ISO/IEC 17043 ASSESSMENT WORKSHEET

Self-assessment

This self-assessment worksheet may be used in preparation for an assessment. It does not need to be returned to NATA.

4 General requirements

4.1 Impartiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.1.1	PT activities shall be undertaken impartially.	
4.1.2	The PT provider shall be structured and managed so as to safeguard impartiality.	
4.1.3	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	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	If a threat to impartiality is identified, its effect shall be eliminated or minimized so that the impartiality is not compromised.	
4.1.6	The PT provider shall have top management commitment to impartiality.	

4.2 Confidentiality

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
4.2.1	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. The PT provider shall inform the client in advance of the information it intends	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	to place in the public domain. Apart from information that the client makes publicly available, or when agreed between the PT provider and the client, all other information is considered proprietary information and shall be regarded as confidential.	
4.2.2	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	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. The identity of the source shall be kept confidential by the PT provider and shall not be shared with the participant or the customer, unless agreed by the source.	
4.2.4	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	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

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
5.1	The PT provider shall be a legal entity, or a defined part of a legal	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	entity, that is legally responsible for its PT activities.	
5.2	The PT provider shall identify management that has overall responsibility for the PT activities.	
5.3	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	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. These requirements apply to all PT activities performed in its permanent facilities and any other facility or site.	
5.5	The PT provider shall: a) define its organization and management structure, its place in any parent organization and the relationships between the management, technical operations and support services; b) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of its PT activities; c) document its procedures to the extent necessary to ensure the consistent application and validity of its PT activities.	
5.6	The PT provider shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including: a) implementation, maintenance and improvement of the management system;	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	b) identification of deviations from the management system or from the procedures while performing the PT activities; c) initiation of actions to prevent or minimize such deviations; d) reporting to its management on the performance of the management system and any need for improvement; e) ensuring the effectiveness of the PT activities.	
5.7	The PT provider management shall ensure that: a) 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; b) the integrity of the management system is maintained when changes to the management system are planned and implemented.	

6 RESOURCE REQUIREMENTS

6.1 General

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.1.1	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	Measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability, shall be	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
	conducted in accordance with the relevant requirements of ISO/IEC 17025. Measurement procedures To achieve this requirement, the provider should consider at least the following: a) the methods are appropriate to the intended use and are the latest edition unless it is not appropriate or possible to do so; b) in-house, non-standard methods are developed by qualified personnel with adequate resources; c) non-standard methods be appropriately validated before use; d) non-standard methods, including in-house methods and methods used outside of their intended scope, are validated to confirm they are fit for the intended use. The validation must be as extensive as is necessary and a statement as to whether the method is fit for the intended use made; and e) the range and accuracy of values obtainable from methods are relevant to the intended use. Measuring equipment a) the proficiency testing provider and/or its external providers have access to the measuring and test equipment required. The equipment is fit for purpose and has been verified as complying with specified requirements; and b) when the measurement accuracy and measurement uncertainty affect the validity of a property value, measuring equipment is calibrated.	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
6.1.3	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. For tests and measurements that support the production of a Reference Material refer to the requirements under clause 6.1.2 above.	

6.2 Personnel

6.2.1	The PT provider shall have access to a sufficient number of competent personnel to perform its PT activities.	
6.2.2	The PT provider shall ensure that the personnel have the competence to: a) perform PT activities for which they are responsible; b) evaluate the significance of deviations.	
6.2.3	The PT provider shall have a process for managing competence of its personnel.	
6.2.4	All personnel of the PT provider (either internal or external) that can influence the PT activities shall act impartially.	
6.2.5	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.	
6.2.6	The PT provider shall, where appropriate, authorize personnel to perform specific activities within PT schemes, including but not limited to the following:	

	a) plan PT schemes; b) 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; c) evaluate the performance of PT participants; d) give opinions and interpretations as well as advice to the participants; e) review and authorize PT reports.	
6.2.7	The PT provider management shall communicate to all personnel their duties, responsibilities and authorities.	

