Quality Manual: Quality Assurance Forum (QAF)

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Approved By	Name: Dr Dinesh Rathod		Designation: Director		Sign:
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REVISION LOG

Issue No	Effective Date	Author	Revision Summary

INDEX

GENERAL

The numbering of clauses in this Quality Manual directly corresponds to the numbering of clauses in ISO 17043: 2022.
Re-issuing the relevant section of this manual and adapting the issue level in the index will update this manual.
This Quality Manual documents the quality system and demonstrates the organization's ability to execute the indicated tests to meet quality and regulatory requirements in compliance with ISO 17043:2022 and NABL 181.
The following are the authorized holders of the controlled copy of the Quality Manual.

No.	Copy No.	Copy Holder
1.	01	Quality Manager
2.	02	Organization Director
3.	03	Assessor/s (For audit purposes; otherwise held by Quality Manager)

LIST OF ABBREVIATIONS

Annex	Annexure	**ISO**	International Organization for Standardization
CV	Coefficient of Variation	**IT**	Information Technology
DY	Deputy	**IQC**	Internal Quality Control
CLIA	Chemiluminescence immuno-assay	**Lab**	Organization
cumm	Cubic Milli Meter	**LIMS / LIS**	Organization Information Management System
Dr	Doctor	**QAF**	Quality Assurance Forum
CME	Continuous Medical Education	**EQAS**	External Quality Assurance Scheme
NABL	National Accreditation Board for Testing and Calibration Laboratories	**PT**	Proficiency testing
IEC	International Electrotechnical Commission	**e.g.**	Example

INTRODUCTION

QAF was created in 2010 by a group of qualified professionals who aim to provide a platform for quality improvements in medical laboratories and healthcare organizations, providing one-step service and innovative solutions in Quality Management for medical testing laboratories and healthcare organizations.

From partnership firm structure management upgraded structure to LLP in the name of UNIEQAS HEALTHCARE SOLUTIONS LLP. EQAS activities will be done in name of "Quality assurance forum" (QAF).

Our vision is to become a leading service provider for Total Quality Management in Medical Laboratories and healthcare organizations across Gujarat and western India. Our Mission is to help our clients achieve excellence in quality practices through increasing awareness, training, and ability to implement quality standards in medical laboratories and healthcare organizations.

This quality manual is prepared and issued as per the requirement of ISO 17043:2022. All staff members can access the Quality Manual copy kept with the Quality Manager. The soft copy of the Quality Manual is saved on the hard disk of the Quality Manager's computer and is password protected. The PDF version of the Quality Manual is saved in the computer of the Quality Manager.

The quality manager can show and share copies of this manual for audits done by accreditation bodies and regulatory bodies. The Organization Director- Quality Assurance Forum (QAF) (Henceforth termed as The Organization), has the authority to allow inspection of the controlled copy by any visitor, who wishes to go through the Quality Manual, strictly under QA supervision and with prior authorization from senior organization leadership.

Description of Organization:
Organization Name: Quality Assurance Forum (QAF), A UNIT OF UNIQAS HEALTHCARE SOLUTION LLP.
Address: Plot No. Quality Assurance Forum (QAF), 201, Puspraj Arcade, Above Axis Bank, Near Bhuyang Dev Cross Road Ahmedabad 380061
Telephone Number: +91 9925012686

Quality Assurance Forum (QAF), a unit of Uniqas Healthcare Solution LLP. is a Small size organization. The organization is custom-builtfor PT testing and PT-providing purposes.

A team of well-trained medical, and non-medical staff and experienced clinical technicians work to offer various services. A team of doctors on board, including specialists are equipped with the knowledge and expertise for handling various types of medical conditions.

Organization (Institution) Profile:

Initially, Inter Laboratory program was started as a trusted alternative to slit sample exchanges between three to four reputed laboratories in 2008 under the name of Ahmedabad Inter Laboratory Comparison Scheme (AILC) for helping the medical laboratories wanting to follow ISO 15189. Soon number of laboratories participating in this scheme increases not only from Ahmedabad but also from other cities of Gujarat.

In 2010, Quality Assurance Forum (QAF) is formally formed by three Pathologist working in different setups with mindset to provide stage for establishment continual educational activity and inter-laboratory comparison. Three pathologist namely are Dr. Dinesh Rathod, Dr. Bipin Patel and Dr. Viral Patel. Their primary interest in this QMS fields leads to plan this structure. QAF is an organization for all activities of laboratory and involving all staff working in laboratory like pathologist, technician and phlebotomist. QAF is organization CME regularly for the same. All founder members are assessors empaneled as technical and lead assessors in various organizations granting accreditation/ certification for technical competence and management requirements like NABL, NABH etc...

In 2017, QAF developed online indigenous module that allows users lab to enter results and view their reports.

Currently in the same program, more than 80 laboratories from more than 4 states participating in more than 140 parameters for assessing analytical performance among peers. As a part of continual improvement and development, in 2023, This program is not accredited by NABL for ISO 17043.

QAF committee has decided to launch EQAS scheme for the micro and small size medical laboratories to extend benefit of quality healthcare services to maximum people. As per new notification from NABL, Quality Assurance Forum, a Partnership Firm is converted in to a unit of Limited Liability Partnership in 2024 and the new name allowed by ministry of corporate affair for this was **Uniqas Healthcare Solution LLP**. All PT (EQAS Program) will be done under Quality Assurance Forum. In this document, wherever Quality Assurance Forum or QAF is written, It shall be read as "Quality Assurance Forum, A unit of Uniqas Healthcare Solution LLP."

QUALITY POLICY

QAF is committed to providing accurate reliable, timely, and unbiased Professional practice with the complete satisfaction of all participants by maintaining its confidentiality. We are committed to follow good professional practice and comply with the requirements of quality management systems. All staff familiarize themselves with the quality documentation and implement the policies and procedures at all times.

QAF EQAS is designed to monitor laboratories' continuing performance, identification of problems in the lab, and initiation of action for improvement. The program is evaluated the laboratory performance against the pre-established criteria by means of inter-laboratory comparison.

