# INTRODUCTION

1. Purpose

This checklist is prepared for the following purposes:

* 1. To assist both the staff of the Conformity Assessment Body (CAB) and the assessment team in checking that all criteria for accreditation are satisfied.
	2. To index documentation of the quality system and use as part of the preparation for the introduction of ISO/IEC 17043:2023 and an assessment; and
	3. To provide essential background information for briefing PAB assessment team and relevant information during the assessment process.
1. Structure and Use of the Checklist
	1. Compliance with PAB General Requirements
	2. All PAB accredited and applicant CABs are required to comply with the accreditation requirements and the basic technical and management system requirements for CAB based on ISO/IEC 17043:2023.
	3. PAB needs to obtain and maintain information on the specific technical resources available in the laboratory and to be aware of the desired scope of the accreditation by PAB (the approved classification of scopes) and for approved signatories (the specific people authorized to sign PAB endorsed test reports).
2. Preparation of Documented Management System
	1. Each accredited CAB is required to implement a documented quality management system as one of the fundamental conditions for PAB accreditation.
	2. The documented quality management system includes all the policies and operational procedures established to meet requirements for accreditation.
	3. The manner in which a documented quality system is structured is the choice of the CAB. The purpose of the documentation is primarily to advice the staff of the policies and procedures expected by its management to be implemented by all staff.
	4. Typically, a quality management system is documented in a Quality Manual and supporting procedures and records. In some cases, a Quality Manual includes supporting procedures. In other cases, some of the subjects of a Quality Manual may be incorporated in an organization’s more general Quality Manual or procedures.

| **Clause** | **Requirements** | **Reference to CAB’s Documents and/or Information on the Implementation**(to be completed by the CAB) | PAB Remarks |
| --- | --- | --- | --- |
| **4** | **General requirements** |
| **4.1**  | **Impartiality** |
| **4.1.1** | Are the PT activities undertaken impartially? |  |  |
| **4.1.2** | Does the PT provider structured and managed to safeguard impartiality? |  |  |
| **4.1.3** | Does the PT provider responsible for the impartiality of its PT activities and shall not allow commercial, financial, or other pressures to compromise its impartiality? |  |  |
| **4.1.4** | Does the PT provider monitor its activities and its relationship to identify threats to its impartiality including the relationship of its personnel? |  |  |
| **4.1.5** | If a threat to impartiality is identified, does its effect eliminated or minimized so that the impartiality is not compromised? |  |  |
| **4.1.6**  | Does the PT provider have top management commitment to impartiality? |  |  |
| **4.2**  | Confidentiality |
|  | Does the PT provider responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of PT activities and informs the client in advance of the information it intends to place in the public domain; except for 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 required by law or authorized by contractual arrangements to release confidential information, does the client concerned notified of the information released, unless prohibited by law? |  |  |
| **4.2.3** | Does the information about the participant or customer from a source other than the participant or customer (e.g., complainant or regulator) keep confidential by the PT provider? Is the identity of the source kept confidential by the PT provider and shall not be shared with the participants or the customers unless agreed by the source? |  |  |
| **4.2.4** | Do the personnel, including committee members, contractors, personnel of external bodies, or persons acting on the PT provider’s behalf, keep confidential all information obtained or created during the performance of the PT activities?  |  |  |
| **4.2.5** | Does the identity of participants in a PT scheme 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**  | Is the PT provider a legal entity, or a defined part of a legal entity, that is legally responsible for its PT activities? |  |  |
| **5.2** | Is the PT provider has identified management that has overall responsibility for the PT activities? |  |  |
| **5.3** | Does the PT provider define and document the PT schemes for which it conforms to this document and claim conformity with this document for those PT schemes? |  |  |
| **5.4** | Does the PT provider carry out PT activities in such a way to meet the requirements of this document and address the requirements of the participants, customers, regulatory authorities, and organizations providing recognition? And are these requirements applying to all PT activities performed in its permanent facilities and any other facility or site? |  |  |
| **5.5** | Does the PT provider:define its organization and management structure, its place in any parent organization and the relationships between the management, technical operations, and support services?1. specify the responsibility, authority and interrelationships of all personnel who manage, perform, or verify work affecting the results of its PT activities?
