



General Accreditation Guidance

ISO/IEC 17043:2023 Gap analysis in the program of Proficiency Testing Providers

December 2023

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ISO/IEC 17043:2023 Gap analysis

Purpose and background information

This document serves as an informative guide correlating the clauses in ISO/IEC 17043:2023 to the previous 2010 version of the standard.

CASCO is the ISO committee concerned with the development of policy and publishes standards related to conformity assessment, which includes ISO/IEC 17043.

ISO/CASCO specifies the minimal mandatory content of those standards it maintains or develops. This includes the structure and mandatory requirements relating to impartiality, confidentiality, complaints/appeals, and management systems.

ISO/IEC 17043:2023 has adopted the revised structure specified by ISO/CASCO. The structure of the standard is different to the previous version in compliance with CASCO, however requirements are clearer and more direct (simplified).

The main changes compared to the previous edition are as follows:

- Change in the title of the standard;
- Incorporation of ISO/CASCO Common Elements;
 - Includes a risk-based approach in the Management System requirements;
 - Includes a new section on Appeals;
- Harmonisation with ISO/IEC 17025:2017, including technical requirements and structure;
- Harmonisation with ISO 13528:2022 in terms of terminology;
- Inclusion of the requirement that testing activities, calibration activities and PT item production conform to the relevant requirements of appropriate ISO conformity assessment standards;
- Inclusion of other conformity assessment activities in addition to testing and calibration:
 - Recommendation to use other related documents as appropriate (e.g., ISO/IEC 17020 and ISO 15189)
 - Definitions
- Better clarity in wording;
- Revision of Annexes A and B;
- Deletion of Annex C.

ISO/IEC 17043: 2023 Clause No.	Corresponding ISO ISO/IEC 17043:2010 Clause No.	Emphasis of Change	Summary of text/extract from ISO/IEC 17043:2023	Comments
Title				Additional wording - "the competence" and "providers"
Introduction				Additional information about proficiency testing and introduction of risk.
Normative references				Inclusion of ISO/IEC 17025 and ISO 17034
Terms and definitions				Modifications to existing terms and addition/removal of some terms.
4			General requirements	
4.1			Impartiality	
4.1.1	5.1.4		PT activities shall be undertaken impartially.	
4.1.2		New	The PT provider shall be structured and managed so as to safeguard impartiality.	
4.1.3		New	The PT provider shall be responsible for the impartiality of its PT activities and shall not allow commercial, financial or other pressures to compromise its impartiality.	
4.1.4		New	The PT provider shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include the relationships of its personnel.	

4.1.5		New	If a threat to impartiality is identified, its effect shall be eliminated or minimised so that the impartiality is not compromised.	
4.1.6		New	The PT provider shall have top management commitment to impartiality.	
4.2			Confidentiality	
4.2.1		Major	The PT provider shall be responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of PT activities.	
4.2.2	4.10.3; 4.10.4	Minor	When the PT provider is required by law or authorized by contractual arrangements to release confidential information, the client concerned shall be notified of the information released, unless prohibited by law.	
4.2.3	4.10.2	Minor	Information about the participant or customer from a source other than the participant or customer (e.g. complainant or regulator) shall be kept confidential by the PT provider, unless agreed by the source.	
4.2.4	4.10.1	Minor	Personnel, including any committee members, contractors, personnel of external bodies, or persons acting on the PT provider's behalf, shall keep confidential all information obtained or created during the performance of the PT activities.	
4.2.5	4.10.2	Editorial	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 or the customer waives confidentiality.	

5			Structural requirements	
5.1	5.1.1	Editorial	The PT provider shall be a legal entity.	
5.2	5.1.5 i)	Editorial	The PT provider shall identify management that has overall responsibility for the PT activities.	
5.3		New	The PT provider shall define and document the PT schemes for which it conforms with this document. The PT provider shall only claim conformity with this document for those PT schemes.	
5.4	5.1.2, 5.1.3	Minor	The PT provider shall carry out PT activities in such a way so as to meet the requirements of this document and address the requirements of participants, customers, regulatory authorities, and organizations providing recognition.	Inclusion of “organisations providing recognition”
5.5 a)	5.1.5 e)	Editorial	The PT provider shall define its organization and management structure, its place in any parent organization and the relationships between the management, technical operations and support services.	
5.5 b)	5.1.5 f)	Minor	The PT provider shall specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of its PT activities.	
5.5 c)	5.5.1; 5.2.2	Minor	The PT provider shall document its procedures to the extent necessary to ensure the consistent application and validity of its PT activities.	
5.6 a)	5.1.5 a)	Editorial	The PT provider shall have personnel who have the authority and resources needed to carry out	

			implementation, maintenance and improvement of the management system.	
5.6 b)	5.1.5 a)	Editorial	The PT provider shall have personnel who have the authority and resources needed to carry out identification of deviations from the management system or from the procedures while performing the PT activities.	
5.6 c)	5.1.5 a)	Editorial	The PT provider shall have personnel who have the authority and resources needed to carry out initiation of actions to prevent or minimize such deviations.	
5.6 d)	5.1.5 j)	Minor	The PT provider shall have personnel who have the authority and resources needed to carry out reporting to its management on the performance of the management system and any need for improvement.	
5.6 e)		Major	The PT provider shall have personnel who have the authority and resources needed to carry out ensuring the effectiveness of the PT activities.	
5.7a)	5.1.5g); 5.1.6; 5.2.5	Minor	The PT provider management shall ensure that communication takes place regarding the effectiveness of the management system and the importance of meeting the requirements of participants, customers, regulatory authorities and organizations providing recognition.	
5.7b)	5.2.8	Minor	The PT provider management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.	
6			Resource requirements	

6.1			General	
6.1.1	4.2.1, 4.3.1, 4.4.1.4, 4.4.1.5	Minor	The PT provider shall have access to the personnel, facilities, equipment, systems and support services necessary to manage and perform its PT activities.	
6.1.2	4.1, 4.3.6	Major	Measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability, shall be conducted in accordance with the relevant requirements of ISO/IEC 17025.	
6.1.3		Major	Where the PT item is a material that meets the definition of “reference material”, it shall be produced under conditions that meet the relevant requirements of ISO 17034.	
6.2			Personnel	
6.2.1	5.1.5a)	Minor	The PT provider shall have access to a sufficient number of competent personnel to perform its PT activities.	
6.2.2 a)	4.2.1	Minor	The PT provider shall ensure that the personnel have the competence to perform PT activities for which they are responsible.	
6.2.2 b)		Major	The PT provider shall ensure that the personnel have the competence to evaluate the significance of deviations.	
6.2.3	4.2.7	Minor	The PT provider shall have a process for managing competence of its personnel.	
6.2.4	5.1.4, 5.1.5b), 5.1.5d)	Minor	All personnel of the PT provider (either internal or external) that can influence the PT activities shall act impartially.	