- To improve the quality of analytical measurement in the laboratory.
- To establish the effectiveness and precision of the testing method.
- To check the individual testing performance.
- To develop confidence in the test results of the laboratory.

Quality Objectives

- Maximum benefit of our service for our participants with the highest possible quality.
- Achieve participant satisfaction through regular interaction and feedback.
- Strictly confidential treatment of all information obtained within the scope of activity.
- Rise of our competence by intensive development of the quality of our services.

Director - Quality Assurance Forum (QAF), A unit of Uniqas Healthcare Solution LLP.

4. General Requirements

4.1 Impartiality

The proficiency testing (PT) activities are conducted with the utmost impartiality, ensuring fairness and objectivity at every stage.

4.1.1 PT activities are undertaken impartially, guaranteeing unbiased assessment and results. This ensures that all participants are treated fairly and equally in the testing process.

4.1.2 The organization have established a robust organizational structure and management system to safeguard impartiality throughout our PT operations. This includes clearly defined roles and responsibilities, accountability mechanisms, and regular reviews to uphold impartiality.

4.1.3 The organization is committed to upholding impartiality in all PT activities, free from any commercial, financial, or external pressures that may compromise integrity. We maintain independence and avoid conflicts of interest to ensure unbiased outcomes.

4.1.4 The organization regularly monitors its activities and relationships to identify any potential threats to impartiality, ensuring transparency and accountability. This includes assessing relationships with personnel, stakeholders, and external entities to mitigate any conflicts of interest.

4.1.5 Identified threats to impartiality are promptly addressed and mitigated to prevent any compromise to impartiality. This involves implementing corrective actions, adjusting procedures, or reassessing relationships to maintain objectivity.

4.1.6 Top management is fully committed to impartiality, providing leadership and support to maintain unbiased practices across all PT activities. They ensure that impartiality is prioritized and integrated into the organization's culture and decision-making processes.

4.2 Confidentiality

Confidentiality is paramount in the PT operations to ensure the protection of sensitive information and maintain trust with our clients and participants.

4.2.1 The organization manage all information obtained or created during PT activities responsibly, ensuring confidentiality through legally enforceable agreements. Clients are informed in advance about any information intended for public disclosure, and their consent is

obtained when necessary. All other information is considered proprietary information and shall be regarded as confidential.

4.2.2 In cases where we are required by law or contractual arrangements to release confidential information, affected clients are duly notified, unless prohibited by law. We strive to balance legal obligations with the protection of confidentiality.

4.2.3 Information received from external sources, such as complainants or regulators, is treated with strict confidentiality. The identity of the source is kept confidential, unless agreed otherwise by the source, to protect the privacy and integrity of all parties involved.

4.2.4 All personnel involved in PT activities including any committee members, contractors, personnel of external bodies, or persons acting on the PT provider's behalf are bound by confidentiality agreements and must maintain the confidentiality of all information obtained or created during the performance of PT activities. This includes ensuring secure storage, handling, and disposal of confidential information.

4.2.5 The identity of participants in our PT schemes is kept confidential and known only to individuals directly involved in the operation of the scheme unless participants or customers waive confidentiality. We respect the privacy of participants and uphold strict confidentiality measures to protect their identity and data.

5. Structural Requirements

5.1 Legal Entity Responsibility

The Organization operates as a legally recognized entity, ensuring accountability and responsibility for all PT activities conducted.

5.2 Management Identification

Management is identified and assigned overall responsibility for overseeing PT activities, ensuring effective leadership and decision-making.

5.3 PT Scheme Definition

The Organization has defined and documented the specific PT schemes for which it adheres to the requirements outlined in ISO 17043:2023. Our conformity claim is limited to these defined PT schemes.

5.4 Compliance and Addressing Requirements

The Organization conducts PT activities in compliance with ISO 17043:2023 and addresses the requirements of participants, customers, regulatory authorities, and organizations providing recognition. This commitment extends to all PT activities conducted in our permanent facilities as well as any other designated facility or site.

5.5 Organizational Structure and Management

a. The organizational and management structure is clearly defined, and the relationships between management, technical operations, and support services. There is no parent organization.
b. Responsibilities, authorities, and interrelationships of all personnel involved in managing, performing, or verifying work affecting PT results are specified.
c. Procedures necessary to ensure the consistent application and validity of PT activities are documented.

5.6 Personnel Authority and Resources

The organization has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a. Personnel have the authority and resources required to carry out their duties effectively, including the implementation, maintenance, and improvement of the management system.
b. Personnel are empowered to identify deviations from the management system or procedures during PT activities.
c. Actions to prevent or minimize deviations are initiated as necessary.
d. Reporting to management on the performance of the management system and any need for improvement is conducted regularly.
e. Personnel ensure the effectiveness of PT activities through diligent execution of their duties.

5.7 Management Oversight

The management has ensured that:

a. The 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., ensuring continued compliance with ISO 17043:2023.

6. Resource Requirements

6.1 General

6.1.1 Access to Necessary Resources

The organization ensures comprehensive access to essential resources including personnel, facilities, equipment, systems, and support services. This encompasses the entire spectrum required to effectively manage and execute PT activities with precision and reliability.

6.1.2 Measurement and Test Compliance

All measurements or tests conducted under the purview of our organization, related to PT item characterization or the evaluation of homogeneity and stability, strictly adhere to the pertinent requirements delineated in ISO/IEC 17025.

This ensures that the validity and integrity of PT activities remain uncompromised by maintaining rigorous compliance with established metrological standards.

It is also ensured that in the medical Testing area, the relevant requirements of ISO 17043 apply in place of ISO/IEC 17025.

6.1.3 Handling Reference Materials

In QAF EQAS, PT items does not qualify as the reference material. However, whenever the PT item qualifies as a reference material or meets the definition of "reference material", our procedures **will be aligned** with the rigorous mandates stipulated in ISO 17034:2016. This **will** ensure that the production, handling, and management of reference materials meet the stringent requirements necessary for upholding the validity and reliability of PT activities.

It will be also ensured that in the medical area, the relevant requirements of ISO 15194 will be applied for CRMs in place of ISO 17034, when applicable.