2. document its procedures to the extent necessary to ensure the consistent application and validity of its PT activity?
 |  |  |
| **5.6**  | Does the PT provider have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties including:1. implementation, maintenance, improvement of the management system?
2. identification of deviations from the management system of from the procedures while performing the PT activities?
3. initiation of actions to prevent or minimize such deviations?
4. reporting to its management on the performance of the management system and any need for improvement?
5. ensuring the effectiveness of the PT activities?
 |  |  |
| **5.7** | Does the PT provider management ensure that:1. 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?
2. 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** | Does the PT provider have access to the personnel, facilities, equipment, systems and support services necessary to manage and perform its PT activities? |  |  |
| **6.1.2** | Are the measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability conducted in accordance with the relevant requirements of ISO/ICE 17025? |  |  |
| **6.1.3** | Does the PT item is a material that meets the definition of “reference material,” produced under conditions that meet the relevant requirements of ISO 17034? |  |  |
| **6.2** | **Personnel** |
| **6.2.1** | Does the PT provider have access to a sufficient number of competent personnel to perform its PT activities? |  |  |
| **6.2.2** | Does the PT provider ensure that the personnel have the competence to:1. perform PT activities for which they are responsible?
2. evaluate the significance of deviations?
 |  |  |
| **6.2.3** | Does the PT provider have a process for managing the competence of its personnel? |  |  |
| **6.2.4** | Do all the personnel of the PT provider (either internal or external) that could influence the PT activities act impartially?  |  |  |
| **6.2.5** | Does the PT provider have documented information demonstrating competence of its personnel that can influence the results of its PT activities? Does the documented information include requirements for education, qualification, training, technical knowledge, skills, and experience?  |  |  |
| **6.2.6** | Does the PT provider have appropriate, authorize personnel to perform specific activities within PT schemes, including but not limited to the following: plan PT schemes?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?evaluate the performance of PT participants?gives opinions and interpretations as well as advice to the participants? and review and authorize PT reports? |  |  |
| **6.2.7** | Does the PT provider management communicate to all personnel their duties, responsibilities, and authorities? |  |  |
| **6.3** | Facilities and environmental conditions |
| **6.3.1** | Does the PT provider ensure that there are appropriate facilities for the operations of the PT scheme to ensure the validity of the PT activities? |  |  |
| **6.3.2** | Does the PT provider 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? |  |  |
| **6.3.4** | Does access control to, and use of, areas affecting the PT activities managed? Does the PT provider shall determine the extent of access control based on its particular circumstances? |  |  |
| **6.3.5** | Is there an appropriate separation between neighboring areas in which there are incompatible PT activities and action taken to prevent cross-contamination, interference, or adverse influences on PT activities? |  |  |
| **6.4** | Externally provided products and services  |
| **6.4.1** | Is the PT provider not used external service providers for the following activities?the design and planning of PT schemes; the evaluation of performance;the authorization of reports. |  |  |
| **6.4.2** | Does the PT provider 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** | Does the PT provider inform the 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** | Does the PT provider have a procedure and retain records for:1. defining, reviewing, and approving the PT provider’s requirements for externally provided products and services?
2. defining the criteria for selection of the external providers and for evaluating and monitoring their performance?
3. ensuring that externally provided products and services conform to the PT provider’s established requirements and, when applicable, to the relevant requirements of this documents?
 |  |  |
| **6.4.5** | Does the PT provider communicate its requirements to external providers for:1. the product and services to be provided;
2. the acceptance criteria;
3. competence including any required qualification of the organization or personnel involved;
4. PT activities that the PT provider or its customer intend to perform at the external provider’s premises?
 |  |  |
| **6.4.6** | Does the PT provider 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 request, tenders, and contracts |
| **7.1.1.1** | Does the PT provider have a procedure for the review of requests, tenders, and contracts? Does the procedure ensure that:1. the objectives of the PT scheme are sufficiently defined and in agreement with the customers’ needs;
2. the requirements are adequately defined, documented, and understood;
3. the PT provider has the capability and resources necessary to meet the requirements;
4. the PT scheme is technically appropriate taking into account the needs of the given application or field of application.