6.2.5	4.2.2, 4.2.5; 4.2.6	Minor	The PT provider shall have documented information demonstrating competence of its personnel, that can influence the results of its PT activities. Documented information shall include requirements for education, qualification, training, technical knowledge, skills and experience.	Additional wording - "that can influence the results of its PT activities".
6.2.6 a)	4.2.4	Minor	The PT provider shall, where appropriate, authorize personnel to plan PT schemes.	
6.2.6 b)	4.2.4	Editorial	The PT provider shall, where appropriate, authorize personnel to assess data/information to determine stability and homogeneity, if applicable, as well as assigned values and associated uncertainties of the properties or characteristics of the PT item.	
6.2.6 c)	4.2.4	Editorial	The PT provider shall, where appropriate, authorize personnel to evaluate the performance of PT participants.	
6.2.6 d)	4.2.4	Minor	The PT provider shall, where appropriate, authorize personnel to give opinions and interpretations as well as advice to the participants.	
6.2.6 e)	4.2.4	Editorial	The PT provider shall, where appropriate, authorize personnel to review and authorize PT reports.	
6.3			Facilities and environmental conditions	
6.3.1	4.3.1	Editorial	To ensure the validity of the PT activities, the PT provider shall ensure that there are appropriate facilities for the operation of the PT scheme.	
6.3.2	4.3.2	Editorial	The PT provider shall ensure that the environmental conditions do not compromise the PT activities, including operations that are	

			undertaken at sites away from the PT provider's permanent facilities or that are undertaken by external service providers.	
6.3.3	4.3.4	Editorial	The PT provider shall document environmental conditions that can influence the validity of the PT items and any measurements or tests carried out, including conditions that are required by relevant specifications and measurement or test methods. The PT provider shall control, monitor and periodically review these conditions and shall record all relevant monitoring activities. If environmental conditions compromise the validity of PT activities, the activities shall be halted (see 7.5.4).	
6.3.4	4.3.3	Editorial	Access control to, and use of, areas affecting the PT activities shall be managed. The PT provider shall determine the extent of access control based on its particular circumstances.	
6.3.5	4.3.5	Editorial	There shall be appropriate separation between neighbouring areas in which there are incompatible PT activities. Action shall be taken to prevent cross-contamination, interference or adverse influences on PT activities.	
6.4			Externally provided products and services	Wording changed from “subcontracting”
6.4.1a)	4.4.1.2; 5.5.2	Editorial	The PT provider shall not use external service providers for the design and planning of PT schemes.	
6.4.1 b)	4.7.2.1; 5.5.2	Editorial	The PT provider shall not use external service providers for the evaluation of performance.	
6.4.1 c)	4.8.1; 5.5.2	Editorial	The PT provider shall not use external service providers for the authorisation of reports.	

6.4.2	5.5.1	Minor	The PT provider shall have procedures to ensure that the experience and technical competence of the providers of external products and services are sufficient for their assigned tasks and that they comply with the relevant clauses of this document and other appropriate documents.	
6.4.3	5.5.3	Minor	The PT provider shall inform participants and customers, in advance and in writing, of products and services that are or can be provided externally, when they affect the validity of the PT activities.	Additional wording - "when they affect the validity of the PT activities".
6.4.4 a)	5.6.1; 5.6.4	Minor	The PT provider shall have a procedure and retain records for defining, reviewing and approving the PT provider's requirements for externally provided products and services.	
6.4.4 b)	5.6.1; 5.6.4	Minor	The PT provider shall have a procedure and retain records for defining the criteria for selection of the external providers and for evaluating and monitoring their performance.	
6.4.4 c)	5.6.2	Minor	The PT provider shall have a procedure and retain records for ensuring that externally provided products and services conform to the PT provider's established requirements and, when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer or participant.	
6.4.4 d)	5.6.4	Minor	The PT provider shall have a procedure and retain records for taking any actions arising from the performance monitoring and evaluation of the external providers.	

6.4.5 a)	5.6.3	Minor	The PT provider shall communicate its requirements to external providers for the products and services to be provided.	
6.4.5 b)	5.6.3	Minor	The PT provider shall communicate its requirements to external providers for the acceptance criteria.	
6.4.5 c)	5.6.3	Minor	The PT provider shall communicate its requirements to external providers for competence, including any required qualification of the organization or personnel involved.	
6.4.5 d)		Minor	The PT provider shall communicate its requirements to external providers for PT activities that the PT provider or its customers intend to perform at the external provider's premises.	
6.4.6	5.5.4	Minor	The PT provider shall be responsible to the participants or customers for the externally provided products and services.	
7			Process requirements	
7.1			Establishing, contracting and communicating the PT scheme objectives	
7.1.1	5.7.1		Review of requests, tenders and contract	
7.1.1.1 a)	5.4.1	Minor	The PT provider shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that the objectives of the PT scheme are sufficiently defined and in agreement with the customers' needs.	
7.1.1.1 b)	5.4.1 a)	Editorial	The PT provider shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that the requirements are	

			adequately defined, documented and understood.	
7.1.1.1 c)	5.4.1 b)	Editorial	The PT provider shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that the PT provider has the capability and resources necessary to meet the requirements.	
7.1.1.1 d)	5.4.1 c)	Editorial	The PT provider shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that the PT scheme is technically appropriate taking into account the needs of the given application or field of application.	
7.1.1.2	5.4.3	Editorial	The review shall cover all aspects of the request, including any externally provided products and services.	The word subcontractor is now external providers of products and services.
7.1.1.3	5.4.2	Minor	Records of such reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to their requirements, or the results of the PT activities.	
7.1.1.4	5.4.4	Editorial	The customer shall be informed of any deviation from the contract.	
7.1.1.5	5.4.5	Editorial	If a request or contract is amended after the PT scheme is underway, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.	
7.1.2			PT scheme communication	
7.1.2.1 a)	4.9.1 a)	Editorial	The PT provider shall make detailed information available about the PT scheme to participants	