6.2 Personnel

6.2.1 Sufficient Competent Personnel

The organization maintains a robust workforce comprising a sufficient number of personnel who exhibit high levels of competence in their respective domains. This ensures that PT activities are executed with precision, efficiency, and a steadfast commitment to quality.

6.2.2 Competence Requirements

Personnel engaged in PT activities possess the requisite competence

a. To proficiently execute their assigned tasks and responsibilities.
b. Moreover, they are equipped with the analytical acumen to discern the significance of any deviations encountered during the course of PT activities,

Thereby ensuring proactive and effective problem-solving.

6.2.3 Competence Management

The organization has established a systematic process for managing the competence of our personnel, encompassing mechanisms for recruitment, training, skill development, performance assessment, and continuous improvement initiatives. This ensures that our workforce remains abreast of the latest developments in their respective fields and is equipped with the necessary skills to excel in their roles.

6.2.4 Impartiality

The organization upholds the principles of impartiality across all facets of operations, ensuring that personnel (both internal and external) involved in PT activities maintain strict adherence to impartiality, ethical standards, and professional integrity. This fosters an environment of fairness, objectivity, and trust, essential for the credibility and reliability of PT outcomes.

6.2.5 Documented Competence

The organization maintain comprehensive documentation pertaining to the competence of personnel involved in PT activities, encompassing educational qualifications, professional certifications, training records, technical knowledge, skills, and relevant experience. This ensures transparency, accountability, and traceability in personnel management practices.
Refer: Personal File

6.2.6 Authorized Activities

Personnel are duly authorized, based on their qualifications, expertise, and experience, to undertake specific activities within PT schemes. These activities may include but are not limited to scheme planning, data assessment, performance evaluation, provision of expert opinions, and review and authorization of PT reports.

6.2.6 Authorization of Personnel

The organization has taken meticulous steps to authorize personnel to undertake specific activities within PT schemes, ensuring that the requirements are comprehensively addressed. These activities include, but are not limited to:

a. Planning PT schemes: Personnel are empowered to meticulously plan every aspect of PT schemes, from defining objectives to coordinating logistics and allocating resources. This comprehensive planning ensures the smooth execution of PT activities.
b. Assessing data/information: Authorized personnel are tasked with conducting thorough assessments of data and information to ascertain the stability and homogeneity, where applicable, as well as determine assigned values and associated uncertainties of the

properties or characteristics of the PT item. This meticulous analysis guarantees the accuracy and reliability of PT results.

c. Evaluating participant performance: Personnel are entrusted with the responsibility of rigorously evaluating the performance of PT participants. This includes assessing adherence to protocols, accuracy of measurements, and overall proficiency in carrying out PT activities. Such evaluations uphold the integrity and credibility of the PT scheme.
d. Providing opinions and interpretations: Authorized personnel are equipped to offer informed opinions, interpretations, and advice to participants as needed. This includes providing guidance on measurement techniques, data analysis, and interpretation of results, ensuring clarity and accuracy throughout the PT process.
e. Reviewing and authorizing PT reports: Personnel have the authority to meticulously review and authorize PT reports, verifying that all necessary information is accurately documented and that the reports meet the standards and requirements set forth by the PT scheme. This thorough review process guarantees the completeness and accuracy of PT reports, thereby enhancing the credibility of the overall scheme.

6.2.7 Communication of Duties

Clear and effective communication channels are established to articulate the duties, responsibilities, and authorities assigned to personnel engaged in PT activities. This ensures alignment with organizational objectives, fosters a culture of accountability, and facilitates seamless coordination and collaboration across various functional units.

6.3 Facilities and Environmental Conditions

6.3.1 Facility Adequacy

The organization ensures the adequacy of facilities essential for the seamless operation of PT schemes. These facilities are meticulously designed and equipped to meet the unique requirements of PT activities while adhering to the highest standards of quality, safety, and efficiency.

6.3.2 Environmental Condition Control

Stringent measures are implemented to monitor and control environmental conditions across all operational settings, including on-site facilities and external locations that are undertaken by external service providers. This encompasses temperature regulation, humidity control, contamination prevention, and other factors crucial for preserving the integrity and validity of PT activities.

6.3.3 Documentation and Monitoring

Comprehensive documentation is maintained regarding environmental conditions that may influence the validity of PT items and associated measurements or tests carried out, including conditions that are required by relevant specifications and measurement or test methods. Control, regular monitoring and periodic reviews are conducted to ensure compliance with established specifications, methods, and standards, thereby mitigating potential risks and enhancing the reliability of PT outcomes. All the relevant monitoring activities are recorded. If environmental conditions compromise the validity of PT activities, the activities shall be halted and the issue will be addressed.

6.3.4 Access Control

Access control mechanisms are implemented to manage entry to areas directly affecting PT activities. These measures are tailored to the specific requirements of our operational context, ensuring that only authorized personnel have access to critical facilities and resources, thereby safeguarding the integrity and confidentiality of PT processes.

6.3.5 Area Separation

Appropriate measures are instituted to ensure effective separation between areas housing incompatible PT activities. This includes the implementation of physical barriers, spatial zoning, and procedural controls to prevent cross-contamination, interference, or adverse influences on PT outcomes, thereby upholding the integrity and reliability of PT activities.

6.4 Externally Provided Products and Services

6.4.1 Limitations on External Providers

The organization unequivocally refrains from engaging external service providers for certain critical activities, including:

a. the design and planning of PT schemes;
b. the evaluation of performance;
c. the authorization of reports.

These remain within the purview of internal expertise. This ensures greater control, oversight, and accountability over key aspects of PT operations.
However, this prohibition does not preclude the organization from seeking advice or assistance from advisors, experts, or steering groups.

6.4.2 Provider Competence Assurance

The organization maintains robust procedures to ensure that the experience and technical competence of external product and service providers are adequate for their designated tasks.

This includes rigorous vetting processes, performance evaluations, and compliance checks to ensure alignment with prescribed standards and requirements.
Additionally, it is also ensured that the providers must comply with the relevant clauses of ISO 17043:2023 and other applicable standards.

