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|  | **NABL 220E** |
|  | **National Accreditation Board for Testing**  **and Calibration Laboratories (NABL)** |

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| **Document Review Checklist**  **(as per ISO/IEC 17043: 2023)** |

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| **ISSUE NO.: 01**  **ISSUE DATE: 16-Oct-2023** | **AMENDMENT NO.: 01**  **AMENDMENT DATE: 15-Nov-2023** |
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**AMENDMENT SHEET**

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| **S. No.** | **Amendment No.** | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment** | **Reasons** | **Signature**  **QA Team** | **Signature Competent Authority** |
|  | 01 | 28 | 8.4 | 15.11.2023 | As highlighted | Internal review | -Sd/- | -Sd/- |
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**Introduction**

Lead assessor is required to review the information provided by the Proficiency Testing Provider (PTP) in line with NABL policies relevant to applicant PTP. This document review checklist is for providing remarks/ comments on the overall completeness of the information on the application forms and the quality manual / management system document in conformance with the requirements of ISO/IEC 17043:2023.

Lead assessor is required to submit the Document Review Report (DRR) directly to NABL within 10 days along with duly filled Form 74 ‘Declaration of Impartiality and Confidentiality’.

**Annexure**- Form-74 ‘Declaration of Impartiality and Confidentiality’

**Document Review Checklist (as per ISO/IEC 17043:2023)**

(Remarks / Comments of Lead Assessor on Application form &

Quality Manual / Management System Document)

|  |  |
| --- | --- |
| Name and Address of the PTP |  |
| Name of Lead Assessor (with Assessor ID) |  |
| Date of Document Review |  |

**Part ‘A’ - Comments on Completeness of Application (NABL 180)**

|  |  |  |
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| **S. No.** | **Requirements as per Application form** | **Adequate/ Inadequate (if inadequate, mention comments)** |
|  | Name and location details of the PTP |  |
|  | Legal identity |  |
|  | Details on other accreditations |  |
|  | Information on PT Schemes |  |
|  | Scope of the PTP |  |
|  | Required details of senior management |  |
|  | Proposed personnel to give opinions and interpretations; and authorize the issue of proficiency testing reports |  |
|  | Organization chart of the PTP |  |
|  | Details of staff |  |
|  | Details of Steering/ Advisory committee |  |
|  | List of equipment/ Reference materials/ reference standards |  |
|  | Internal audit |  |
|  | Management Review |  |
|  | Any general points |  |

**Part ‘B’ - Remarks on Quality Manual/ Management System Document**

The Assessor must review the laboratory’s documented management system to verify compliance with the requirements of ISO/IEC 17043: 2023 and it can be assessed further to verify that the documented management system is indeed implemented as described, record conclusion/comments related to any requirements. All non-conformity (ies) must be identified and reported.

| **DOCUMENTATION** | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | **IMPLEMENTATION** | | | |
| **REQUIREMENTS OF ISO/IEC 17043: 2023** | | | | | |  |  | | **OBSERVATIONS/CONCLUSION** | |
| **4** | **GENERAL REQUIREMENTS** | | | | | | | | | |
|  | **4.1** | **IMPARTIALITY** | | | | | | | | |
|  |  | 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.  *NOTE A relationship can be based on ownership, governance, management, personnel, shared resources, finances, contracts or marketing (including branding). Such relationships do not necessarily present a PT provider with a threat to impartiality.* |  |  | |  | |
|  |  | 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** | | | | | | | | |
|  |  | 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 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.  *NOTE The terms “proprietary” and “confidential” do not preclude publication for academic and new insights of information purposes, provided that neither clients nor participants can be identified, including by inference.* |  |  |  | | |
|  |  | 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** | | | | |  |  |  | | |
| **5.1** | | The PT provider shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its PT activities.  *NOTE For the purposes of this document, a governmental PT provider is deemed to be a legal entity on the basis of its governmental status.* | | |  |  |  | |
|  | **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; | |  |  |  | |
|  |  | | 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. | |  |  |