 |  |  |
| **7.1.1.2** | Does the review cover all the aspects of the request, including any externally provided products and services? |  |  |
| **7.1.1.3** | Are records of such reviews, including any significant changes and pertinent discussions with a customer relating to their requirements, or the results of the PT activities retained? |  |  |
| **7.1.1.4** | Does the customer inform of any deviation from the contract? |  |  |
| **7.1.1.5** | if a request or contract is amended after the PT scheme is underway, does the contract review repeated, and any amendment communicated to all affected personnel? |  |  |
| **7.1.2** | PT scheme communication |
| **7.1.2.1** | Does the PT provider make detailed information available about the PT scheme to participants and customers? Does the information include the following:1. objectives and relevant details of the PT scheme;
2. criteria to be met for participation;
3. criteria for determining the assigned value and the evaluation of performance;
4. confidentiality arrangements;
5. criteria timelines;
6. any fees for participation;
7. details of how to apply.
 |  |  |
| **7.1.2.2** | Are the participants and customers advised in a timely manner by the PT provider of any changes in PT scheme design or operation? |  |  |
| **7.1.2.3** | Are records of relevant communications maintained and retained by the PT provider, as appropriate? |  |  |
| **7.2** | Design and planning of a PT scheme |
| **7.2.1.1** | Does the PT provider identify, design, and plan those activities which directly affect the validity of the PT scheme and ensure that activities are carried out in accordance with prescribed procedures? |  |  |
| **7.2.1.2** | Does the PT provider identify and manage the risk to ensure the validity of the PT scheme is maintained when a PT provider intends to introduce significant changes to activities which can affect the validity of the PT scheme? |  |  |
| **7.2.1.3** | Does the PT provider 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:1. the personnel involved in the design and operation of the PT scheme;
2. the activities to be undertaken by external providers of product and services and their contract details;
3. criteria to be met for participation in the PT scheme;
4. the number and type of expected participants in the PT scheme;
5. description of activities to be performed and results to be reported by participants;
6. a description of the range of values or characteristics, or both, to be expected for the PT items;
7. the potential major sources of errors involved in the area of PT offered;
8. requirements for the production quality control, storage, and distribution of PT items;
9. arrangement to prevent collusion between participants and falsification or results and procedures to be employed if collusion or falsification of results is suspected;
10. a description of the information which will be supplied to participants and the time schedule for the various phases of the PT scheme;
11. for continuous PT scheme, the frequency, or dates upon which PT items will be distributed to participants, the deadlines for the return of results by the participants and, where appropriate, the dates on which measurements or tests will be carried out by the participants;
12. any information on methods or
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|  | procedures which participants must use to store, handle, prepare, ship or dispose of the PT item and perform the measurements or tests;1. 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 validity;
2. preparation of any standardized reporting formats to be used by participants;
3. a detailed description of the statistical analysis to be used;
4. the origin, metrological traceability, and uncertainty of any assigned values;

the treatment of results from different measurement or test methods, where permitted by the PT scheme;criteria for the evaluation of the performance of participants;1. a description of the data, interim reports, or information to be returned to participants;
2. 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;
3. actions to be taken in the case lost, delayed or damaged PT items.