			and customers and include objectives and relevant details of the PT scheme.	
7.1.2.1 b)	4.9.1 c)	Editorial	The PT provider shall make detailed information available about the PT scheme to participants and customers and include criteria to be met for participation.	
7.1.2.1 c)		Major	The PT provider shall make detailed information available about the PT scheme to participants and customers and include criteria for determining the assigned value and the evaluation of performance.	Additional information
7.1.2.1 d)	4.9.1 d)	Editorial	The PT provider shall make detailed information available about the PT scheme to participants and customers and include confidentiality arrangements.	
7.1.2.1 e)		Minor	The PT provider shall make detailed information available about the PT scheme to participants and customers and include critical timelines.	Additional information
7.1.2.1 f)	4.9.1 b)	Editorial	The PT provider shall make detailed information available about the PT scheme to participants and customers and include any fees for participation.	
7.1.2.1 g)	4.9.1 e)	Editorial	The PT provider shall make detailed information available about the PT scheme to participants and customers and include details of how to apply.	
7.1.2.2	4.9.2	Editorial	Participants and customers shall be advised in a timely manner by the PT provider of any changes in PT scheme design or operation.	

7.1.2.3	4.9.4		Records of relevant communications shall be maintained and retained by the PT provider, as appropriate.	
7.2			Design and planning of a PT scheme	
7.2.1			General	
7.2.1.1	4.4.1.1	Editorial	The PT provider shall identify, design and plan those activities which directly affect the validity of the PT scheme and shall ensure that activities are carried out in accordance with prescribed procedures.	
7.2.1.2		Minor	When a PT provider intends to introduce significant changes to activities which can affect the validity of the PT scheme, the PT provider shall identify and manage the risk to ensure the validity of the PT scheme is maintained.	Includes - identify and manage the risk to ensure the validity of the PT scheme is maintained.
7.2.1.3	4.4.1.3	Editorial	The PT provider shall develop a documented plan before commencement of the PT scheme that addresses the objectives, purpose and basic design of the PT scheme.	
7.2.1.3 a)	4.4.1.3 b)	Editorial	The plan shall include the personnel involved in the design and operation of the PT scheme	
7.2.1.3 b)	4.4.1.3 c)	Editorial	The plan shall include the activities to be undertaken by external providers of products and services and their contact details.	The word subcontractor is now external providers of products and services.
7.2.1.3 c)	4.4.1.3 d)	Editorial	The plan shall include criteria to be met for participation in the PT scheme.	
7.2.1.3 d)	4.4.1.3 e)	Editorial	The plan shall include the number and type of expected participants in the PT scheme.	

7.2.1.3 e)	4.4.1.3 f)	Editorial	The plan shall include description of activities to be performed and results to be reported by participants.	
7.2.1.3 f)	4.4.1.3 g)	Editorial	The plan shall include a description of the range of values or characteristics, or both, to be expected for the PT items.	
7.2.1.3 g)	4.4.1.3 h)	Editorial	The plan shall include the potential major sources of errors involved in the area of PT offered.	
7.2.1.3 h)	4.4.1.3 i)	Editorial	The plan shall include requirements for the production, quality control, storage and distribution of PT items.	
7.2.1.3 i)	4.4.1.3 j)	Editorial	The plan shall include arrangements to prevent collusion between participants or falsification of results and procedures to be employed if collusion or falsification of results is suspected.	
7.2.1.3 j)	4.4.1.3 k)	Editorial	The plan shall include a description of the information which will be supplied to participants and the time schedule for the various phases of the PT scheme.	
7.2.1.3 k)	4.4.1.3 l)	Editorial	The plan shall include for continuous PT schemes, the frequency or dates upon which PT items will be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which measurements or tests will be carried out by participants.	
7.2.1.3 l)	4.4.1.3 m)	Editorial	The plan shall include any information on methods or procedures which participants must use to store, handle, prepare, ship or dispose of the PT item and perform the measurements or tests.	

7.2.1.3 m)	4.4.1.3 n)	Editorial	The plan shall include procedures for the measurement or test methods to be used for the homogeneity and stability testing of PT items and, where applicable, to determine their biological viability.	
7.2.1.3 n)	4.4.1.3 o)	Editorial	The plan shall include preparation of any standardized reporting formats to be used by participants.	
7.2.1.3 o)	4.4.1.3 p)	Editorial	The plan shall include a detailed description of the statistical analysis to be used.	
7.2.1.3 p)	4.4.1.3 q)	Editorial	The plan shall include the origin, metrological traceability and uncertainty of any assigned values.	Note included.
7.2.1.3 q)		Minor	The plan shall include the treatment of results from different measurement or test methods, where permitted by the PT scheme.	Additional requirement
7.2.1.3 r)	4.4.1.3 r)	Editorial	The plan shall include criteria for the evaluation of the performance of participants.	
7.2.1.3 s)	4.4.1.3 s)	Editorial	The plan shall include a description of the data, interim reports or information to be returned to participants.	
7.2.1.3 t)	4.4.1.3 t)	Editorial	The plan shall include a description of the extent to which participant results, and the conclusions that will be based on the outcome of the PT scheme, will be made public or shared.	
7.2.1.3 u)	4.4.1.3 u)	Editorial	The plan shall include actions to be taken in the case of lost, delayed or damaged PT items.	
7.2.2			Statistical design	
7.2.2.1	4.4.4.1	Editorial	Statistical designs shall be developed to meet the objectives of the PT scheme, based on the	