| DOCUMENTATION | | |
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|  | IMPLEMENTATION | |
| **REQUIREMENTS OF ISO/IEC 17043: 2023** | | | | |  |  | OBSERVATIONS/CONCLUSION |
| **6** | **RESOURCE REQUIREMENTS** | | | | | | |
|  | **6.1** | **GENERAL** | | | | | |
|  |  | 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 conducted in accordance with the relevant requirements of ISO/IEC 17025.  *NOTE 1 The relevant requirements are requirements that relate to the validity of the measurement or test results, which can impact the validity of PT activities (e.g. metrological traceability). They are not intended to include management system requirements or other requirements unrelated to the PT activities.*  *NOTE 2 In the medical area, the relevant requirements of ISO 15189 apply in place of ISO/IEC 17025.* | |  |  |  |
|  |  | 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.  *NOTE 1 Such materials include reference materials for quality control (e.g. chemical solutions with or without reference values) and reference materials with certified property values (CRMs).*  *NOTE 2 The relevant requirements are requirements that relate to the validity of operations to produce a reference material that directly impacts the PT activities (e.g. mixing, or handling and storage). They are not intended to include management system requirements or other requirements not directly related to the PT activities (e.g. contents of certificates).*  *NOTE 3 In the medical area, the relevant requirements of ISO 15194 can apply for CRMs in place of ISO 17034, when applicable.* | |  |  |  |
|  | **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; and |  |  |  |
|  |  | 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. |  |  |
|  | **6.3** | **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).  EXAMPLE Examples of such conditions include biological sterility, dust, electromagnetic disturbances, radiation, illumination (light), humidity, electrical supply, temperature, sound and vibration levels, as appropriate to the technical activities concerned. | |  |  |  |
|  | 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 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. |  |  |
|  | *NOTE This does not prevent the PT provider from using advice or assistance from any advisors, experts or steering groups.* | |  |  |  |
|  | 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.  *NOTE In cases where the customer or a regulatory authority specifies which external provider is to be used, being responsible can be interpreted as taking actions to minimize any undesired effects that directly affect the validity of PT activities.* | |  |  |  |