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| **7.2.2** | Statistical design |
| **7.2.2.1** | Does the statistical design developed to meet the objectives of the PT scheme, based on the type of data (quantitative or qualitative, including ordinal or nominal), statistical assumptions, the type of errors and expected number of results? |  |  |
| **7.2.2.2** | Does the PT provider document the statistical design and data analysis methods to be used to determine the assigned value and to evaluate the participant results and document the reasons for the selection and the assumptions upon which the statistical design and data analysis are based and does the PT provider able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures?  |  |  |
| **7.2.2.3** | Does the PT provider give careful consideration in designing a statistical analysis to the following:1. the accuracy, as well as the uncertainty, required or expected for the assigned value for each property or characteristics in the PT scheme;
2. 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 statistical meaningful analysis of participants results, the PT provider shall document, and provide to participants, details of the alternative approaches used to assess participant performance;
3. the relevance of significant figures to the reported participant results, including the number of decimal places;
4. the number of PT items to be measured or tested and the number of repeat measurements tests to be conducted on each PT item or for each determination;
5. the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria;
6. the procedures to be used to treat the participant results from different measurements or test methods which are not technically equivalent, where permitted by the PT scheme;
7. whether the measurement uncertainty of participant shall be report and how it will be used to evaluate the participant’ performance;
8. the procedures to be used to identify or handle outliers, or both;
9. where relevant, the procedures for the evaluation of values excluded from statistical analysis;
10. where appropriate, the objectives to be met for the design and the frequency of PT rounds.
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| **7.2.3** | Determination of assigned value |
| **7.2.3.1** | Does the PT provider document the procedure determining the assigned values for the properties or characteristics in a particular PT scheme? Where applicable, do this procedure take into account the metrological traceability and uncertainty required to demonstrate that the PT scheme is fit for its purpose? |  |  |
| **7.2.3.2** | Are the PT schemes in the area of calibration have assign values with metrological traceability? |  |  |
| **7.2.3.3** | Are the 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 determined by taking into account the purpose of the PT scheme? |  |  |
| **7.2.3.4** | When a consensus is used as assigned value, does the PT provider provide an estimate of the uncertainty of the assigned value (see note 7.2.1.3 item p) as prescribed in the plan for the PT scheme? |  |  |
| **7.2.3.5** | Does the PT provider have a policy regarding the disclosure of assigned values and the policy 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** | Does the PT provider 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** | Does the PT provider 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, does the PT provider 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** | Is the criteria for suitable homogeneity and stability established and based on the risks that inhomogeneity and instability can impact the evaluation of the performance of participants? |  |  |
| **7.3.2.2** | Are the procedures for the assessment of homogeneity and stability documented and conducted, where applicable, in accordance with appropriate statistical designs? |  |  |
| **7.3.2.3** | Does the assessment of homogeneity and stability 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), does the PT provider use appropriate methods to assess the homogeneity and stability of the PT item? |  |  |
| **7.3.2.5** | Are the PT items 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, does the stability qualified 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 round are retained for another PT round, does the property values or characteristics to be determined in the PT scheme 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, does the PT provider ensure that PT items are appropriately identified and stored to prevent contamination, damage, and deterioration? |  |  |
| **7.3.3.2** | Does the PT provider have appropriate procedures for dispatch to, and receipt from, storage? |  |  |
| **7.3.3.3** | Does the condition of stored PT items assessed at specified intervals or prior to distribution in order to detect possible deterioration? |  |  |
| **7.3.3.4** | When potentially hazardous PT items are used, does facilities available to ensure their safe handling, decontamination and disposal? |  |  |
| **7.3.4** | Packaging, labelling, and distribution of PT items |
| **7.3.4.1** | Does the PT provider control the 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** | Does the PT provider document relevant environmental conditions for the transport of PT items? If necessary, does environmental conditions monitored during transport? |  |  |
| **7.3.4.3** | In PT schemes where participants are required to transport PT items to other participants, or return them to the PT provider, does documented instructions for this transport, to ensure the validity of the PT item, supplied? |  |  |
| **7.3.4.4** | Does the PT provider 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** | Does the PT provider follow a procedure to enable the conformation of delivery of the PT items? |  |  |
| **7.3.5** | Instructions for participants |