6.4.3 Advance Notification

Participants and customers are proactively informed, in writing and well in advance, about any externally provided products or services that may impact the validity or reliability of PT activities. This ensures transparency, accountability, and informed decision-making, thereby enhancing stakeholder confidence and satisfaction.

6.4.4 Procedure for External Providers

The organization has established and maintains procedures while retaining records for:

a. defining, reviewing, and approving the organization's requirements for externally provided products and services;
b. establishing criteria for selecting external providers, evaluating their performance, and monitoring their ongoing adherence to requirements;
c. ensuring that externally provided products and services meet the organization's established requirements and, where applicable, the relevant clauses of this document before utilization or direct provision to customers or participants;
d. taking necessary actions based on the performance monitoring and evaluation of external providers.

6.4.5 Communication of Requirements

Clear and unambiguous communication channels are established to convey our requirements to external providers. The organization effectively communicates its requirements to external providers, specifying:

a. the products and services to be delivered;
b. the acceptance criteria;
c. required competence, including qualifications of personnel or organizations involved;
d. PT activities intended to be conducted at the external provider's premises by the organization or its customers.

This facilitates mutual understanding, alignment of expectations, and adherence to prescribed standards, thereby ensuring seamless collaboration and effective outcomes.

6.4.6 Responsibility for External Providers

The organization assumes full responsibility for the quality and integrity of externally provided products and services, taking proactive measures to mitigate any potential risks or adverse

impacts on PT activities. This includes robust oversight, quality assurance, and accountability mechanisms to safeguard the interests of participants, customers, and other stakeholders, thereby upholding the credibility and reliability of PT outcomes.

In situations where the customer or regulatory authority mandates the selection of an external provider, being responsible entails taking measures to minimize any adverse effects that directly impact the validity of PT activities.

7. Process requirements

7.1 Establishing, contracting, and communicating the PT scheme objectives

7.1.1 Review of requests, tenders, and contracts

7.1.1.1 Procedure for the review of requests, tenders, and contracts

The organization has established a comprehensive procedure for the systematic review of requests, tenders, and contracts to ensure:

a. The PT scheme objectives align clearly with the needs of the customers.
b. Requirements are thoroughly defined, documented, and well-understood.
c. Adequate capability and resources are available to fulfill the requirements.
d. The technical appropriateness of the PT scheme is ensured, considering the specific application or field.

Emphasis is placed on reviewing customer requests with unique purposes or different participation levels.
Streamlined review processes are implemented for well-documented PT schemes and routine enrollments.

7.1.1.2 Comprehensive review coverage

The review process encompasses all aspects of the request, including external products and services.
Records of reviews, significant changes, and customer interactions/results are diligently maintained.

7.1.1.3 Record retention

Records pertaining to reviews, significant changes, and customer interactions relating to their requirements, or the results of the PT activities are retained for reference.

7.1.1.4 Timely deviation notification

Prompt communication is ensured with customers in case of any deviations from the contract.

Effective amendment management
In the event of amendments post-PT scheme initiation, the contract review is reiterated, and amendments are communicated to all relevant personnel.

7.1.2 PT scheme communication

7.1.2.1 Detailed information provision

The organization ensures the dissemination of comprehensive information regarding the PT scheme to participants and customers, covering:

a. Clear objectives and pertinent details of the PT scheme;
b. Criteria participants must satisfy for participation;
c. Criteria used to determine the assigned value and evaluate performance;
d. Confidentiality arrangements to safeguard sensitive information;
e. Essential timelines to adhere to;
f. Any applicable fees for participation;
g. Application procedures, including necessary details on how to apply.

7.1.2.2 Information to Participants and customers

Participants and customers are promptly notified of any alterations in PT scheme design or operation.

7.1.2.3 Record maintenance communication

As appropriate relevant communication records are meticulously maintained by the organization.

7.2 Design and planning of a PT scheme

7.2.1 General

7.2.1.1 Identification, design, and planning

The organization meticulously identifies, designs, and plans activities directly influencing PT scheme validity, ensuring strict adherence to prescribed procedures.
During PT scheme design and planning, consideration of relevant standards and specific scheme objectives, such as ISO/IEC 17025, ISO 17043, and ISO/IEC 17020, along with safety and ethical considerations, has been integrated into the design and planning process.

7.2.1.2 Management of Significant Changes

Significant changes affecting PT scheme validity have been identified and the risks are managed to maintain scheme integrity. Examples include new approaches to PT item production, homogeneity and stability assessments, determination of assigned values, statistical analyses, and new PT activity types.

7.2.1.3 Documented Plan Requirements

Before PT scheme commencement, a documented plan addressing scheme objectives, purpose, and basic design of PT scheme has been prepared.

The plan includes the following information and, where appropriate, reasons for the selection or exclusion of the specific information:

a. Personnel Involvement: Identification of personnel involved in scheme design and operation.
b. External Providers: Activities to be undertaken by external product/service providers, including contact details.
c. Participation Criteria: Criteria for participation have been established.
d. Expected Participants: The expected number and types of participants have been determined.
e. Participant Activities: A description of participant activities and expected results has been provided.
f. Expected Range: The expected range of PT item values/characteristics has been defined.
g. Error Sources: Potential major error sources in the PT area have been identified.
h. Requirements: Requirements for PT item production, quality control, storage, and distribution have been outlined.
i. Collusion Prevention: Procedures to prevent collusion or result falsification, including actions if suspected, have been developed.
j. Participant Information: Participant information and a schedule for PT scheme phases have been communicated.
k. Distribution Details: Distribution frequency, result return deadlines, and participant measurement/test dates for continuous PT schemes have been established.
l. Participant Procedures: Participant procedures for PT item handling, preparation, shipping, disposal, and testing have been provided.
m. Testing Procedures: Homogeneity, stability testing, and, if applicable, biological viability measurement procedures have been defined.
n. Reporting Formats: Standardized reporting format preparation has been completed.
o. Statistical Analysis: A detailed statistical analysis description has been developed.
p. Assigned Values: The origin, metrological traceability, and uncertainty of assigned values have been determined.
q. Results Treatment: Treatment of results from different measurement/test methods has been addressed.
r. Performance Evaluation: Criteria for participant performance evaluation have been established.

s. Data Description: A description of data, interim reports, or information returned to participants has been provided.
t. Public Sharing: The extent of public sharing of participant results and scheme outcome-based conclusions has been determined.
u. Actions for Issues: Actions for lost, delayed, or damaged PT items have been outlined.