			type of data (quantitative or qualitative, including ordinal and nominal), statistical assumptions, the type of errors and the expected number of results.	
7.2.2.2	4.4.4.2	Editorial	The PT provider shall document the statistical design and data analysis methods to be used to determine the assigned value and to evaluate the participant results, and it shall document the reasons for the selection and the assumptions upon which the statistical design and data analysis methods are based. The PT provider shall be able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures	
7.2.2.3 a)	4.4.4.3 a)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to the accuracy, as well as the uncertainty, required or expected for the assigned value for each property or characteristic in the PT scheme.	
7.2.2.3 b)	4.4.4.3 b)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to 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 participant results, the PT provider shall document, and provide to participants, details of the alternative approaches used to assess participant performance.	
7.2.2.3 c)	4.4.4.3 c)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to the relevance of significant figures to the reported	

			participant result, including the number of decimal places.	
7.2.2.3 d)	4.4.4.3 d)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to measured or tested and the number of repeat measurements or tests to be conducted on each PT item or for each determination.	
7.2.2.3 e)	4.4.4.3 e)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria.	
7.2.2.3 f)	4.5.1; 4.5.2	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to the procedures to be used to treat participant results from different measurement or test methods which are not technically equivalent, where permitted by the PT scheme.	
7.2.2.3 g)		Major	In designing a statistical analysis, the PT provider shall give careful consideration to whether the measurement uncertainty of participant results shall be reported and how it will be used to evaluate the participant's performance.	
7.2.2.3 h)	4.4.4.3 f)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to the procedures to be used to identify or handle outliers, or both.	
7.2.2.3 i)	4.4.4.3 g)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to where relevant, the procedures for the evaluation of values excluded from statistical analysis.	

7.2.2.3 j)	4.4.4.3 h)	Editorial	In designing a statistical analysis, the PT provider shall give careful consideration to where appropriate, the objectives to be met for the design and the frequency of PT rounds.	
7.2.3			Determination of assigned values	
7.2.3.1	4.4.5.1	Editorial	The PT provider shall document the procedure for determining the assigned values for the properties or characteristics in a particular PT scheme. Where applicable, this procedure shall take into account the metrological traceability and uncertainty required to demonstrate that the PT scheme is fit for its purpose.	
7.2.3.2	4.4.5.2	Editorial	PT schemes in the area of calibration shall have assigned values with metrological traceability.	
7.2.3.3	4.4.5.3	Editorial	For PT schemes in areas other than calibration, the relevance, need and feasibility for the establishment of metrological traceability and the associated uncertainty of the assigned value shall be determined by taking into account the purpose of the PT scheme.	
7.2.3.4	4.4.5.4	Minor	When a consensus value is used as the assigned value, the PT provider shall provide an estimate of the uncertainty of the assigned value [see Note to 7.2.1.3 item p)] as described in the plan for the PT scheme.	
7.2.3.5	4.4.5.5	Editorial	The PT provider shall have a policy regarding the disclosure of assigned values. The policy shall ensure that participants cannot gain advantage from early disclosure.	
7.3			Production and distribution of PT items	

7.3.1			Production of PT items	
7.3.1.1	4.4.2.1	Minor	The PT provider shall establish and implement procedures to ensure that PT items are produced in accordance with the plan described in 7.2 and are fit for the PT scheme's purpose.	Additional wording - and are fit for the PT scheme's purpose.
7.3.1.2	4.4.2.2	Editorial	The PT provider shall establish and implement procedures to ensure appropriate selection, acquisition, collection, identification, preparation, handling, storage and, where required, disposal of all PT items.	
7.3.1.3	4.4.2.4	Editorial	In PT schemes that require participants to sample, prepare or manipulate the PT item and submit it to the PT provider, the PT provider shall issue appropriate instructions for preparation, environmental conditions (where applicable), packaging, handling, storage and shipping of the PT item.	
7.3.2			Homogeneity and stability assessment of PT items	
7.3.2.1	4.4.3.1	Minor	Criteria for suitable homogeneity and stability shall be established and shall be based on the risks that inhomogeneity and instability can impact the evaluation of the performance of participants.	Includes risks
7.3.2.2	4.4.3.2	Minor	The procedures for the assessment of homogeneity and stability shall be documented and conducted, where applicable, in accordance with appropriate statistical designs.	

7.3.2.3	4.4.3.3	Editorial	The assessment of homogeneity and stability shall be performed for every PT round after the PT items have been packaged in their final form.	
7.3.2.4		Minor	Where experimental evidence is needed to assess homogeneity or stability of the PT item (or both), the PT provider shall use appropriate methods to assess the homogeneity and stability of the PT item.	
7.3.2.5	4.4.3.4	Editorial	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 round, including storage and transport. When this is not possible, the stability shall be quantified and considered as an additional component of the uncertainty associated with the assigned value of the PT item and/or taken into account in the evaluation criteria.	
7.3.2.6	4.4.3.5	Editorial	When PT items from previous PT rounds are retained for another PT round, property values or characteristics to be determined in the PT scheme shall be confirmed by the PT provider prior to distribution.	
7.3.3			Handling and storage of PT items	
7.3.3.1	4.6.2.1, 4.6.2.2	Editorial	From the time of production to their distribution to participants, the PT provider shall ensure that PT items are appropriately identified and stored to prevent contamination, damage or deterioration.	
7.3.3.2	4.6.2.2	Editorial	The PT provider shall have appropriate procedures for dispatch to, and receipt from, storage.	

7.3.3.3	4.6.2.3	Minor	The condition of stored PT items shall be assessed at specified intervals or prior to distribution in order to detect possible deterioration.	
7.3.3.4	4.6.2.4	Editorial	Where potentially hazardous PT items are used, facilities shall be available to ensure their safe handling, decontamination and disposal.	
7.3.4			Packing, labelling and distribution of PT items	
7.3.4.1	4.6.3.1	Editorial	The PT provider shall control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements.	
7.3.4.2	4.6.3.2	Editorial	The PT provider shall document relevant environmental conditions for the transport of PT items. If necessary, environmental conditions shall be monitored during transport.	
7.3.4.3	4.6.3.3	Editorial	In PT schemes where participants are required to transport the PT items to other participants, or return them to the PT provider, documented instructions for this transport, to ensure the validity of the PT item, shall be supplied.	
7.3.4.4	4.6.3.4	Editorial	The PT provider 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.	
7.3.4.5	4.6.3.5	Editorial	The PT provider shall follow a procedure to enable the confirmation of delivery of the PT items.	
7.3.5			Instructions for participants	