| **7.3.5.1** | Does the PT provider 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** | Does the PT provider give detailed documented instructions to all participants? Instructions to participants shall include:the necessity to treat PT items in the same manner as routine samples, including used of routine measurement or test methods, unless there are particular requirements of the PT scheme which require departure from this principle;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;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;1. any appropriate instructions on handling the PT items, including any safety requirements;
2. any specific environmental conditions for the participant to conduct measurements or tests, or both, and, if relevant, any requirement for the participants to report environmental conditions during the time of the measurement of test;
3. specific and detailed instructions on the manner of recording and reporting results and associated requirement uncertainties, e.g., when the instruction include reporting of the expanded measurement uncertainty, the reported uncertainty shall include the coverage factor and the coverage probability;
4. 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;
5. instructions on return or forwarding of the items, when applicable;
6. the last date for the PT provider to receive the results from the participants;

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** | Are the results received from the participants recorded and analysed by appropriate methods? Does have procedures established and implemented to check the validity of data entry, data transfer, statistical analysis, and reporting? |  |  |
| **7.4.1.2** | Does the data analysis generate summary statistics and performance statistics and associated information consistent with the statistical designed of the PT scheme? |  |  |
| **7.4.1.3** | Is the influence of outliers on summary statistics minimized by using an appropriate statistical approach? |  |  |
| **7.4.1.4** | Does the PT provider have procedures for treatment of results from different measurements or test methods, where the PT scheme allows participant to use different measurement or test methods? |  |  |
| **7.4.1.5** | Does the PT provider have document criteria and procedures for dealing measurement or test results that are inappropriate for statistical evaluation, e.g., because of calculations errors, transpositions and other gross errors? |  |  |
| **7.4.1.6** | Does the PT provider have document 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 inhomogeneity and instability, damage or contamination? |  |  |
| **7.4.2** | **Evaluation of performance**  |
| **7.4.2.1** | Does the PT provider use valid methods of evaluation which meet the objectives of the PT scheme and the method document and include description of the basis for the evaluation? |  |  |
| **7.4.2.2** | Where applicable for the objectives of the PT scheme, does the PT provider provide expert commentary on the performance of participants with regard to the following:1. overall performance against prior expectations, taking measurement uncertainties into account;
2. variation within and between participants, and comparisons with any previous PT rounds, similar Pt scheme, or published data;
3. variation between measurement or test methods;
4. possible sources of error (with reference to outliers or poor performance) and suggestions for improving performance;
5. advise and feedback to participants as part of the continuous improvement procedures of participants;
6. situations unusual factors make evaluation of reports and commentary on performance impossible;
7. any other suggestions, recommendations or general comments;
8. conclusions.
 |  |  |
| **7.4.3**  | **PT reports** |
| **7.4.3.1** | Are the PT reports 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** | Does the report include the following, unless it is not applicable, or the PT provider has valid reason for not doing so:1. the name and contact details of the PT provider;
2. identification of person (s) authorizing the report;
3. 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;
4. the date of issue and status (e.g., preliminary, interim, or final) of the report;
5. unique identification that all its components are recognized as portion of a complete report and a clear identification of the end;
6. a statement of the extent to which results are confidential;
7. a unique identification of the report and the PT scheme;
8. a clear description of the PT items used, including necessary details of the PT item’s production and homogeneity and stability assessment;
9. the results of the participants, including the reported measurement uncertainties
10. procedures used to statistical analyse the data;
11. statistical data and summaries, including assigned values, range of acceptable results and graphical displays;
12. details of metrological traceability, and uncertainty of any assigned value;
13. procedures used to establish any assigned value and its uncertainty;
14. assigned values, their uncertainties and summaries statistics for measurement and test methods used by each group or participants (in different measurement or test methods are used by different groups of participants;
15. procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;
16. comments on the performance of participants
17. information about the design and implementation of the PT scheme;
18. advice on the interpretation of the statistical analysis;
19. comments or recommendations based on the outcomes of the PT round.
 |  |  |
| **7.4.3.3** | Are the reports shall made available to participants within planned timescale? 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** | Does the PT provider have a policy for the use of reports by participants and customers? |  |  |
| **7.4.3.5** | Does the report shall include the following when it is necessary to issue a new or amended report for a PT scheme or PT round?1. a unique identification;
2. a reference to the original report that it replaces or amends;
3. identification of the amendment and a statement concerning the reason for the amendment or reissue.