7.2.2 Statistical Design

7.2.2.1 Development of Statistical Designs

Statistical designs have been developed to align with PT scheme objectives, considering data type (quantitative or qualitative), statistical assumptions, error types, and expected result numbers.

Statistical design encompasses PT scheme planning, data collection, analysis, and reporting, often based on scheme objectives like error detection or assigned value determination.

Data analysis methods range from simple descriptive statistics to complex statistical models, potentially derived from customer or regulatory specifications.

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 are been taken directly from the specification.

In the absence of reliable information, preliminary interlaboratory comparisons may inform statistical design.

7.2.2.2 Documentation of Statistical Design

The organization has documented statistical designs and data analysis methods for assigned value determination and participant result evaluation.

Selection reasons and underlying assumptions for statistical design and data analysis methods have been documented.

It is also demonstrated that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures

7.2.2.3 Considerations in Statistical Analysis Design

When designing statistical analyses, careful consideration has been given to the following factors:

a. Accuracy and Uncertainty: Requirements or expectations for the assigned value's accuracy and uncertainty.
b. Participant Numbers: Determination of the minimum participant count to meet statistical design objectives, with documented alternative approaches if participant numbers are insufficient to meet the objectives.

c. Reporting Precision: Relevance of significant figures and decimal places in reported participant results.
d. Measurement Details: Number of PT items, repeat measurements, and tests per item or determination.
e. Proficiency Assessment: Procedures for establishing standard deviation or other evaluation criteria.
f. Treatment of Results: Procedures for treating participant results from different methods, if allowed by the scheme.
g. Measurement Uncertainty: Reporting and utilization of measurement uncertainty in participant performance evaluation.
h. Outlier Handling: Procedures for outlier identification or handling.
i. Excluded Values: Procedures for evaluating excluded values from statistical analysis.
j. Design Objectives: Objectives for design and PT round frequency, if applicable.

7.2.3 Determination of Assigned Values

7.2.3.1 Procedure Documentation: Procedures for determining assigned values for PT scheme properties or characteristics have been documented, considering metrological traceability and required uncertainty to demonstrate that the PT scheme is fit for its purpose. ISO 13528 is taken into consideration for statistical methods for assigned value determination.

7.2.3.2 Calibration Area PT Schemes: For calibration-related PT schemes, assigned values with metrological traceability are ensured.

7.2.3.3 Non-Calibration Area PT Schemes: In non-calibration areas, the organization determines the relevance, need, and feasibility of metrological traceability and associated uncertainty for assigned values, aligning with PT scheme purposes.
Metrological traceability chains can vary based on PT item type, property, characteristic, and calibration/reference material availability.

7.2.3.4 Use of Consensus Values: When using consensus values as assigned values, the organization provides an uncertainty estimate of the assigned value, as described in the PT scheme plan.

7.2.3.5 Policy on Assigned Value Disclosure

The organization maintains a policy that assigned value disclosure is not done till final release of participants' reports to prevent participants from gaining early advantage.

7.3 Production and Distribution of PT Items

7.3.1 Production of PT Items

7.3.1.1 Establishment of Production Procedures

Stringent procedure wide **Doc. No. QAF – 414 & QAF – 415** have been established and meticulously implemented to ensure that PT items are produced in strict accordance with the comprehensive plan outlined in section 7.2. These procedures are carefully designed to ensure that the PT items are not only produced efficiently but are also perfectly suited for the specific objectives of the PT scheme.

7.3.1.2 Handling and Preparation Procedures

A comprehensive set of procedures governs every aspect of the handling and preparation of PT items, including their selection, acquisition, collection, identification, preparation, handling, storage, and, if necessary, disposal. These procedures are meticulously followed to guarantee the quality and consistency of the PT items throughout their entire lifecycle.

The selection of PT items is conducted with great care to ensure that they closely resemble materials commonly encountered in routine laboratory activities, thereby ensuring their relevance and practical applicability to participant laboratories.

7.3.1.3 Instructions for Participant-Sourced PT Items

In this PT scheme, participant sourced PT items are not used.

7.3.2 Homogeneity and Stability Assessment

7.3.2.1 Establishment of Homogeneity and Stability Criteria

Rigorous criteria for assessing the homogeneity and stability of PT items are meticulously established, considering the potential risks associated with any inhomogeneity or instability that could impact the evaluation of participant performance.

7.3.2.2 Documentation of Assessment Procedures

Comprehensive procedures for homogeneity and stability assessment are meticulously documented and conducted, adhering to appropriate statistical designs to ensure accuracy and reliability in the assessment process.

Timing of Assessment

7.3.2.4 Homogeneity and stability assessments

Homogeneity and stability assessments are conducted for each PT round following the final packaging of PT items. Additionally, where feasible, homogeneity may be assessed before packaging, particularly if the packaging is unlikely to significantly influence the results.

Methodologies for assessing homogeneity and stability, including scenarios where experimental studies are impractical, are explored extensively in relevant documentation.

The assessment process is guided by stringent statistical designs to ensure accuracy and reliability in the evaluation of PT item characteristics.

7.3.2.5 Experimental Evidence

In cases where experimental evidence is necessary to assess homogeneity or stability, appropriate methods are employed to conduct thorough evaluations, ensuring the validity and reliability of the assessment results.

7.3.2.6 Stability Assurance

The stability of PT items throughout the entire PT round is meticulously ensured, with stability considerations factored into the assigned value uncertainty or evaluation criteria if deemed necessary to maintain the integrity of the PT scheme.

7.3.2.7 PT Item Reuse

QAF do not use PT items retained from previous round for new cycle. However, if due to unavoidable circumstances, if retained PT item needs to be used, before distribution, the property values of retained PT items from previous rounds will be checked for ensuring their suitability and reliability for subsequent PT rounds.