| DOCUMENTATION | | | | |
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|  | | IMPLEMENTATION | | |
| **REQUIREMENTS OF ISO/IEC 17043: 2023** | | | | | | |  | |  | | OBSERVATIONS/CONCLUSION |
| **7** | **PROC ESS REQUIREMENT** | | | | | | | | | | |
|  | **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. |  | |  | |
|  |  | *NOTE 1 This review is particularly important when a customer requests a PT scheme to be created for a specific purpose or for a different level or frequency of participation from that normally offered.* | |  | |  | |  |
|  |  | *NOTE 2 This review can be simplified when the PT scheme is fully described in a catalogue or other notice and the participant is enrolling for a routine PT round.* | |  | |  | |  |
|  |  | 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.  *NOTE When designing and planning the PT scheme, the relevant standards and requirements specific to the objectives of the PT scheme can be considered, e.g. ISO/IEC 17025, ISO 15189, ISO/IEC 17020. Safety and ethical issues can also be considered.* | |  |  | |  | |
|  |  | 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.  EXAMPLE: Examples of significant changes are new approaches for PT item production, assessment of homogeneity and stability, determination of the assigned value, statistical analysis and new types of PT activities. | |  |  | |  | |
|  |  | 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;  *NOTE Assigned values can have uncertainty contributions from sources in addition to the uncertainty of measurement results used for characterization, such as in homogeneity and instability, and interlaboratory differences if more than one laboratory is used for characterization.* |  |  | |
|  |  | 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.  *NOTE 1 Statistical design covers the process of planning of the PT scheme and the collection, analysis and reporting of the PT scheme data. Statistical designs are often based on stated objectives for the PT scheme, such as detection of certain types of errors with specified power or determination of assigned values with a specified uncertainty.*  *NOTE 2 Data analysis methods can vary from the very simple (e.g. descriptive statistics) to the complex, using statistical models with probabilistic assumptions or combinations of results for different PT items.*  *NOTE 3 In cases where the PT scheme design is mandated by a specification given by, for example, a customer or regulatory authority, the statistical design and data analysis methods can be taken directly from the specification.*  *NOTE 4 In the absence of reliable information needed to produce a statistical design, a preliminary interlaboratory comparison can be used.* | |  |  | |  | |
|  |  | 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.  *NOTE ISO 13528 provides statistical methods for the determination of the assigned value.* | |  |  | |  | |
|  |  | 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.  *NOTE The required metrological traceability chain can differ depending on the type of PT item, the property or characteristic and the availability of traceable calibrations and reference materials.* | |  |  | |  | |
|  |  | 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 [see Note to 7.2.1.3 item p)] 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.  *NOTE PT items usually match the type of items or materials encountered in routine laboratory activities.* | |  |  | |  | |
| 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 in homogeneity 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.  *NOTE 1 Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected or when stability studies indicate that the material is preferably stored in bulk form.*  *NOTE 2 Different approaches for the assessment of homogeneity and stability, including situations where experimental study is not feasible, are described in Annex B of this document, in ISO 13528 and in ISO Guide 35.* | |  |  | |  | |
|  |  | 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;  *NOTE This instruction usually includes parameters such as the units of measurement, the number of significant figures or decimal places, and the reporting basis (e.g. on “dry weight” or “as received”).* |  |  | |
|  |  | 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 analyzed 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.  *NOTE Examples of valid methods of evaluation are described in ISO 13528.* | |  |  | |  | |
|  |  | 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.  *NOTE It can be useful to provide individual summary sheets for participants periodically during or after completion of a particular PT round. These can include updated summaries of performance for individual participants over successive PT rounds of a continuous PT scheme. Such summaries can be further analyzed, and trends highlighted, if required.* |  |  | |
|  |  | 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.  *NOTE When it is not practical to report all original data to participants, a summary of the results, e.g., in tabulated or graphical form, can be supplied.* | |  |  | |  | |
|  |  | 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.  *NOTE For continuous PT schemes, it can be sufficient to have simpler reports, such that many of the elements in this clause can be excluded from routine reports but included in the PT scheme procedures or in periodic summary reports that are available to participants.* |  |  | |
|  |  | 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.  *NOTE Preliminary or anticipated results allow for early investigation of possible errors.* | |  |  | |  | |
|  |  | 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.  *NOTE 1 In this document, a PT provider information management system includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.*  *NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered sufficiently validated.* | |  |  | |  | |
|  |  | 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  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.  *NOTE Depending on the PT scheme, surveillance activities can include:*  *— evaluation of externally provided products and services;*  *— use of reference materials or other control items;*  *— the transmission of results from participants;*  *— control of statistical conditions to confirm the validity of performance evaluation;*  *— checking of reports;*  *— for continuous schemes, comparisons against previous PT rounds.* | | | |  |  | |  | |
|  |  | 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.  *NOTE Identification of nonconforming work or problems with the management system or with technical activities can occur at various places within the management system and technical operations. Examples are participant or customer complaints, management reviews and internal or external audits, surveillance of the processes, production of PT items, homogeneity and stability assessments, data analysis, instructions to participants and materials handling and storage.* |  |  | |
|  |  | 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.  *NOTE PT providers that only have PT schemes using purely statistically derived evaluation procedures do not usually handle appeals. Appeals concerning performance evaluations can be addressed as a complaint.* | | |  |  | |
|  |  | 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. | | | |  |  | |  | |

