SADCAS Ref. No:											

MANAGEMENT REQUIREMENTS FOR PROFICIENCY TESTING SCHEMES
ISO/IEC 17043:2023 Conformity Assessment – General Requirements

Date/s of evaluation	
Assessor/s & Observers	
Name of Proficiency Testing Provider (PTP)	
Area / field of operation	
Laboratory Representative	

This report covers the following:

Document Review only		Implementation on Site Visit only		Document Review and Site Visit		Other		

Compliance = C, Non-compliance = NC

REQUIREMENTS & COMMENTS.

Compliance = C, Non-compliance = NC. Where a clause is marked as NA, reason must be provided as to why it's not applicable

NB1: *References to ISO/IEC 17043:2023 are in italics. The order of assessment need not follow the order of the checklist. Assessors are expected to know & have the standard, this worksheet is designed as guidance to prompt detailed recording of the process.*

REFER TO ISO/IEC 17043:2023 FOR DETAIL AND FOR CLARIFICATION NOTES.

CLAUSE	ISO/IEC 17043:2023 REQUIREMENTS	CAB's COMMENTS *The CAB must provide information on **how** requirements have been addressed, documented and/or implemented. Make reference to policies / procedures, incl. clause numbers.*	C/ NC/ NA	ASSESSOR's COMMENTS *Indicate **WHAT** has been checked and **HOW** requirements have been implemented.*
4.1	**Impartiality**			
4.1.1	Are PT activities undertaken impartially?			
4.1.2	Is the PT provider structured and managed so as to safeguard impartiality?			
4.1.3	Is the PT provider responsible for the impartiality of its PT activities and does the PT provider prohibit commercial, financial or other pressures to compromise its impartiality?			
4.1.4	Does the PT provider monitor the activities and relationships (including personnel) to identify threats to impartiality?			
4.1.5	If a threat to impartiality is identified, does the PT provider eliminate or minimize the effects so that the impartiality is not compromised?			
5.1.6	Does the PT provider have top management who are committed to impartiality?			

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4.2 Confidentiality				
4.2.1	Is the PT provider responsible, through legally enforceable agreements, for the management of all information obtained or created during the performance of PT activities?			
4.2.1	Does the PT provider inform the client in advance of the information it intends to place in the public domain?			
4.2.1	Except for information that the client makes publicly available, or when agreed between the PT provider and the client (e.g. for the purpose of responding to complaints), is all other information considered proprietary information and regarded as confidential?			
4.2.2	When the PT provider is required by law or authorized by contractual arrangements to release confidential information, is the client concerned, unless prohibited by law, notified of the information released?			
4.2.3	Is the information about the participant or customer from a source other than the participant or customer (e.g. complainant or regulator) kept confidential by the PT provider? Is the identity of the source kept confidential by the PT provider and not be shared with the participant or the customer, unless agreed by the source?			

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4.2.4	Do personnel, including any committee members, contractors, personnel of external bodies, or persons acting on the PT provider's behalf, keep confidential all information obtained or created during the performance of the PT activities?			
4.2.5	Is the identity of participants in a PT scheme dealt with confidentially and known only to persons involved in the operation of the PT scheme, unless the participant or the customer waives confidentiality?			
5. Structural Requirements				
5.1	Is the PT provider a legal entity, or a defined part of a legal entity, that is legally responsible for its PT activities?			
5.2	Has the PT provider identified management that has overall responsibility for the PT activities?			
5.3	Does the PT provider define and document the PT schemes for which it conforms with this document? Does the PT provider only claim conformity with this document for those PT schemes?			
5.4	Are the PT activities carried out 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?			

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5.4	Are these requirements being applied to all PT activities performed in the PT provider's permanent facilities and any other facility or site?			
5.5	Does the PT provider:			
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	Does the PT provider 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?			

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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	Does the PT provider management 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?			
5. Resource Requirements				
6.1.1	Does the PT provider have access to the personnel, facilities, equipment, systems and support services necessary to manage and perform its PT activities?			

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6.1.2	Are the measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability, conducted in accordance with the relevant requirements of ISO/IEC 17025 standard?			
	Is the PT item, a material that meets the definition of "reference material", produced under conditions that meet			
6.1.3	the relevant requirements of ISO 17034 standard?			
6.4.	**Externally provided products and services**			
6.4.1	Does the PT provider ensure that it does not use external service providers for the following activities:			
a)	the design and planning of PT schemes?			
b)	the evaluation of performance?			
c)	the authorization of reports?			
6.4.2	Does the PT provider have procedures to ensure that the experience and technical competence of the providers of external products and services are sufficient for their assigned tasks?			
6.4.2	Does the PT provider have procedures to ensure that providers of external products and services comply with the relevant clauses of ISO/IEC 17043:2023 and other appropriate documents?			

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6.4.3	Does the PT provider 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	Does the PT provider have a procedure for, 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	Does the PT provider communicate its requirements to external providers for:			

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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	Is the PT provider responsible to the participants or customers for the externally provided products and services?			
7	***Resource Requirements***			
7.1	**Establishing, contracting and communicating the PT scheme objectives**			
7.1.1	**Review of requests, tenders and contracts**			
7.1.1.1	Does the PT provider have a procedure for the review of requests, tenders and contracts to 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?			

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d)	the PT scheme is technically appropriate taking into account the needs of the given application or field of application?			
7.1.1.2	Does the review cover all aspects of the request, including any externally provided products and services?			
7.1.1.3	Are records of such reviews, including any significant changes, and the pertinent discussions with a customer relating to their requirements, or the results of the PT activities retained?			
7.1.1.4	Is the customer informed of any deviation from the contract?			
7.1.1.5	If a request or contract is amended after the PT scheme is underway, is the same review process repeated and are the amendments communicated to all affected personnel?			
8	***Management System Requirements***			
8.1	**General Requirements**			
8.1.1	Does the PT provider establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of ISO/IEC 17043:023 and its scope of PT activities?			
8.1.2	As a minimum, does the management system of the PT provider include at least the following:			
a)	policies?			