7.3.5.1	4.6.1.1	Editorial	The PT provider shall give participants sufficient notice before sending PT items, providing the date on which the PT items are likely to arrive or to be dispatched, unless the design of the PT scheme makes it inappropriate to do so.	
7.3.5.2 a)	4.6.1.2 a)	Editorial	The PT provider shall give detailed documented instructions to all participants and shall include the necessity to treat PT items in the same manner as routine samples, including use of routine measurement or test methods, unless there are particular requirements of the PT scheme which require departure from this principle.	
7.3.5.2 b)	4.6.1.2 b)	Editorial	The PT provider shall give detailed documented instructions to all participants and shall include details of factors which can influence the measurements or tests of the PT items, e.g. the nature of the PT items, conditions of storage, whether the PT scheme is limited to selected measurement or test methods and the timing of the measurements or tests.	
7.3.5.2 c)	4.6.1.2 c)	Minor	The PT provider shall give detailed documented instructions to all participants and shall include instructions for preparing or conditioning, or both, of the PT items before conducting the measurements or tests that would not be considered part of a laboratory's usual expected practices, unless these activities are part of the PT scheme.	
7.3.5.2 d)	4.6.1.2 d)	Editorial	The PT provider shall give detailed documented instructions to all participants and shall include any appropriate instructions on handling the PT items, including any safety requirements.	

7.3.5.2 e)	4.6.1.2 e)	Editorial	The PT provider shall give detailed documented instructions to all participants and shall include any specific environmental conditions for the participant to conduct measurements or tests, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement or test.	
7.3.5.2 f)	4.6.1.2 f)	Minor	The PT provider shall give detailed documented instructions to all participants and shall include specific and detailed instructions on the manner of recording and reporting results and associated measurement uncertainties, i.e. when the instructions include reporting of the expanded measurement uncertainty, the reported uncertainty shall include the coverage factor and the coverage probability.	Now states expanded uncertainty
7.3.5.2 g)	4.5.1, 4.5.2	Minor	The PT provider shall give detailed documented instructions to all participants and shall include specific instructions on providing details concerning the measurement or test method used by the participant, where a single specific measurement or test method is not required.	
7.3.5.2 h)	4.6.1.2 i)	Editorial	The PT provider shall give detailed documented instructions to all participants and shall include instructions on return or forwarding of the PT items, when applicable.	
7.3.5.2 i)	4.6.1.2 g)	Editorial	The PT provider shall give detailed documented instructions to all participants and shall include the last date for the PT provider to receive the results from the participants.	
7.3.5.2j)	4.6.1.2 h)	Editorial	The PT provider shall give detailed documented instructions to all participants and shall include	

			information on the contact details of the PT provider for enquiries.	
7.4			Evaluation and reporting of PT scheme results	
7.4.1			Data analysis	
7.4.1.1	4.7.1.2	Editorial	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.	
7.4.1.2	4.7.1.3	Editorial	Data analysis shall generate summary statistics, performance statistics, and associated information consistent with the statistical design of the PT scheme.	
7.4.1.3	4.7.1.4	Editorial	The influence of outliers on summary statistics shall be minimized by using an appropriate statistical approach.	
7.4.1.4		Minor	The PT provider shall have procedures for treatment of results from different measurement or test methods, where the PT scheme allows participants to use different measurement or test methods.	
7.4.1.5	4.7.1.5	Editorial	The PT provider shall have documented criteria and procedures for dealing with measurement or test results that are inappropriate for statistical evaluation, e.g. because of calculation errors, transpositions and other gross errors.	
7.4.1.6	4.7.1.6	Editorial	The PT provider shall have documented criteria and procedures to identify and manage situations where PT items that have been distributed and the collected data are subsequently found to be unsuitable for performance evaluation, e.g.	

			because of inhomogeneity, instability, damage or contamination.	
7.4.2			Evaluation of performance	
7.4.2.1	4.7.2.1	Editorial	The PT provider shall use valid methods of evaluation which meet the objectives of the PT scheme. The methods shall be documented and include a description of the basis for the evaluation.	
7.4.2.2 a)	4.7.2.2 a)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for overall performance against prior expectations, taking measurement uncertainties into account.	
7.4.2.2 b)	4.7.2.2 b)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for variation within and between participants, and comparisons with any previous PT rounds, similar PT schemes, or published data.	
7.4.2.2 c)	4.7.2.2 c)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for variation between measurement or test methods.	
7.4.2.2 d)	4.7.2.2 d)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for possible sources of error (with reference to outliers or poor performance) and suggestions for improving performance.	

7.4.2.2 e)	4.7.2.2 e)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for advice and feedback to participants as part of the continuous improvement procedures of participants.	
7.4.2.2 f)	4.7.2.2 f)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for situations where unusual factors make evaluation of results and commentary on performance impossible.	
7.4.2.2 g)	4.7.2.2 g)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for any other suggestions, recommendations or general comments.	
7.4.2.2 h)	4.7.2.2 h)	Editorial	Where applicable for the objectives of the PT scheme, the PT provider shall provide expert commentary on the performance of participants for conclusions.	
7.4.3			PT reports	
7.4.3.1	4.8.1	Editorial	PT reports shall be clear, accurate, objective and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants.	
7.4.3.2 a)	4.8.2 a)	Editorial	Reports shall include the name and contact details of the PT provider;	
7.4.3.2 b)	4.8.2 c)	Editorial	Reports shall include identification of person(s) authorizing the report;	

