participants
- t) a description of the extent to which participant and results, and the conclusions that will be based on the outcome of the PT Scheme are to be made public
- u) actions to be taken in the case of lost or damaged PT items

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4.4 Design of proficiency schemes

- PT Provider shall have access to the necessary technical expertise experience in the relevant field of testing, calibration, sampling or inspection as well as statistics. This may be achieved, if necessary, by establishing an advisory group.
- Technical expertise shall be used to determine matters such as the following:
 - a) planning requirements
 - b) identification and resolution of any difficulties expected in
 - * the preparation and maintenance of homogeneous PT items, or
 - * the provision of a stable assigned value for a PT item
 - c) preparation of detailed instructions for participants

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4.4 Design of proficiency schemes

- d) comments on
 - * any technical difficulties or
 - * other remarks raised by participants in previous PT rounds
- e) provision of advice in evaluating the performance of participants
- f) comments on the results and performance of participants
- g) provision of advice for participants
- h) responding to feedback from participants
- i) planning or participating in technical meetings with participants

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4.4 Design of proficiency schemes

Preparation of PT items

- PTP shall establish and implement procedure in accordance with the plan.
- PT items should match in terms of matrix, measurands and concentrations, the type of items encountered in routine testing.

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4.4 Design of proficiency schemes

Homogeneity and stability

- Criteria for suitable homogeneity and stability shall be established and shall be based on the effect that inhomogeneity and instability will have on the evaluation of the participants' performance.
- The procedures for the assessment of homogeneity and stability shall be documented and conducted, where applicable, in accordance with appropriate statistical designs. Where possible, the PTP of a representative number of PT items from the whole batch of test material in order to assess the homogeneity of the material.

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4.4 Design of proficiency schemes

Homogeneity and stability

- The **assessment of homogeneity shall normally be performed after the PT items have been packaged in the final form and before distribution to participants** unless, for example, stability studies indicate that they should be stored in bulk form.
- PT items shall be demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the PT, including **storage and transport conditions**. When this is not possible, the stability shall be quantified and considered as an additional component of the measurement uncertainty associated with the assigned value of the PT item, and/or taken into account in the evaluation criteria.

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4.4 Design of proficiency schemes

Homogeneity and stability

- When PT items from previous rounds are retained for future use, the property values to be determined in the PT scheme shall be confirmed by PTP prior to distribution.
- In circumstances where homogeneity and stability testing is not feasible, PTP shall demonstrate that the procedures used to collect, produce, package and distribute the PT items are sufficient for the purpose of the PT.

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4.4 Design of proficiency schemes

Statistical design

- Statistical designs shall be developed to meet the objectives of the scheme, based on the nature of the data (quantitative or qualitative, including ordinal and categorical), statistical assumptions, the nature of errors, and the expected number of results
- PTP shall document the statistical design and data analysis methods to be used to identify the assigned value and evaluate participant results, and shall provide a description of the reasons for their selection and assumptions upon which they are based. PTP shall be able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures.

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4.4 Design of proficiency schemes

Statistical design

- In designing a statistical analysis, PTP shall give careful consideration to the following:
 - a) the accuracy (trueness and precision) as well as the measurement uncertainty required or expected for each measure and or characteristic in the PT;
 - b) the **minimum number of participants** in the PT scheme needed to meet the objectives of the statistical design; in cases where there is an insufficient number of participants to meet these objectives or to produce statistically meaningful analysis of results, PTP shall document, and provide to participants, details of the alternative approaches used to assess participant performance;
 - c) the relevance of significant figures to the reported result, including the **number of decimal places**;

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4.4 Design of proficiency schemes

Statistical design

- d) the number of PT items to be tested or measured and the number of repeat tests, calibrations or measurements to be conducted on each PT item or for each determination;
- e) The procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria;
- f) procedures to be used to identify or handle outliers, or both;
- g) where relevant, the procedures for the evaluation of values excluded from statistical analysis; and
- h) where appropriate, the objectives to be met for the design and the frequency of PT rounds.