6.3 Facilities and environmental conditions

6.3.1	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	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	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	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	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

6.4.1	The PT provider shall not use external service providers for the following activities: a) the design and planning of PT schemes; b) the evaluation of performance; c) the authorization of reports.	
6.4.2	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	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.	
6.4.4	The PT provider shall have a procedure and retain records for: a) defining, reviewing and approving the PT provider's requirements for externally provided products and services; b) defining the criteria for selection of the external providers and for evaluating and monitoring their performance;	

	c) 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; d) taking any actions arising from the performance monitoring and evaluation of the external providers.	
6.4.5	The PT provider shall communicate its requirements to external providers for: a) the products and services to be provided; b) the acceptance criteria; c) competence, including any required qualification of the organization or personnel involved; d) PT activities that the PT provider or its customers intend to perform at the external provider's premises.	
6.4.6	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	**Review of requests, tenders and contracts**	
7.1.1.1	The PT provider shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that: a) the objectives of the PT scheme are sufficiently defined and in agreement with the customers' needs;	

	b) the requirements are adequately defined, documented and understood; c) the PT provider has the capability and resources necessary to meet the requirements; d) the PT scheme is technically appropriate taking into account the needs of the given application or field of application.	
7.1.1.2	The review shall cover all aspects of the request, including any externally provided products and services.	
7.1.1.3	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	The customer shall be informed of any deviation from the contract.	
7.1.1.5	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	The PT provider shall make detailed information available about the PT scheme to participants and customers. This information shall include: a) objectives and relevant details of the PT scheme; b) criteria to be met for participation; c) criteria for determining the assigned value and the evaluation of performance; d) confidentiality arrangements; e) critical timelines; f) any fees for participation; g) details of how to apply.	

7.1.2.2	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	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	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	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.	
7.2.1.3	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. The plan shall include the following information and, where appropriate, reasons for the selection or exclusion of the specific information: a) the personnel involved in the design and operation of the PT scheme; b) the activities to be undertaken by external providers of products and services and their contact details; c) criteria to be met for participation in the PT scheme; d) the number and type of expected participants in the PT scheme;	

	e) description of activities to be performed and results to be reported by participants; f) a description of the range of values or characteristics, or both, to be expected for the PT items; g) the potential major sources of errors involved in the area of PT offered; h) requirements for the production, quality control, storage and distribution of PT items; i) arrangements to prevent collusion between participants or falsification of results and procedures to be employed if collusion or falsification of results is suspected; j) a description of the information which will be supplied to participants and the time schedule for the various phases of the PT scheme; k) 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; l) 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; m) 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; n) preparation of any standardized reporting formats to be used by participants; o) a detailed description of the statistical analysis to be used;	

	p) the origin, metrological traceability and uncertainty of any assigned values; q) the treatment of results from different measurement or test methods, where permitted by the PT scheme; r) criteria for the evaluation of the 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 results, and the conclusions that will be based on the outcome of the PT scheme, will be made public or shared; u) actions to be taken in the case of lost, delayed or damaged PT items.	
7.2.2	**Statistical design**	
7.2.2.1	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	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	In designing a statistical analysis, the PT provider shall give careful consideration to the following: a) the accuracy, as well as the uncertainty, required or expected for the assigned value for each	

	property or characteristic in the PT scheme; 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 participant results, the PT provider 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 participant result, including the number of decimal places; d) the number of PT items to be measured or tested and the number of repeat measurements or tests 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) 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; g) whether the measurement uncertainty of participant results shall be reported and how it will be used to evaluate the participant's performance; h) the procedures to be used to identify or handle outliers, or both; i) where relevant, the procedures for the evaluation of values excluded from statistical analysis; j) 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	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	PT schemes in the area of calibration shall have assigned values with metrological traceability.	
7.2.3.3	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	When a consensus value is used as the assigned value, the PT provider shall provide an estimate of the uncertainty of the assigned value as described in the plan for the PT scheme.	
7.2.3.5	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	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.	
7.3.1.2	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	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	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.	
7.3.2.2	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	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	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	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	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	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	The PT provider shall have appropriate procedures for dispatch to, and receipt from, storage.	
7.3.3.3	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	Where potentially hazardous PT items are used, facilities shall be available to ensure their safe handling, decontamination and disposal.	
7.3.4	**Packaging, labelling and distribution of PT items**	
7.3.4.1	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	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	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	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	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	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	The PT provider 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 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; b) 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; c) 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; d) any appropriate instructions on handling the PT items, including any safety requirements; e) 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; f) 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; g) 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; h) instructions on return or forwarding of the PT items, when applicable; i) the last date for the PT provider to receive the results from the participants; j) 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	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	Data analysis shall generate summary statistics, performance statistics, and associated information consistent with the statistical design of the PT scheme.	
7.4.1.3	The influence of outliers on summary statistics shall be minimized by using an appropriate statistical approach.	
7.4.1.4	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	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	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	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	Where applicable for the objectives of the PT scheme, the PT provider 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 data; c) variation between measurement or test methods; d) possible sources of error (with reference to outliers or poor performance) and suggestions for improving performance; e) advice and feedback to participants as part of the	