 |  |  |
| **7.4.3.6** | When issuing an amended report to a subset of participant (s), does an analysis of the potential impact on the other participants for the PT scheme and/or PT round shall be made to ensure there is no influence on the general performance of the participants? |  |  |
| **7.4.3.7** | If the PT provider issues a statement of participation or performance in addition to the PT report, does the statement shall not be misleading? |  |  |
| **7.5**  | **Technical records** |
| **7.5.1.1** | Does the PT provider 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 and the technical records include the date and the identity of personnel responsible for each PT activity and for checking data and results? |  |  |
| **7.5.1.2** | Does the data used to verify the PT items, instructions to participants, the original responses of participants and any other information included in reports recorded at the time they are made and shall be identifiable with the specific task? |  |  |
| **7.5.1.3** | Does the PT provider 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 retained, including the data of alteration, an indication of the altered aspects and the personnel responsible for alterations? |  |  |
| **7.5.2** | **Control of data and information statement**  |
| **7.5.2.1** | Does the PT provider have access to the data and information needed to perform its activities? |  |  |
| **7.5.2.2** | Does the PT provider information management system used for the collection, processing, recording, reporting, storage or retrieval of data validated for functionality, including the proper functioning of interfaces before introduction?  |  |  |
| **7.5.2.3** | Does the PT provider information management system:1. be protected from unauthorized access;
2. be safeguarded against tampering and loss;
3. be operated in an environment that complies with the system supplier or PT provider specifications or, in case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
4. be maintained in a mannered that ensures the integrity of the data and information;
5. include recording of system failures and the appropriate immediate and corrective actions.
 |  |  |
| **7.5.2.4** | Does the provider ensure that the external service provider or operator of the system complies with all applicable requirements of this document when a PT provider information management system is managed and maintained off-site or through an external service provider? |  |  |
| **7.5.2.5** | Does the PT provider 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** | Are calculations and data transfers check in an appropriate and systematic manner? |  |  |
| **7.5.3** | **Surveillance of the processes** |
|  | Does the PT provider have a procedure to ensure the validity of the PT scheme, the surveillance activities planned and reviewed (see also the 8.9.2 item n), and the resulting data recorded for the continuous improvement process? |  |  |
| **7.5.4** | **Nonconforming work** |
| **7.5.4.1** | Does the PT provider have a procedure that shall be implemented when any aspect of its PT scheme does not conform to its own procedures or the agreed requirements of its participants or customers? The procedure (s) shall ensure that:1. the responsibilities and authorities for the management of conforming work are defined;
2. actions (including halting work of ongoing of PT schemes and/or PT rounds and withholding PT schemes and/or PT round reports, as necessary) are defined are based upon the risk levels established by the PT provider;
3. an evaluation of the significance of the conforming work is made, including an impact analysis on previous PT activities.
4. a decision on the end for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work;
5. 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;
6. the responsibility and authorization of the resumption of work is defined.
 |  |  |
| **7.5.4.2** | Does the PT provider retain records of nonconforming work and actions as specified 7.5.4.1 items b to f.? |  |  |
| **7.5.4.3** | Where the evaluation indicates that nonconforming work cam recur or that there is doubt about the compliance of the PT provider with their own procedures, does the corrective action procedure in 8.7 shall be promptly followed? |  |  |
| **7.6** | **Handling of complaints** |
| **7.6.1** | Does the PT provider have a documented procedure for handling complaints that shall include at least the following:1. a description of the process for receiving, substantiating and investigating complaint and deciding what actions shall be taken in response;
2. tracking and recording the complaint, including the actions undertaken to resolve it;
3. ensuring that any appropriate action is taken.