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4.4 Design of proficiency schemes

Assigned value

- PTP shall document the procedure for determining the assigned values for the measurands or characteristics in a particular PT scheme. This procedure shall take into account the metrological traceability and measurement uncertainty required to demonstrate that the PT scheme is fit for its purpose.
- When a consensus value is used as the assigned value (see Annex B), PTP shall document the reason for that selection and shall estimate the uncertainty of the assigned value as described in the plan for the PT scheme.
- PTP shall have a policy regarding the disclosure of assigned values. The policy shall ensure that participants cannot gain advantage from early disclosure.

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4.5 Choice of method or procedure

- Participants shall normally be expected to use the test method, calibration of measurement procedure of their choice, which should be consistent with their routine procedures. PTP may instruct participants to use a specified method in accordance with the design of the PT scheme.
- Where participants are permitted to use a method of their choice, the PTP shall:
 - a) have a policy and follow a procedure regarding comparison of results obtained by different test or measurement methods;
 - b) be aware of which different test or measurement methods for any measurand are technically equivalent, and take steps to assess participants' results using these methods accordingly.

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4.6 Operation of proficiency schemes

Instructions for participants

- PTP shall give participants sufficient prior notice before sending PT items provide the date on which the PT items are likely to arrive or to be despatched unless the design of the PT scheme makes it inappropriate to do so.
- PTP shall give detailed documented instructions to all participants.
Instructions to participants shall include:
 - a) the necessity to treat PT items in the same manner as the majority of routinely tested samples (unless there are particular requirements of the PT scheme which require departure from this principle

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4.6 Operation of proficiency schemes

Instructions for participants

- b) details of factors which could influence the testing or calibration of the PT items, e.g. the nature of the PT items, conditions of storage, whether the PT scheme is limited to selected test methods, and the timing of the testing or measurement
- c) detailed procedure for preparing or conditioning, or both preparing and conditioning of PT items before conducting the tests or calibrations
- d) any appropriate instructions on handling the PT items, including and safety requirements
- e) any specific environmental conditions for the participant to conduct tests or calibrations, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement

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4.6 Operation of proficiency schemes

Instructions for participants

- f) specific and detailed instructions on the manner of recording and test or reporting measurement results and associated uncertainties if the instructions include reporting of the uncertainty of the reported result or measurement, this shall include the coverage factor and, whenever practicable, the coverage probability
- g) the latest date for the provider to receive the PT or measurement results for analysis
- h) on the contact details of the PTP for enquiries; and
- i) Instructions on return of the PT items, when applicable

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4.6 Operation of proficiency schemes

Proficiency test items handling and storage

- PTP shall ensure that the PT items are appropriately identified and segregated and cannot become contaminated or degraded, from the time of preparation to their distribution to participants.
- PTP shall provide secure storage areas or stock rooms, or both prevent damage or deterioration of any PT item between preparation and distribution. Appropriate procedures for authorizing despatch to, and receipt from, such areas shall be defined.
- When appropriate, the condition of stored or stocked PT items, chemicals and materials shall be assessed at specified intervals during their storage life in order to detect possible deterioration.
- Where potentially hazardous PT items, chemicals and materials are used, facilities shall be available to ensure their safe handling, decontamination and disposal.

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4.6 Operation of proficiency schemes

Packaging, labelling and distribution of proficiency test items

- PTP shall control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements.
- PTP shall specify relevant environmental conditions for the transport of PT items. Where relevant, PTP shall monitor the pertinent environmental conditions of the PT item during transport and assess the impact of environmental influences on the PT item.
- PTP shall ensure that labels are securely attached to the packaging of individual PT items and are designed to remain legible and intact throughout the PT round.
- PTP shall follow a procedure to enable the confirmation of delivery of the PT items

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4.7 Data analysis and evaluation of proficiency testing scheme results

Data analysis and records

- All data processing equipment and software shall **be validated** in accordance with procedures before being brought into use. Computer system maintenance shall include a **black-up process and system recovery plan**. The results of such maintenance and operational checks shall be recorded.
- Results received from participants shall be recorded and analysed by appropriate methods. Procedures shall be established and implemented to **check the validity of data entry, data transfer, statistical analysis, and reporting**.
- The influence of outliers on summary statistics shall be minimized by the use of **robust statistical methods** or appropriate tests to detect statistical outliers.

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4.7 Data analysis and evaluation of proficiency testing scheme results

Data analysis and records

- PTP shall have documented criteria and procedures for dealing with test results that may be inappropriate for statistical evaluation, e.g. miscalculations, transpositions and other gross errors.
- PTP shall have documented criteria and procedures to identify and manage PT items that have been distributed and are subsequently found to be unsuitable for performance evaluation, e.g. because of inhomogeneity, instability, damage or contamination.