	continuous 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; h) conclusions.	
7.4.3	**PT Reports**	
7.4.3.1	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	Reports shall include the following, unless it is not applicable or the PT provider has valid reasons for not doing so: a) the name and contact details of the PT provider; b) identification of person(s) authorizing the report; c) 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; d) the date of issue and status (e.g. preliminary, interim, or final) of the report; e) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; f) a statement of the extent to which results are confidential; g) a unique identification of the report and the PT scheme; h) a clear description of the PT items used, including necessary details of the PT item's production and homogeneity and stability assessment;	

	i) the results of participants, including the reported measurement uncertainties; j) procedures used to statistically analyse the data; k) statistical data and summaries, including assigned values, range of acceptable results and graphical displays; l) details of the metrological traceability, and uncertainty of any assigned value; m) procedures used to establish any assigned value and its uncertainty; n) 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); o) procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation; p) comments on the performance of participants; q) information about the design and implementation of the PT scheme; r) advice on the interpretation of the statistical analysis; s) comments or recommendations based on the outcomes of the PT round.	
7.4.3.3	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	The PT provider shall have a policy for the use of reports by participants and customers.	

7.4.3.5	When it is necessary to issue a new or amended report for a PT scheme or PT round, this report shall include the following: a) a unique identification; b) a reference to the original report that it replaces or amends; c) identification of the amendment and a statement concerning the reason for the amendment or re-issue.	
7.4.3.6	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	If the PT provider issues a statement of participation or performance in addition to the PT report, the statement shall not be misleading.	

7.5 Control of the PT scheme process

7.5.1	**Technical records**	
7.5.1.1	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	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	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	The PT provider shall have access to the data and information needed to perform its activities.	
7.5.2.2	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.	
7.5.2.3	The PT provider information management system shall: a) be protected from unauthorized access; b) be safeguarded against tampering and loss; c) 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; d) be maintained in a manner that ensures the integrity of the data and information; e) include recording of system failures and the appropriate immediate and corrective actions.	

7.5.2.4	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	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	Calculations and data transfers shall be checked in an appropriate and systematic manner.	
7.5.3	**Surveillance of the processes**	
7.5.3	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	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: a) the responsibilities and authorities for the management of nonconforming work are defined; b) 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; c) an evaluation of the significance of the nonconforming work is	

	made, including an impact analysis on previous PT activities; d) a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work; e) 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; f) the responsibility for authorization of the resumption of work is defined.	
7.5.4.2	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	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 Handling of complaints

7.6.1	The PT provider shall have a documented procedure for handling complaints that shall include at least the following: a) a description of the process for receiving, substantiating and investigating the complaint and deciding what actions shall be taken in response; b) tracking and recording the complaint, including the actions undertaken to resolve it; c) ensuring that any appropriate action is taken.	
7.6.2	A description of the process for handling complaints shall be publicly available.	
7.6.3	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	The PT provider receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.	
7.6.5	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	Investigation and resolution of complaints shall not result in any discriminatory actions.	
7.6.7	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	Whenever possible, the PT provider shall give formal notice of the end of the handling of the complaint to the complainant.	
7.6.9	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	The PT provider shall have a documented procedure for handling appeals that shall include at least the following: a) a description of the process for receiving and investigating the appeal and deciding what actions shall be taken in response; b) tracking and recording the appeal, including the actions undertaken to resolve it; c) ensuring appropriate action is taken.	

7.7.2	A description of the process for handling appeals shall be publicly available.	
7.7.3	The PT provider shall acknowledge receipt of the appeal and provide the appellant with the outcome and, if applicable, progress reports.	
7.7.4	The PT provider receiving the appeal shall be responsible for gathering all necessary information to determine whether the appeal is valid.	
7.7.5	The PT provider shall be responsible for all decisions during the process for handling appeals.	
7.7.6	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	Investigation and decision on appeals shall not result in any discriminatory actions.	