7.4.3.2 c)	4.8.2 d)	Minor	Reports shall include an indication of which activities are provided by external providers when they affect the production or characterization of the PT items or the services provided;	Inclusion of - when they affect the production or characterization of the PT items or the services provided;
7.4.3.2 d)	4.8.2 e)	Editorial	Reports shall include the date of issue and status (e.g. preliminary, interim, or final) of the report;	
7.4.3.2 e)	4.8.2 f)	Editorial	Reports shall include unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;	
7.4.3.2 f)	4.8.2 g)	Editorial	Reports shall include a statement of the extent to which results are confidential;	
7.4.3.2 g)	4.8.2 h)	Editorial	Reports shall include a unique identification of the report and the PT scheme;	
7.4.3.2 h)	4.8.2 i)	Editorial	Reports shall include a clear description of the PT items used, including necessary details of the PT item's production and homogeneity and stability assessment;	
7.4.3.2 i)	4.8.2 j)	Minor	Reports shall include the results of participants, including the reported measurement uncertainties;	Inclusion of - including the reported measurement uncertainties
7.4.3.2 j)	4.8.2 r)	Editorial	Reports shall include procedures used to statistically analyse the data;	
7.4.3.2 k)	4.8.2 k)	Editorial	Reports shall include statistical data and summaries, including assigned values, range of acceptable results and graphical displays;	
7.4.3.2 l)	4.8.2 m)	Editorial	Reports shall include details of the metrological traceability, and uncertainty of any assigned value;	

7.4.3.2 m)	4.8.2 l)	Minor	Reports shall include procedures used to establish any assigned value and its uncertainty;	Inclusion of uncertainty
7.4.3.2 n)	4.8.2 o)	Minor	Reports shall include assigned values, their uncertainties and summary statistics for measurement or test methods used by each group of participants (if different measurement or test methods are used by different groups of participants);	Inclusion of - their uncertainties
7.4.3.2 o)	4.8.2 n)	Editorial	Reports shall include procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;	
7.4.3.2 p)	4.8.2 p)	Editorial	Reports shall include comments on the performance of participants;	
7.4.3.2 q)	4.8.2 q)	Editorial	Reports shall include information about the design and implementation of the PT scheme;	
7.4.3.2 r)	4.8.2 s)	Editorial	Reports shall include advice on the interpretation of the statistical analysis;	
7.4.3.2 s)	4.8.2 t)	Editorial	Reports shall include comments or recommendations based on the outcomes of the PT round.	
7.4.3.3	4.8.3	Editorial	Reports shall be made available to participants within planned timescales. In sequential PT schemes, e.g. where the turn-around time can be very long, and in PT schemes involving perishable materials, preliminary or anticipated results may be provided before final results are disclosed.	
7.4.3.4	4.8.4	Minor	The PT provider shall have a policy for the use of reports by participants and customers.	Was individuals and organisations

7.4.3.5 a)	4.8.5 a)	Editorial	When it is necessary to issue a new or amended report for a PT scheme or PT round shall include a unique identification	
7.4.3.5 b)	4.8.5 b)	Editorial	When it is necessary to issue a new or amended report for a PT scheme or PT round shall include a reference to the original report that it replaces or amends	
7.4.3.5 c)	4.5.8 c)	Editorial	When it is necessary to issue a new or amended report for a PT scheme or PT round shall include identification of the amendment and a statement concerning the reason for the amendment or re-issue.	
7.4.3.6		Major	When issuing an amended report to a subset of participants, an analysis of the potential impact on the other participants for that PT scheme and/or PT round shall be made to ensure there is no influence on the general performance of the other participants.	
7.4.3.7	4.9.5	Minor	If the PT provider issues a statement of participation or performance, in addition to the PT report, the statement shall not be misleading.	Additional wording - in addition to the PT report
7.5			Control of the PT scheme process	
7.5.1			Technical records	
7.5.1.1	5.13.2.1	Minor	The PT provider shall ensure that technical records for each PT activity contain the results, reports and sufficient information to facilitate, if possible, identification of factors affecting the PT performance evaluation and its associated characteristics and enable the repetition of the PT activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel	

			responsible for each PT activity and for checking data and results.	
7.5.1.2	5.13.2.2	Minor	Data used to verify the PT items, instructions to participants, the original responses of participants and any other information included in reports shall be recorded at the time they are made and shall be identifiable with the specific task.	
7.5.1.3	5.13.2.3	Minor	The PT provider shall ensure that amendments to technical records can be tracked to previous versions or to original information submitted by participants. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.	
7.5.2			Control of data and information management	
7.5.2.1		New	The PT provider shall have access to the data and information needed to perform its activities.	
7.5.2.2	4.7.1.1	Minor	The PT provider information management system used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces before introduction. Whenever there are any changes, including PT provider software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.	Greater detail and includes changes/modification to software.
7.5.2.3 a)	5.13.1.4	Minor	The PT provider information management system be protected from unauthorized access;	

7.5.2.3 b)	5.13.1.4	Minor	The PT provider information management system be safeguarded against tampering and loss.	
7.5.2.3 c)		Minor	The PT provider information management system be operated in an environment that complies with the system supplier or PT provider specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription.	
7.5.2.3 d)		Minor	The PT provider information management system be maintained in a manner that ensures the integrity of the data and information;	
7.5.2.3 e)		Major	The PT provider information management system include recording of system failures and the appropriate immediate and corrective actions.	
7.5.2.4		Major	When a PT provider information management system is managed and maintained off-site or through an external service provider, the PT provider shall ensure that the external service provider or operator of the system complies with all applicable requirements of this document.	
7.5.2.5		Major	The PT provider shall ensure that instructions, manuals and reference data relevant to the PT provider information management system are made readily available to personnel.	
7.5.2.6	4.7.1.2	Minor	Calculations and data transfers shall be checked in an appropriate and systematic manner.	
7.5.3			Surveillance of the processes	

7.5.3		Major	The PT provider shall have a procedure to ensure the validity of the PT scheme. Surveillance activities shall be planned and reviewed [see also 8.9.2 item n)], and the resulting data shall be recorded for the continuous improvement process.	
7.5.4			Nonconforming work	
7.5.4.1 a)	5.9.1	Minor	The PT provider shall have a procedure that shall be implemented when any aspect of its PT schemes does not conform to its own procedures or the agreed requirements of its participants or customers. The procedure(s) shall ensure that the responsibilities and authorities for the management of nonconforming work are defined.	
7.5.4.1 b)	5.9.1 a)	Editorial	The procedure(s) shall ensure that actions (including halting work of ongoing PT schemes and/or PT rounds and withholding PT schemes and/or PT round reports, as necessary) are defined and are based upon the risk levels established by the PT provider.	
7.5.4.1 c)	5.9.1 b)	Editorial	The procedure(s) shall ensure that the procedure(s) shall ensure that an evaluation of the significance of the nonconforming work is made, including an impact analysis on previous PT activities.	
7.5.4.1 d)	5.9.1 c)	Editorial	The procedure(s) shall ensure that a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work.	