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4.7 Data analysis and evaluation of proficiency testing scheme results

Evaluation of performance

- PTP shall use valid methods of evaluation which meet the purpose of the PT scheme. The methods shall be documented and include a description of the basis for the evaluation. **The evaluation of performance shall not be subcontracted.**
- Where appropriate for the purpose of the PT scheme, PTP shall provide expert commentary on the performance of participants with regard to the following:
 - a) overall performance against prior expectations, taking measurement uncertainties into account;
 - b) variation within and between participants, and comparisons with any previous PT rounds, similar PT schemes, or published precision data:

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4.7 Data analysis and evaluation of proficiency testing scheme results

Evaluation of performance

- c) variation between methods or procedures;
- d) possible sources of error (with reference to outliers) and suggestions for improving performance;
- e) advice and educational feedback to participants as part of the continual improvement procedures of participants;
- f) situations where unusual factors make evaluation of results and commentary on performance impossible;
- g) any other suggestions, recommendations or general comments; and
- h) conclusions.

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4.8 Reports

- PT reports shall be clear and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants.
The authorization of the final report shall not be subcontracted.
- Reports shall include the following,
 - a) the name and contact details for PTP;
 - b) the name and contact details for the coordinator;
 - c) the name (s), functions(s), and signature(s) or equivalent identification of person (s) authorizing the report;
 - d) an indication of which activities are subcontracted by PTP;

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4.8 Reports

- e) the date of issue and status (e.g. preliminary, interim, or final) of the report;
- f) page numbers and a clear indication of the end of the report;
- g) a statement of the extent to which results are confidential;
- h) the report number and clear identification of the PT scheme;
- i) a clear description of the PT items used, including necessary details of PT item's preparation and homogeneity and stability assessment;
- j) the participants' results;

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4.8 Reports

- k) statistical data and summaries, including assigned values and range of acceptable results and graphical displays;
- l) procedures used to establish any assigned value;
- m) details of the metrological traceability and measurement uncertainty of any assigned value;
- n) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;
- o) assigned values and summary statistics for test methods/procedures used by each group of participants (if different methods are used by different groups of participants);

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4.8 Reports

- p) comments on participants' performance by PTP and technical advisers;
- q) information about the design and implementation of the PT scheme;
- r) procedures used to statistically analyse the data;
- s) advice on the interpretation of the statistical analysis;
- t) comments or recommendation, based on the outcomes of the PT round.

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4.8 Reports

- Reports shall be made available to participants within planned timescales. In sequential PT schemes, e.g. where the turn-around time may be very long and in schemes involving perishable materials, preliminary or anticipated results may be provided before final results are disclosed.

Note This allows for early investigate of possible error.

- PTP shall have a policy for the use of reports by individuals and organizations.

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4.8 Reports

- When it is necessary to issue a new or amended report for a PT scheme, this shall include the following;
 - a) a unique identification;
 - b) a reference to the original report that it replaces or amends; and
 - c) a statement concerning the reason for the amendment or re-issue.

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4.9 Communication with participants

- PTP shall make detailed information available about the PT scheme. This shall include:
 - a) relevant details of the scope of the PT scheme;
 - b) any fees for participation;
 - c) documented eligibility criteria for participation;
 - d) confidentiality arrangements; and
 - e) details of how to apply.

- Participants shall be advised promptly by the PTP of any changes in PT scheme design or operation.

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4.9 Communication with participants

- There shall be documented procedures for enabling participants to appeal against the evaluation of their performance in a PT scheme. The availability of this process shall be communicated to PT scheme participants.

- Relevant records of communications with participants shall be maintained and retained, as appropriate.

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4.10 Confidentiality

- The identity of participants in a PT scheme shall be confidential and known only to persons involved in the operation of the PT scheme; unless the participant waives confidentiality.
- All information supplied by a participant to the PTP shall be treated as confidential.
- When an interested party requires the PT results to be directly provided by PTP, the participants shall be made aware of the arrangement in advance of participation.
- In exceptional circumstances, when a regulatory authority requires PT results to be directly provided to the authority by PTP. The affected participants shall be notified of this action in writing.