7.3.3 Handling and Storage

7.3.3.1 Storage and Contamination Prevention

From the moment of production to participant distribution, the PT items are meticulously stored and identified to prevent any potential contamination, damage, or deterioration, thus safeguarding their integrity and reliability.

7.3.3.2 Dispatch Procedures

Comprehensive procedures are in place to govern the dispatch to and receipt from storage, ensuring efficiency and accuracy in the handling of PT items throughout their lifecycle.

7.3.3.3 Condition Monitoring

Regular assessments of the condition of stored PT items are conducted at specified intervals or before distribution to detect any signs of deterioration, thus ensuring the continued integrity and reliability of the PT items.

7.3.3.4 Safety Measures

Specialized facilities and protocols are in place to ensure the safe handling, decontamination, and disposal of potentially hazardous PT items, thereby minimizing any potential risks to personnel and the environment.

7.3.4 Packaging, Labeling, and Distribution

7.3.4.1 Packaging and Labeling Compliance

The packaging and labeling processes are meticulously controlled to ensure full compliance with relevant national, regional, or international safety and transport requirements, thus ensuring the safe and secure transport of PT items.

7.3.4.2 Environmental Considerations

Relevant environmental conditions for the transport of PT items are thoroughly documented, with monitoring conducted during transport when necessary to ensure compliance with specified requirements.

7.3.4.3 Participant Transport Instructions

Clear and detailed instructions are provided to participants for the transport of PT items, ensuring their safe and secure handling throughout the transportation process to maintain their integrity and validity.

7.3.4.4 Label Security

Labels are securely attached to the packaging of individual PT items, designed to remain legible and intact throughout the entire PT round, thus ensuring accurate and reliable identification of PT items.

7.3.4.5 Delivery Confirmation

Procedures are followed to confirm the delivery of PT items to participants, providing assurance of successful receipt and subsequent participation.

7.3.5 Participant Instructions

7.3.5.1 Notice to Participants

Participants are provided with sufficient notice before the receipt or dispatch of PT items, ensuring adequate preparation and participation in the PT scheme.

7.3.5.2 Detailed Instructions

Comprehensive instructions covering all aspects of participation, including handling, preparation, recording, and reporting of results, are provided to participants, ensuring consistency and accuracy in their participation in the PT scheme.

Instructions to participants includes:

a. Treatment of PT Items: The necessity to treat PT items in the same manner as routine samples, including use of routine measurement or test methods, unless there are particular requirements of the PT scheme which require departure from this principle;
b. Details of factors which can influence the measurements or tests of the PT items, e.g. the nature of the PT items, conditions of storage, whether the PT scheme is limited to selected measurement or test methods and the timing of the measurements or tests;
c. Instructions for preparing or conditioning, or both, of the PT items before conducting the measurements or tests that would not be considered part of a laboratory's usual expected practices, unless these activities are part of the PT scheme;
d. Any appropriate instructions on handling the PT items, including any safety requirements;
e. Any specific environmental conditions for the participant to conduct measurements or tests, or both, and, if relevant, any requirement for the participants to report relevant environmental conditions during the time of the measurement or test;
f. Specific and detailed instructions on the manner of recording and reporting results and associated measurement uncertainties, i.e. when the instructions include reporting of the expanded measurement uncertainty, the reported uncertainty shall include the coverage factor and the coverage probability;
g. NOTE: This instruction 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").
h. 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;
i. Instructions on return or forwarding of the PT items, when applicable;
j. the last date for the PT provider to receive the results from the participants;
k. 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 Validity Checks:

Results received from participants undergo rigorous validity checks, including verification of data entry, transfer, statistical analysis, and reporting. Procedures are meticulously established and implemented to ensure the integrity and accuracy of the data analysis process.

7.4.1.2 Summary Statistics:

A comprehensive analysis generates summary statistics and performance metrics consistent with the statistical design of the PT scheme. This analysis provides a detailed overview of participant performance, facilitating meaningful comparisons and insights into proficiency levels.

7.4.1.3 Outlier Management:

Specialized statistical approaches are employed to minimize the impact of outliers on summary statistics. By identifying and appropriately handling outliers, the accuracy and reliability of the evaluation process are enhanced, ensuring fair and unbiased assessments.

7.4.1.4 Handling Different Methods:

Robust procedures are in place to handle results obtained from different measurement or test methods used by participants within the PT scheme. This ensures consistency and fairness in the evaluation process, regardless of the methodological variations among participants.

7.4.1.5 Dealing with Inappropriate Results:

Documented criteria and procedures are established to address inappropriate measurement or test results, such as those affected by calculation errors or gross inaccuracies. These procedures ensure that erroneous data are identified and appropriately handled to maintain the integrity of the evaluation process.

7.4.1.6 Management of Unsuitable PT Items:

Comprehensive procedures are outlined to identify and manage situations where PT items are deemed unsuitable for evaluation due to factors like inhomogeneity, instability, damage, or contamination. These procedures ensure that only valid and reliable data are used in the assessment of participant performance, safeguarding the credibility of the PT scheme.

7.4.2 Evaluation of Performance

7.4.2.1 Valid Evaluation Methods:

The PT provider utilizes a range of valid evaluation methods tailored to meet the specific objectives of the PT scheme. These methods are meticulously documented, providing a transparent basis for the evaluation process and ensuring alignment with scheme objectives. Examples of valid methods of evaluation described in ISO 13528 are considered.

7.4.2.2 Expert Commentary:

Where applicable for the objectives of the PT scheme, the organization provides 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.

When possible, organization provides individual summary sheets for participants periodically during or after completion of a particular PT round. These 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 Comprehensive Reporting: PT reports are meticulously prepared to be clear, accurate, objective, and comprehensive, providing participants with a detailed overview of their performance. These reports include all relevant data covering participant results, statistical analyses, and performance evaluations, ensuring transparency and accountability in the reporting process.

When it is not practical to report all original data to participants, a summary of the results, e.g. in tabulated or graphical form, is been supplied.

7.4.3.2 Report Components:

Reports 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.