7.5.4.1 e)	5.9.1 d)	Editorial	The procedure(s) shall ensure that PT scheme participants and customers, as appropriate, are informed and the nonconforming PT items or PT reports already sent to participants are recalled or disregarded.	
7.5.4.1 f)	5.9.1 e)	Editorial	The procedure(s) shall ensure that the responsibility for authorization of the resumption of work is defined.	
7.5.4.2		Minor	The PT provider shall retain records of nonconforming work and actions as specified in 7.5.4.1 items b) to f).	
7.5.4.3	5.9.2	Editorial	Where the evaluation indicates that nonconforming work can recur or that there is doubt about the compliance of the PT provider with their own procedures, the corrective action procedure in 8.7 shall be promptly followed.	
7.6	5.8		Handling of complaints	
7.6.1 a)		Major	The PT provider shall have a documented procedure for handling complaints that shall include at least a description of the process for receiving, substantiating and investigating the complaint and deciding what actions shall be taken in response;	
7.6.1 b)		Major	The PT provider shall have a documented procedure for handling complaints that shall include at least tracking and recording the complaint, including the actions undertaken to resolve it;	
7.6.1 c)		Major	The PT provider shall have a documented procedure for handling complaints that shall include at least ensuring that any appropriate action is taken.	

7.6.2		Major	A description of the process for handling complaints shall be publicly available.	
7.6.3		Major	Upon receipt of a complaint, the PT provider shall confirm whether the complaint relates to PT activities and, if so, shall resolve the complaint.	
7.6.4		Major	The PT provider receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.	
7.6.5		Major	Whenever possible the PT provider shall acknowledge receipt of the complaint and provide the complainant with the outcome and, if applicable, progress reports.	
7.6.6		Major	Investigation and resolution of complaints shall not result in any discriminatory actions.	
7.6.7		Major	The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.	
7.6.8		Major	Whenever possible, the PT provider shall give formal notice of the end of the handling of the complaint to the complainant.	
7.6.9		Major	The PT provider shall be responsible for all decisions at all levels of the handling process for complaints.	
7.7			Handling of appeals	
7.7.1 a)	4.9.3	Minor	The PT provider shall have a documented procedure for handling appeals that shall include at least a description of the process for receiving	

			and investigating the appeal and deciding what actions shall be taken in response;	
7.7.1 b)		Major	The PT provider shall have a documented procedure for handling appeals that shall include at least tracking and recording the appeal, including the actions undertaken to resolve it;	
7.7.1 c)		Major	The PT provider shall have a documented procedure for handling appeals that shall include at least ensuring appropriate action is taken.	
7.7.2		Major	A description of the process for handling appeals shall be publicly available.	
7.7.3		Major	The PT provider shall acknowledge receipt of the appeal and provide the appellant with the outcome and, if applicable, progress reports.	
7.7.4		Major	The PT provider receiving the appeal shall be responsible for gathering all necessary information to determine whether the appeal is valid..	
7.7.5		Major	The PT provider shall be responsible for all decisions during the process for handling appeals.	
7.7.6		Major	The decision on the appeal shall be made by, or reviewed and approved by, persons not involved in the decision that is the subject of the appeal in question.	
7.7.7		Major	Investigation and decision on appeals shall not result in any discriminatory actions.	
8			MANAGEMENT SYSTEM REQUIREMENTS	

8.1			General requirements	
8.1.1	5.2.1	Minor	Management system is established, documented, implemented and maintained to support and demonstrate the consistent fulfilment of the requirements of the Standard	
8.1.2	5.11.1	Minor	Management system addresses: <ul style="list-style-type: none"> • policies • responsibilities clauses 8.2 to 8.9	
8.1.3		New option	Quality Management System has been established and meets clause 8.1.2	e.g. in accordance with the requirements of ISO 9001
8.1.4		Minor	Evidence of commitment to development and implement management system and to continually improve its effectiveness	
8.2			Management system documentation	
8.2.1	5.1.5 d)	Minor	Policies and objectives address: <ul style="list-style-type: none"> • competence • impartiality • consistent operation 	
8.2.2	5.2.2	Editorial	Documents, processes, systems and records relating to fulfilment of the requirements of the Standard are included or referenced from the management system	
8.2.3	5.2.2	Editorial	All personnel have access to relevant parts of the management system applicable to their responsibilities	
8.3			Control of management system documents	

8.3.1	5.3.1	Major	Control of documents <ul style="list-style-type: none"> both internal and external documents relating to the fulfilment of the requirements of the Standard 	
8.3.2 a)	5.3.2.1	Minor	The PT provider shall ensure that documents are approved by authorised personnel prior to issue.	
8.3.2 b)	5.3.2.2 b)	Editorial	The PT provider shall ensure that documents are periodically reviewed and updated as necessary.	
8.3.2 c)	5.3.3.1; 5.3.3.2	Editorial	The PT provider shall ensure that changes and current revision status of documents are identified.	
8.3.2 d)	5.3.3.2 a)	Editorial	The PT provider shall ensure that relevant versions of documents are available and their distribution controlled as necessary.	
8.3.2 e)	5.3.2.3	Editorial	The PT provider shall ensure that documents are uniquely identified.	
8.3.2 f)	5.3.2.2 d)	Editorial	The PT provider shall ensure that unintended use of obsolete documents is prevented.	
8.4			Control of records	
8.4.1	5.13.1.1	Minor	Records retention to demonstrate fulfilment of the requirements of the Standard	
8.4.2	5.13.1.1; 5.13.1.4	Minor	Controls are implemented for <ul style="list-style-type: none"> identification storage protection back-up 	

			<ul style="list-style-type: none"> • archive • retrieval • retention times disposal	
8.4.3	5.13.1.2; 5.13.1.3	Minor	Records <ul style="list-style-type: none"> • retained for period consistent with contractual obligations • consistent with confidentiality commitments • readily available 	
8.5			Actions to address risks and opportunities	There is no requirement for formal methods for risk management or a documented risk management process
8.5.1 a)		Major	The PT provider shall consider the risks and opportunities associated with the PT activities in order to give assurance that the management system achieves its intended results.	
8.5.1 b)		Major	The PT provider shall consider the risks and opportunities associated with the PT activities in order to enhance desirable effects to achieve the purpose and objectives of the PT provider.	
8.5.1 c)		Major	The PT provider shall consider the risks and opportunities associated with the PT activities in order to prevent, or reduce, undesired impacts and potential failures in the PT activities.	
8.5.1 d)		Major	The PT provider shall consider the risks and opportunities associated with the PT activities in order to achieve improvement.	
8.5.2 a)		Major	The PT provider shall plan actions to address these risks and opportunities.	