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 General requirements

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.1.1 General		
8.1.1	Management system is established, documented, implemented and maintained to support and demonstrate the consistent fulfilment of the requirements of the Standard	
8.1.2	Management system addresses: • policies • responsibilities clauses 8.2 to 8.9	

8.1.3	Quality Management System has been established and meets clause 8.1.2	☐ Yes ☐ No	(Complete table under Quality Management System (certified by IAF MLA signatory)
8.1.4	Evidence of commitment to development and implement management system and to continually improve its effectiveness		

Quality Management System

If the facility has implemented a QMS in accordance with clause 8.1.3	Evidence
1) the QMS is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA).	
2) <u>For ISO 9001</u> Evidence the CB's accreditation covers ISO/IEC 17021 Parts 1 and 3. If Part 3 is not specifically listed in the CB's scope of accreditation, then it must be clear that its accreditation covers the certification of Quality Management Systems to ISO 9001 (which may be included in the scope of accreditation or other documentation provided by the accreditation body signatory to the IAF MLA). <u>For other QMS standards</u> Relevant evidence the CB's accreditation covers the applicable standard.	
3) copies of the most recent certification audit report(s) issued by the CB covering the complete review of the QMS in full.	
4) confirmation from the CB of the close out of any nonconformities raised during certification audits and detailed in the audit report(s).	
5) the QMS satisfies the requirements of ISO/IEC 17043, clause 8.1.2.	

If the facility has implemented a QMS in accordance with clause 8.1.3	Evidence
6) the QMS supports and demonstrates the consistent fulfilment of the requirements of ISO/IEC 17043 for the activities covered (or proposed to be covered) by the NATA scope of accreditation.	

8.2 Management system documentation

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.2.1	Policies and objectives address: • competence • impartiality • consistent operation	
8.2.2	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	All personnel have access to relevant parts of the management system applicable to their responsibilities	

8.3 Control of management system documents

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.3.1	Control of documents • both internal and external documents relating to the fulfilment of the requirements of the Standard	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.3.2	Document control process a) documents are approved by authorised personnel prior to issue b) documents are periodically reviewed and updated as necessary c) changes and current revision status of documents are identified d) relevant versions of documents are available and their distribution controlled as necessary e) documents are uniquely identified f) unintended use of obsolete documents is prevented	

8.4 Control of records

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.4.1	Records retention • to demonstrate fulfilment of the requirements of the Standard	
8.4.2	Controls are implemented for • identification • storage • protection • back-up • archive • retrieval • retention times • disposal	
8.4.3	Records • retained for period consistent with contractual obligations • consistent with confidentiality commitments • readily available	

8.5 Actions to address risks and opportunities

Note: There is no requirement for formal methods for risk management or a documented risk management process

8.6 Improvement

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.6.1	Opportunities • are identified and any necessary action implemented	
8.6.2	Customer feedback • both positive and negative are sought, analysed and used to improve the management system, PT activities and customer service	

8.7 Corrective actions

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.7.1	Nonconformities • when occur, the PT provider shall a) react and, as applicable, take action, correct the issue and address the consequences; b) evaluate the need for action to eliminate the cause so that it does not recur; c) implement any action necessary; d) review the effectiveness of any corrective action; e) update any risk and opportunities; f) make any necessary changes to the management system.	
8.7.2	Corrective action taken is appropriate to the effects of the nonconformity	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.7.3	Records retained a) of the nature of the nonconformity, cause(s) and any action(s) taken; b) effectiveness of corrective action.	

8.8 Internal audits

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.8.1	Conducted at planned intervals • to establish whether the management system a) conforms to – the management system, including PT activities – the requirements of the Standard b) is effectively implemented and maintained.	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.8.2	Audit requirements a) is planned and implemented, including frequency, methods, responsibilities, planning and reporting, taking into account – the importance of the PT activities concerned – changes affecting the PT provider – the results of previous audits b) conducted by personnel knowledgeable in conducting PT activities, auditing and the Standard, and independent of activities being audited; c) criteria and the scope of each audit are defined; d) results are reported to relevant management; e) corrective actions, where necessary, are implemented promptly; f) records of the audit program, including results, are retained.	

8.9 Management reviews

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.1	Review of management system • is conducted at planned intervals by management to ensure – continued suitability, adequacy and effectiveness; – covers the stated policies and objectives related to the fulfilment of the Standard.	

Clause No.	General Requirements	Evidence (outcome of discussions with staff observations; procedures & documentation reviewed)
8.9.2	Records of inputs • including information related to a) changes in internal and external issues; b) fulfilment of objectives; c) suitability of policies and procedures; d) status of actions from previous reviews; e) outcomes of recent internal audits; f) corrective actions; g) assessment by external bodies; h) changes in volume, type of work or range of PT activities; i) customer, participant and personnel feedback; j) complaints and appeals; k) effectiveness of any implemented improvements; l) adequacy of resources; m) results of risk identification; n) outcomes of the surveillance of the processes; o) any other relevant factors.	
8.9.3	Records of outputs • include all decisions and actions relating to a) effectiveness of the management system; b) improvement of the activities relating to satisfying the requirements of the Standard; c) provision of required resources; d) any need for change(s).	