 |  |  |
| **7.6.2** | Are the description of the process for handling complaints publicly available? |  |  |
| **7.6.3** | Does the PT provider confirm whether the complaint relates to PT activities and, if so, remove the complaint? |  |  |
| **7.6.4** | Does the PT provider receiving the complaint responsible for gathering all necessary information to determine whether the complaint is substantiated? |  |  |
| **7.6.5** | Does the PT provider acknowledge receipt of the complaint and provide the complainant with the outcome? |  |  |
| **7.6.6** | Are the investigation and resolution of complaints shall not result in any discriminatory actions?  |  |  |
| **7.6.7** | Is the resolution of complaints 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** | Does the PT provider give formal notice of the end of the handling of the complaint to the complainant whenever possible? |  |  |
| **7.6.9** | Does the PT provider responsible for all decisions at all levels of the handling process for the complaints? |  |  |
| **7.7** | **Handling of appeals** |
| **7.7.1** | Does the PT provider have a documented procedure for handling appeals that shall include at least the following:1. a description of the process for receiving and investigating the appeals and deciding what actions shall be taken in response;
2. tracking and recording the appeal, including the actions undertaken to resolve it;
3. ensuring appropriate action is taken.
 |  |  |
| **7.7.2** | Does the description of the process for handling appeals publicly available? |  |  |
| **7.7.3** | Does the PT provider acknowledge receipt of the appeal and provide the appellant with the outcome and, if applicable, progress reports? |  |  |
| **7.7.4** | Does the PT provider receiving the appeal responsible for gathering all necessary information to determine whether the appeal is valid?  |  |  |
| **7.7.5** | Does the PT provider responsible for all decisions during the process for handling appeals? |  |  |
| **7.7.6** | Is the decision on the appeal 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** | Are the investigation and decision on appeals shall not results in any discriminatory actions? |  |  |
| **8** | **Management system requirements** |
| **8.1** | **General requirements** |  |  |
| **8.1.1** | Does the PT provider establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document and its scope of PT activities? |  |  |
| **8.1.2** | Does the management system of the PT provider include at least the following:* policies;
* responsibilities;
* management system documentation;
* control of management system documents (see 8.2);
* control of records (see 8.4);
* action to address risks and opportunities (see 8.5);
* improvement (see 8.6);
* corrective actions (see 8.7);
* internal audits (see 8.8);
* management reviews (see 8.9).
 |  |  |
| **8.1.3** | Does the PT provider meet 8.1.2 by establishing, implementing and maintaining a quality management system (e.g., in accordance with the requirements of ISO 9001)? This quality management system shall support and demonstrate the consistent fulfilment of the requirements of this document. |  |  |
| **8.1.4** | Does the PT provider management system provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? |  |  |
| **8.2** | **Management system documentation**  |
| **8.2.1** | Are the policies and objectives addressing the competence, impartiality and consistent operation of the PT provider? |  |  |
| **8.2.2** | Are all documentation, processes, systems and records related to the fulfilment of the requirements of this document included in, or referenced from, the management system? |  |  |
| **8.2.3** | Are all personnel involved in PT activities, have access to the parts of the management system documentation and related information that are applicable to their responsibilities? |  |  |
| **8.3** | **Control of management system documents** |
| **8.3.1** | Does the PT provider control the documents (internal and external) that relate of the fulfilment of this document? |  |  |
| **8.3.2** | Does the PT provider ensure that:1. documents are approved for adequacy prior to issue by authorized personnel;
2. documents are periodically reviewed and updated as necessary;
3. changes and current revision status of documents are identified;
4. relevant revisions are applicable documents are available at points of use and their distribution is controlled;
5. documents are uniquely identified;
6. the unintended use of obsolete documents is prevented and that suitable identification is applied to them if they are retained for any purposes.
 |  |  |
| **8.4** | **Control of records** |
| **8.4.1** | Does the PT provider establish and retain legible records to demonstrate fulfilment of the requirements of this document? |  |  |
| **8.4.2** | Does the PT provider implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time and disposal of its records? |  |  |
| **8.4.3** | Does the PT provider retain records for a period consistent with its contractual obligations and access to these records consistent with the confidentiality commitments and records shall be readily available? |  |  |
| **8.5** | **Actions to address risks and opportunities**  |
| **8.5.1** | Does the PT provider consider the risks and opportunities associated with the PT activities in order to:1. give assurance that the management system achieves its intended results;
2. enhance desirable effects to achieve the purpose and objectives to the PT provider;
3. prevent, or reduce, undesired impacts and potential failures in the PT activities;
4. achieve improvement
 |  |  |
| **8.5.2** | Does the PT provider plan:1. actions to address these risks and opportunities;
2. how to integrate and implement these actions into its management system;
3. how to evaluate the effectiveness of these actions.