8.5.2 b)		Major	The PT provider shall plan how to integrate and implement these actions into its management system.	
8.5.2 c)		Major	The PT provider shall plan how to evaluate the effectiveness of these actions.	
8.6	5.2.4		Improvement	
8.6.1	5.12.1	Editorial	Opportunities are identified and any necessary action implemented.	
8.6.2	5.7.2	Editorial	Customer feedback both positive and negative are sought, analysed and used to improve the management system, PT activities and customer service.	
8.7	5.11.3		Corrective actions	
8.7.1 a)	5.11.3.1	Editorial	When nonconformities occur the PT provide shall react and, as applicable, take action, correct the issue and address the consequences.	
8.7.1 b)	5.11.2	Minor	When nonconformities occur the PT provide shall evaluate the need for action to eliminate the cause so that it does not recur.	
8.7.1 c)	5.11.3.1	Editorial	When nonconformities occur the PT provide shall implement any action necessary.	
8.7.1 d)	5.11.4	Minor	When nonconformities occur the PT provide shall review the effectiveness of any corrective action.	
8.7.1 e)		Minor	When nonconformities occur the PT provide shall update any risk and opportunities.	

8.7.1 f)		Minor	When nonconformities occur the PT provide shall make changes to the management system, if necessary.	
8.7.2	5.11.3.2	Editorial	Corrective action taken is appropriate to the effects of the nonconformity.	
8.7.3 a)	5.11.3.3	Editorial	The PT provider shall retain records as evidence of the nature of the nonconformity, cause(s) and any action(s) taken	
8.7.3 b)		Minor	The PT provider shall retain records as evidence of effectiveness of corrective action.	
8.8			Internal audits	
8.8.1 a)	5.14.1	Editorial	Conducted at planned intervals to establish whether the management system conforms to <ul style="list-style-type: none"> – the management system, including PT activities – the requirements of the Standard. 	
8.8.1 b)	5.14.1	Editorial	Conducted at planned intervals to establish whether the management system is effectively implemented and maintained.	
8.8.2 a)	5.14.1	Minor	a) The PT provider shall plan and implemented, including frequency, methods, responsibilities, planning and reporting, taking into account <ul style="list-style-type: none"> – the importance of the PT activities concerned – changes affecting the PT provider – the results of previous audits 	

8.8.2 b)	5.14.1	Editorial	The PT provider shall conduct by personnel knowledgeable in conducting PT activities, auditing and the Standard, and independent of activities being audited wherever resources permit.	
8.8.2 c)	5.14.1	Minor	The PT provider shall define criteria and the scope of each audit.	
8.8.2 d)		Minor	The PT provider shall ensure results are reported to relevant management	
8.8.2 e)	5.14.2	Editorial	The PT provider shall implement corrective actions, where necessary.	
8.8.2f)	5.14.3	Minor	The PT provider shall retain records of the audit program, including audit results.	
8.9			Management reviews	
8.9.1	5.15.1	Editorial	The PT provider management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.	
8.9.2 a)	5.15.1 b)	Minor	Records of inputs shall include information related to changes in internal and external issues	
8.9.2 b)		Minor	Records of inputs shall include information related to fulfilment of objectives	
8.9.2 c)	5.15.1 a)		Records of inputs shall include information related to suitability of policies and procedures	
8.9.2 d)		Minor	Records of inputs shall include information related to status of actions from previous reviews	

8.9.2 e)	5.15.1 c)	Editorial	Records of inputs shall include information related to outcomes of recent internal audits	
8.9.2 f)	5.15.1 d)	Editorial	Records of inputs shall include information related to corrective actions	
8.9.2 g)	5.15.1 e)	Editorial	Records of inputs shall include information related to assessment by external bodies	
8.9.2 h)	5.15.1 f)	Editorial	Records of inputs shall include information related to changes in volume, type of work or range of PT activities	
8.9.2 i)	5.15.1 g)	Editorial	Records of inputs shall include information related to customer, participant and personnel feedback	
8.9.2 j)	5.15.1 h)	Editorial	Records of inputs shall include information related to complaints and appeals	
8.9.2 k)	5.15.1 i)	Editorial	Records of inputs shall include information related to effectiveness of any implemented improvements	
8.9.2 l)	5.15.1 j)	Editorial	Records of inputs shall include information related to information related to adequacy of resources	
8.9.2 m)		Major	Records of inputs shall include information related to results of risk identification	
8.9.2 n)		Minor	Records of inputs shall include information related to outcomes of the surveillance of the processes	
8.9.2 o)	5.15.1 j)	Editorial	Records of inputs shall include information related to any other relevant factors	

8.9.3 a)	5.15.2	Major	Records of outputs shall include all decisions and actions relating to effectiveness of the management system	
8.9.3 b)	5.15.2	Major	Records of outputs shall include all decisions and actions relating to improvement of the activities relating to satisfying the requirements of the Standard	
8.9.3 c)	5.15.2	Major	Records of outputs shall include all decisions and actions relating to provision of required resources	
8.9.3 d)	5.15.2	Major	Records of outputs shall include all decisions and actions relating to any need for change(s)	
Annex A (informative)		Major	Types of PT schemes	Generally rewritten and with update to types of statistical methods
Annex B (informative)		Major	Statistical methods for PT	Generally rewritten and with update to with references to ISO 13528

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or Clause	Amendment
7.7.2 to 7.7.7	Correction to the Summary of text/extract from ISO/IEC 17043:2023