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 Timely Distribution:

Reports are promptly distributed to participants within planned timeframes, ensuring timely feedback and enabling participants to take necessary actions for improvement. In cases where preliminary or anticipated results are provided, participants benefit from early insights into their performance, allowing for proactive error investigation and resolution.
Preliminary or anticipated results allow for early investigation of possible errors.

7.4.3.4 Policy for Report Use:

There is a clear policy governing the use of reports by participants and customers, ensuring that reports are utilized appropriately to inform decision-making and drive continuous

improvement initiatives. This policy promotes the effective utilization of report data to enhance participant performance and scheme effectiveness.

7.4.3.5 Amendments and Reissues:

Procedures are in place for issuing new or amended reports, with careful consideration given to maintaining traceability and consistency in reporting.

When it is necessary to issue a new or amended report for a PT scheme or PT round, this report includes 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 Impact Assessment:

Before issuing amended reports, thorough assessments are conducted to evaluate the potential impact on other participants within the scheme/ or PT round. By considering the broader implications of report amendments, the organization ensures that all participants receive fair and equitable treatment, maintaining the integrity and credibility of the scheme.

7.4.3.7 Accuracy of Statements:

Statements of participation or performance accompanying PT reports are meticulously crafted to be accurate and non-misleading. Participants rely on these statements to gauge their performance and make informed decisions, highlighting the importance of ensuring accuracy and clarity in their formulation.

7.5 Control of the PT Scheme Process

7.5.1 Technical Records

7.5.1.1 Comprehensive Technical Records: The organization has ensured that technical records for each PT activity contain results, reports, and necessary information for identifying factors affecting PT performance evaluation. These records facilitate the repetition of PT activities under conditions as close as possible to the original, including dates and personnel identities for accountability.

7.5.1.2 Recording Data and Instructions: Data used to verify PT items, participant instructions, original responses, and other relevant information are been recorded contemporaneously and are identifiable with specific tasks.

7.5.1.3 Tracking Amendments: Procedures are been established to ensure that amendments to technical records can be traced to previous versions or original information submitted by participants. Both original and amended data and files are retained, documenting alteration dates and responsible personnel.

7.5.2 Control of Data and Information Management

7.5.2.1 Access to Necessary Data: The organization has access to required data and information for its activities.

7.5.2.2 Validation of Information Management System: The information management system used for the collection, processing, recording, reporting, storage, or retrieval of data has been validated for functionality, including interfaces.

Whenever there are any changes, including software configuration or modifications to commercial off-the-shelf software, are authorized, documented, and validated before implementation.

7.5.2.3 Security and Integrity: The information management system is

a. Protected from unauthorized access;
b. Safeguarded against tampering and loss;
c. Operated in an environment that complies with the system supplier or PT provider specifications or, in the case of non-computerized systems, provides conditions that safeguard the accuracy of manual recording and transcription;
d. Maintained in a manner that ensures the integrity of the data and information;
e. Includes recording of system failures and the appropriate immediate and corrective actions.

7.5.2.4 Oversight of External Providers: The information management system is managed and maintained by organization only. However if in case this is done by off-site or through an external service provider, the organization ensures that the external service provider or operator of the system complies with all applicable requirements of this ISO 17043:2023.

7.5.2.5 Availability of Instructions and Manuals: Instructions, manuals, and reference data relevant to the information management system are readily accessible to concerned personnel.

7.5.2.6 Checks on Calculations and Data Transfers: Calculations and data transfers undergo appropriate and systematic checks.

7.5.3 Surveillance of the Processes

7.5.3.1 Ensuring Validity of PT Scheme: Procedures have been implemented to ensure the validity of the PT scheme, with surveillance activities planned, and reviewed, and the resulting data are recorded for continuous improvement.

Depending on the PT scheme, surveillance activities 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 Management of Nonconforming Work: The organization has developed procedures that are implemented when any aspect of its PT schemes does not conform to its own procedures or the agreed requirements of its participants or customers. These procedures ensure:

a. Defined Responsibilities and Authorities: Clear responsibilities and authorities are established for the management of nonconforming work within the organization.
b. Defined Actions Based on Risk Levels: Actions, including halting ongoing PT schemes or rounds and withholding PT schemes or reports, are defined based on risk levels established by the organization.
c. Evaluation of Significance: The significance of nonconforming work is evaluated, including an impact analysis on previous PT activities.
d. Prompt Decision-Making: Immediate decisions on the need for action and timescale are made, along with determinations regarding the acceptability of the nonconforming work.
e. Communication with Participants and Customers: PT scheme participants and customers are informed as appropriate, and nonconforming PT items or reports already distributed are recalled or disregarded.
f. Defined Responsibility for Authorization: Responsibility for authorizing the resumption of work is clearly defined.

7.5.4.2 Records of nonconforming work and actions are retained as specified in 7.5.4.1 items b) to f), ensuring transparency and accountability.

7.5.4.3 In cases where the evaluation indicates that nonconforming work can recur or there is doubt about the organization's compliance with its own procedures, the corrective action procedure specified in section 8.7 is promptly followed.

7.6 Handling of Complaints

7.6.1 Complaint Management Procedure

The organization has developed and implemented a documented procedure for managing complaints, ensuring that:

a. Clear steps are outlined for receiving, validating, and investigating complaints, with appropriate actions determined based on the findings.
b. All complaints are logged and tracked, along with a record of actions taken to address them.
c. Necessary measures are taken promptly to resolve complaints.

7.6.2 Accessibility of Procedure: The organization ensures that a description of its complaint-handling procedure is accessible to the public.

7.6.3 Confirmation and Resolution: Upon receiving a complaint, the organization promptly confirms its relevance to PT activities and proceeds to address it effectively.

7.6.4 Information Gathering: The organization responsible for handling complaints gathers all relevant information to assess their validity and determine appropriate actions.

7.6.5 Communication with Complainants: Whenever feasible, the organization acknowledges receipt of complaints, communicates the outcome to the complainant, and provides progress reports as necessary.