 |  |  |
| **8.5.3** | Are actions taken to address risks and opportunities proportional to the potential impact on the validity of the PT scheme? |  |  |
| **8.6** | **Improvement**  |
| **8.6.1** | Does the PT provider identify and select opportunities for improvement and implement any necessary actions? |  |  |
| **8.6.2** | Does the PT provider seek feedback, both positive and negative, from its participants and customers? Does feedback analysed and used to improve the management system, PT activities and customer service? |  |  |
| **8.7** | **Corrective actions** |  |  |
| **8.7.1** | When a nonconformity occurs, does the PT provider:1. react to the nonconformity and, as applicable:
* take action to control and correct it;
* address the consequences;
1. evaluate the needed for action to eliminate the cause (s) of the nonconformity, in order that it does not recur or occur elsewhere by:
* reviewing and analysing the nonconformity;
* determining the causes of the nonconformity;
* determining is similar nonconformities exist, or can potentially occur;
1. implement any action needed;
2. review the effectiveness of any corrective action taken;
3. update risks and opportunities determined during planning, if necessary;
4. make changes to the management system, if necessary.
 |  |  |
| **8.7.2** | Are the corrective actions appropriate to the effects of the nonconformities encountered? |  |  |
| **8.7.3** | Does the PT provider retain records as evidence of:1. the nature of nonconformities, cause (s) and any subsequent actions taken;
2. the effectiveness of any corrective action.
 |  |  |
| **8.8** | **Internal audits** |
| **8.8.1** | Does the PT provider conduct internal audits at planned intervals to provide information on whether the management system:1. Conforms to:
* the PT provider’s own requirements for its management system, including the PT activities;
* the requirements of this document.
 |  |  |
|  | 1. Is effectively implemented and maintained.
 |  |  |
| **8.8.2** | Does the PT provider:1. plan, establish, implement and maintained an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the PT activities concerned, changes affecting the PT provider and the results of previous audits;
2. ensure that the internal audits are conducted by personnel knowledgeable in conduct of PT activities and auditing and the requirements of this document and that these personnel are independent of activities being audited, wherever resources permit;
3. define the audit criteria and scope for each audit;
4. ensure that the results of the audits are reported to relevant management;
5. implement appropriate corrections and corrective actions without undue delay;
6. retain records as evidence of the implementation of the audit programme and the audit results.
 |  |  |
| **8.9** | **Management reviews** |
| **8.9.1** | Does the PT provider management 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** | Are the inputs to the management review recorded and include information related to the following:1. changes in internal and external issues that are relevant to the PT provider;
2. fulfilment of objectives;
3. suitability of policies and procedures;
4. status of actions from previous management reviews;
5. outcome of recent internal audits;
6. corrective actions;
7. assessment by external bodies;
8. changes in the volume and type of the work or in the range of PT activities;
9. customer, participant and personnel feedback;
10. complaints and appeals;
11. effectiveness of any implemented improvements;
12. adequacy of resources;
13. results of risk identification;
14. outcomes of the surveillance of the processes;
15. other relevant factors, such as training.
 |  |  |
| **8.9.3** | Are the outputs from the management review record all decisions and actions related to at least:1. the effectiveness of the management system and its processes;
2. improvement of the activities related to the fulfilment of the requirements of this document;
3. provision of required resources;
4. any need for changes
 |  |  |

| **PAB Supplementary Requirements** | **Reference to CAB’s Documents and/or Information on the Implementation**(To be completed by the CAB) | PAB Remarks |
| --- | --- | --- |
| LA/SR 02 (Supplementary Requirements on Traceability of Measurement) |  |  |
| LA/SR 03 (Supplementary Requirements on the Use of PAB Laboratory and Inspection Body Accreditation Symbol) |  |  |

*\*Note: LA/SR 03 is not applicable for Initial Application*