| DOCUMENTATION | | | | | | |
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|  | | | IMPLEMENTATION | | | |
| **REQUIREMENTS OF ISO/IEC 17043: 2023** | | | | | |  | | |  | | OBSERVATIONS/CONCLUSION | |
| **8** | **MANAGEMENT SYSTEM REQUIREMENTS** | | | | | | | | | | | |
|  | **8.1** | **GENERAL REQUIREMENTS** | | | | | | | | | | |
|  |  | 8.1.1 | The PT provider shall establish, document, implement and maintain a management system to support and demonstrate the consistent fulfillment of the requirements of this document and its scope of PT activities. | | | |  | | |  | |  |
|  |  | 8.1.2 | The management system of the PT provider shall include at least the following:   * policies; * responsibilities; * management system documentation (see 8.2); * control of management system documents (see 8.3); * control of records (see 8.4); * actions 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 | A PT provider may 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 fulfillment of the requirements of this document. | | | |  | | |  | |  |
|  |  | 8.1.4 | The PT provider management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. | | | |  | | |  | |  |
|  | **8.2** | **MANAGEMENT SYSTEM DOCUMENTS** | | | | | | | | | | |
|  |  | 8.2.1 | The policies and objectives shall address the competence, impartiality, and consistent operation of the PT provider. | |  | | |  | | |  | |
|  |  | 8.2.2 | All documentation, processes, systems and records related to the fulfilment of the requirements of this document shall be included in, or referenced from, the management system. | |  | | |  | | |  | |
|  |  | 8.2.3 | All personnel involved in PT activities shall 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 | The PT provider shall control the documents (internal and external) that relate to the fulfillment of this document. | |  | | |  | | |  | |
|  |  | 8.3.2 | The PT provider shall ensure that: | |  | | |  | | |  | |
| a | 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. |  | | |  | | |  | |
|  |  | b | 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.  *NOTE PT items usually match the type of items or materials encountered in routine laboratory activities.* |  | | |  | | |
|  |  | c | 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. |  | | |  | | |
|  |  | d | relevant versions of applicable documents are available at points of use and their distribution is controlled; |  | | |  | | |
|  |  | e | documents are uniquely identified; |  | | |  | | |
|  |  | f | the unintended use of obsolete documents is prevented, and that suitable identification is applied to them if they are retained for any purpose. |  | | |  | | |
|  | **8.4** | **CONTROL OF RECORDS** | | |  | | |  | | |  | |
|  | 8.4.1 | The PT provider shall establish and retain legible records to demonstrate fulfillment of the requirements in this document. | |  | | |  | | |  | |
| 8.4.2 | The PT provider shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time and disposal of its records. | |  | | |  | | |  | |
| 8.4.3 | The PT provider shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments and records shall be readily available.  *NOTE Additional requirements regarding technical records are given in 7.5.1.* | |  | | |  | | |  | |
| **8.5** | **ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES** | | |  | | |  | | |  | |
|  | 8.5.1 | The PT provider shall consider the risks and opportunities associated with the PT activities in order to: | |  | | |  | | |  | |
|  |  | a | give assurance that the management system achieves its intended results; |  | | |  | | |  | |
|  |  | b | enhance desirable effects to achieve the purpose and objectives of the PT provider; |  | | |  | | |
|  |  | c | prevent, or reduce, undesired impacts and potential failures in the PT activities; |  | | |  | | |
|  |  | d | achieve improvement. |  | | |  | | |
|  |  | 8.5.2 | The PT provider shall plan: | |  | | |  | | |  | |
|  |  | a | actions to address these risks and opportunities; |  | | |  | | |  | |
| b | how to integrate and implement these actions into its management system; |  | | |  | | |
|  |  | c | how to evaluate the effectiveness of these actions.  *NOTE Although this document specifies that the PT provider plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. PT providers can decide whether or not to develop a more extensive risk management methodology, e.g. through the application of other guidance or standards.* |  | | |  | | |
|  |  | 8.5.3 | Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of the PT scheme.  *NOTE 1 Examples of addressing risks include developing strategies for preventing collusion between participants and performing a feasibility study to evaluate the best transport conditions for the PT items of a PT scheme.*  *NOTE 2 Opportunities can lead to expanding the scope of the PT activities, increasing the number of participants in a PT scheme, making a PT scheme more cost effective for the PT provider as well as the participants (customers), and reducing the time required to produce the PT items.* | |  | | |  | | |  | |
|  | **8.6** | **IMPROVEMENT** | | |  | | |  | | |  | |
|  |  | 8.6.1 | The PT provider shall identify and select opportunities for improvement and implement any necessary actions.  *NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data and external assessments.* | |  | | |  | | |  | |
|  |  | 8.6.2 | The PT provider shall seek feedback, both positive and negative, from its participants and customers. The feedback shall be analysed and used to improve the management system, PT activities and customer service.  EXAMPLE Examples of the types of feedback include participant or customer satisfaction surveys, communication records and review of reports with participants and customers. | |  | | |  | | |  | |
|  | **8.7** | **CORRECTIVE ACTIONS** | | |  | | |  | | |  | |
|  | 8.7.1 | When a nonconformity occurs, the PT provider shall: | |  | | |  | | |  | |
|  | a | react to the nonconformity and, as applicable:   * take action to control and correct it; * address the consequences; |  | | |  | | |  | |
|  |  | b | evaluate the need 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 if similar nonconformities exist, or can potentially occur; |  | | |  | | |
|  |  | c | implement any action needed; |  | | |  | | |
|  |  | d | review the effectiveness of any corrective action taken; |  | | |  | | |
|  |  | e | update risks and opportunities determined during planning, if necessary; |  | | |  | | |
|  |  | f | make changes to the management system, if necessary. |  | | |  | | |
|  |  | 8.7.2 | Corrective actions shall be appropriate to the effects of the nonconformities encountered. | |  | | |  | | |  | |
|  |  | 8.7.3 | The PT provider shall retain records as evidence of: | |  | | |  | | |  | |
|  |  | a | the nature of the nonconformities, cause(s) and any subsequent actions taken; |  | | |  | | |  | |
|  |  | b | the effectiveness of any corrective action. |  | | |  | | |
|  | **8.8** | **INTERNAL AUDITS** | | |  | | |  | | |  | |
|  |  | 8.8.1 | The PT provider shall conduct internal audits at planned intervals to provide information on whether the management system: | |  | | |  | | |  | |
|  |  | a | conforms to:   * the PT provider’s own requirements for its management system, including the PT activities; * the requirements of this document; |  | | |  | | |  | |
|  |  | b | is effectively implemented and maintained. |  | | |  | | |
|  |  | 8.8.2 | The PT provider shall: | |  | | |  | | |  | |
|  |  | a | plan, establish, implement and maintain an audit program 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; |  | | |  | | |  | |
|  |  | b | ensure that 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; |  | | |  | | |
|  |  | c | define the audit criteria and scope for each audit; |  | | |  | | |
|  |  | d | ensure that the results of the audits are reported to relevant management; |  | | |  | | |
| e | implement appropriate corrections and corrective actions without undue delay; |  | | |  | | |
|  |  | f | retain records as evidence of the implementation of the audit programme and the audit results.  *NOTE ISO 19011 provides guidelines for auditing management systems.* |  | | |  | | |
|  | **8.9** | **MANAGEMENT REVIEWS** | | |  | | |  | | |  | |
|  |  | 8.9.1 | The PT provider management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this document. | |  | | |  | | |  | |
|  |  | 8.9.2 | The inputs to management review shall be recorded and shall include information related to the following: | |  | | |  | | |  | |
|  |  | a | changes in internal and external issues that are relevant to the PT provider; |  | | |  | | |  | |
|  |  | b | fulfillment of objectives; |  | | |  | | |
|  |  | c | suitability of policies and procedures; |  | | |  | | |
|  |  | d | status of actions from previous management reviews; |  | | |  | | |
|  |  | e | outcome of recent internal audits; |  | | |  | | |
|  |  | f | corrective actions; |  | | |  | | |
|  |  | g | assessments by external bodies; |  | | |  | | |
|  |  | h | changes in the volume and type of the work or in the 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 | other relevant factors, such as training. |  | | |  | | |
|  |  | 8.9.3 | The outputs from the management review shall record all decisions and actions related to at least: | |  | | |  | | |  | |
|  |  | a | the effectiveness of the management system and its processes; |  | | |  | | |  | |
|  |  | b | improvement of the activities related to the fulfillment of the requirements of this document; |  | | |  | | |
|  |  | c | provision of required resources; |  | | |  | | |
|  |  | d | any need for changes. |  | | |  | | |