7.6.6 Impartiality in Investigation: The organization ensures that the investigation and resolution of complaints are conducted impartially and without bias and without any discriminatory actions

7.6.7 Decision-Making Process: Decisions regarding the resolution of complaints are made by individuals not directly involved in the subject matter of the complaint to maintain objectivity. If resource constraints prevent this, alternative measures are in place to uphold fairness and impartiality not compromised.

7.6.8 Formal Notification: The organization aims to formally notify complainants of the conclusion of the complaint handling process whenever possible.

7.6.9 Overall Responsibility: Throughout the complaint handling process, the organization retains responsibility for all decisions made.

7.7 Handling of Appeals

7.7.1 Appeals Management Procedure: The organization has established a documented procedure for managing appeals, encompassing:

a. Clearly defined steps for receiving, investigating, and deciding on appeals, with actions outlined for resolution.
b. Logging and tracking of appeals, documenting actions taken to address them.
c. Ensuring that appropriate measures are implemented to address appeals effectively.

Note: Appeals on PT schemes using purely statistically derived evaluation procedures are usually not handled. Appeals concerning performance evaluations are addressed as a complaint.

7.7.2 Accessibility of Procedure: The organization ensures that a description of its appeals handling procedure is publicly available.

7.7.3 Confirmation and Communication: Upon receipt of appeals, the organization acknowledges them and communicates the outcome to the appellant, providing progress reports when relevant.

7.7.4 Information Gathering: The organization responsible for handling appeals gathers all necessary information to assess their validity and determine suitable actions.

7.7.5 Decision-Making Responsibility: All decisions made during the appeals handling process are the responsibility of the organization.

7.7.6 Impartial Decision-Making: Decisions on appeals are made by individuals not involved in the original decision being appealed, ensuring fairness and impartiality.

7.7.7 Discrimination-Free Process: The organization ensures that the investigation and decision-making regarding appeals are conducted without discrimination.

8. Management System Requirements

8.1 General Requirements

8.1.1 Establishment of Management System

The organization has meticulously established, documented, implemented, and maintained a management system to ensure consistent fulfillment of the requirements specified in this document and its scope of PT activities.

8.1.2 Components of Management System

The management system of the organization encompasses 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 Quality Management System: The organization may fulfill the requirements outlined in 8.1.2 by implementing a quality management system, in accordance with ISO 9001, to support and demonstrate consistent fulfillment of ISO 17043:2023 standard requirements.

8.1.4 Commitment to Management System: The management of the organization demonstrates commitment to the development, implementation, and continuous improvement of the management system's effectiveness.

8.2 Management System Documentation

8.2.1 Policies and Objectives: Policies and objectives address competence, impartiality, and consistent operation relevant to the organization.

8.2.2 Documentation Inclusion: All documentation, processes, systems, and records related to fulfilling ISO 17043:2022 requirements are included in or referenced from the management system.

8.2.3 Access to Documentation: Personnel involved in PT activities have access to relevant parts of the management system documentation and related information based on their responsibilities.

8.3 Control of Management System Documents

8.3.1 Document Control: The organization controls documents (internal and external) relating to fulfilling ISO 17043:2023's requirements.

8.3.2 Document Control Measures: Measures are in place to ensure

a. Documents are approved for adequacy prior to issue by authorized personnel;
b. Documents are periodically reviewed and updated as necessary;
c. Changes and current revision status of documents are identified;
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 Record Establishment: The organization has established and retains legible records to demonstrate fulfillment of the requirements outlined in ISO 17043:2023 document.

8.4.2 Record Management: Controls are implemented for the identification, storage, protection, backup, archive, retrieval, retention time, and disposal of records.

8.4.5 Record Retention: Records are retained for a duration consistent with contractual obligations. Access to these records shall be consistent with the confidentiality commitments and records shall be readily available.

8.5 Actions to Address Risks and Opportunities

8.5.1 Risk and Opportunity Consideration: The organization considers risks and opportunities associated with PT activities to ensure

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 Planning for Risks and Opportunities: Plans are developed to address

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.

8.5.3 Proportional Actions: Actions taken to address risks and opportunities are proportional to their potential impact on the validity of the PT scheme.

For example:

Risk Mitigation: Strategies may include preventing collusion between participants and conducting feasibility studies to assess the best transport conditions for PT items.

Expanding Opportunities: Opportunities could involve expanding the scope of PT activities, increasing participant numbers, enhancing cost-effectiveness for both the organization and participants, and reducing the time required to produce PT items.

8.6 Improvement

8.6.1 Opportunity Identification:

The organization identifies opportunities for improvement and implements necessary actions. Opportunities for improvement are 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 Feedback Utilization: Feedback from participants and customers is sought, analyzed, and utilized to enhance the management system, PT activities, and customer service.

8.7 Corrective Actions

8.7.1 When a nonconformity occurs, the organization:

a. Reacts to the nonconformity and, as applicable:
- Take action to control and correct it;
- Address the consequences;

b. Evaluates 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 analyzing the nonconformity;
- Determining the causes of the nonconformity;
- Determining if similar nonconformities exist, or can potentially occur;

c. Implements any action needed

d. Reviews the effectiveness of any corrective action taken;

e. Updates risks and opportunities determined during planning, if necessary;

f. Makes changes to the management system, if necessary.

8.7.2 Appropriateness of Corrective Actions: Corrective actions taken are appropriate to the impact of encountered nonconformities.

8.7.3 Record Retention

Records are retained as evidence of nonconformities, including

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 Audit Conduct: Internal audits are conducted at planned intervals to assess conformity to management system requirements and effectiveness of implementation and 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 organization ensures the following:

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. Ensures 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.

ISO 19011 guidelines are considered for auditing management systems.

8.9 Management Reviews

8.9.1 Review Frequency: Management reviews of the management system are conducted at planned intervals to ensure continuing suitability, adequacy, and effectiveness, including policies and objectives related to ISO 17043:2023 fulfillment.

8.9.2 Review Inputs:

The inputs to management review are recorded and includes information related to the following:

a. Changes in internal and external issues that are relevant to the PT provider;
b. Fulfilment 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 Review Outputs:

The outputs from the management review 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 fulfilment of the requirements of this document.
c. provision of required resources.
d. any need for changes.

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