**Form 74**

**DECLARATION OF IMPARTIALITY & CONFIDENTIALITY**

(to be filled in by each Assessor and enclosed with the Assessment report)

|  |  |  |
| --- | --- | --- |
| **Name** |  | Assessor ID:  (To be filled in by NABL) |
| **Designation** |  | |
| **Organisation** |  | |
| **Address** |  | |
| **Capacity** | Lead Assessor / Technical Assessor / Technical Expert / Observer | |
| **CAB\* Assessed** |  | |
| **Date of Assessment** |  | |
| **Type of Assessment** | *Document Review / Pre-Assessment / Initials assessment / Onsite Surveillance*  */ Re-Assessment / Supplementary visit* | |

*\*CAB – Conformity Assessment Body (Testing / Medical / Calibration laboratory / Proficiency Testing Provider (PTP) / Reference Material Producer (RMP))*

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereby declare that I have not offered any consultancy, guidance, supervision or other services to the CAB (e.g. internal audit), in any way.

I am / am not\* an ex-employee of the CAB and am/ am not\* related to any person of the management of the CAB.

I got an opportunity to go through various documents like Quality Manual, Procedural Manuals, Work instructions, Internal reports etc. of the above CAB and other related information that might have been given by NABL. I undertake to maintain strict confidentiality of the information acquired in course of discharge of my responsibility and shall not disclose to any person other than that required by NABL.

*\*Strike out which is not applicable*

|  |  |
| --- | --- |
| Date: |  |
| Place: | Signature |

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