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b)	responsibilities?			
c)	management system documentation?			
d)	control of management system documents?			
e)	control of records?			
f)	actions to address risks and opportunities?			
g)	improvement?			
h)	corrective actions?			
i)	internal audits?			
j)	management reviews?			
8.1.3	Does the PT provider meet the requirement in section 8.1.2 above by establishing, implementing and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001)?			
8.1.3	Does the PT provider's quality management system support and demonstrate the consistent fulfilment of the requirements of ISO/IEC 17043:2023 standard?			
8.1.4	Does the PT provider's management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?			
8.2	**Management system documentation**			
8.2.1	Do the policies and objectives address the competence, impartiality and consistent operation of the PT provider?			

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8.2.2	Are all documentation, processes, systems and records related to the fulfilment of the requirements of ISO/IEC 17043:2023 included in, or referenced from, the management system?			
8.2.3	Do all personnel involved in PT activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?			
8.3	**Control of management system documents**			
8.3.1	Does the PT provider control the documents (internal and external) that relate to the fulfilment of this document?			
8.3.2	Does the PT provider shall ensure that:			
a)	documents are approved for adequacy prior to issue by authorized personnel?			
b)	documents are periodically reviewed and updated as necessary?			
c)	changes and the 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?			

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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	Does the PT provider establish and retain legible records to demonstrate fulfilment of the requirements of ISO/IEC 17043:2023?			
8.4.2	Does the PT provider implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time and disposal of its records?			
8.4.3	Does the PT provider retain records for a period consistent with its contractual obligations?			
8.4.3	Is access to these records consistent with the confidentiality commitments, and are the records readily available?			
8.5	**Actions to address risks and opportunities**			
8.5.1	Does the PT provider consider the risks and opportunities associated with the PT activities in order to:			
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?			

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c)	prevent, or reduce, undesired impacts and potential failures in the PT activities?			
d)	achieve improvement?			
8.5.2	Does the PT provider 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			
8.5.3	Are the actions taken to address risks and opportunities proportional to the potential impact on the validity of the PT scheme?			
8.6	**Improvement**			
8.6.1	Does the PT provider identify and select opportunities for improvement and implement any necessary actions?			
8.6.2	Does the PT provider seek feedback, both positive and negative, from its participants and customers?			
8.6.2	Is the feedback analysed and used to improve the management system, PT activities and customer service?			
8.7	**Corrective actions**			

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8.7.1	When a nonconformity occurs, does the PT provider:			
a)	react to the nonconformity and, as applicable: (i) take action to control and correct it? (ii) 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: (i) reviewing and analysing the nonconformity? (ii) determining the causes of the nonconformity? (iii) 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	Are the corrective actions appropriate to the effects of the nonconformities encountered?			
8.7.3	Does the PT provider retain records as evidence of:			
a)	the nature of the nonconformities, cause(s) and any subsequent actions taken?			

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b)	the effectiveness of any corrective action?			
8.8	**Internal audits**			
8.8.1	Does the PT provider conduct internal audits at planned intervals to provide information on whether the management system:			
a)	conforms to: (i) the PT provider's own requirements for its management system, including the PT activities? (ii) the requirements of this document?			
b)	is effectively implemented and maintained?			
8.8.2	Does the PT provider:			
a)	plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which 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?			

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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?			
8.9	**Management reviews**			
8.9.1	Does the PT provider review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document?			
8.9.2	Are the inputs to management review recorded and do they include 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?			

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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	Do 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?			

Additional / General Comments *This space may also be used to expand on comments in specific sections*

GENERAL COMMENTS (Applicable Only at Document Review Stage

Below are some examples of general comments for different situations encountered. Follow your instincts and use these general comments section to highlight areas you feel may require specific attention.

Example 1: This could be where you notice from the application form or date on documents that the system has only been documented/ implemented for a short period of time. Or where it is clear that there is no clear direction given in the documentation, no "how" described.

Please note that for the initial assessment sufficient records generated by the system must be available to demonstrate the implementation of the system to give confidence that the laboratory can consistently ensure the quality of its results.

Example 2: Quality documentation is meant to be of benefit to a laboratory. The policies set by management give the overall direction of the laboratory. The objectives are always in line with the policies, usually measurable by some means, more specific to areas and may change. The procedures are the instruction manual defining how the laboratory operates to enable it to achieve the set objectives and thus continue moving in the planned direction as defined by the policies.

Example 3: Although the documentation submitted appeared to be written in accordance with the standard, there was very little direction given to the user thereof. Statements of fact were generally made but detail on how the laboratory was to achieve these requirements was lacking.

Example 4: The specific notes made during the evaluation are not necessarily non-compliances but sometimes areas of lack of clarity that could become obvious during the on-site assessment.

Example 5: The documentation submitted was deemed to be assessable and appeared to be in general compliance with the requirements of ISO/IEC 17025. Whether the laboratory's actual operational procedures are reflected in the Quality documentation can only be determined on-site at the initial assessment.

Example 6: Use of terms that are open to interpretation, such as “where appropriate” and “if possible”, are not suitable as they do not give clear direction to the user to ensure consistency within the laboratory.

Be wary of stating that the manual is excellent / in full compliance with the standards as this may cause problems when the site visit reveals weaknesses overlooked during the document review.

4. RECOMMENDATION (delete inapplicable)

Example 1: The deviations listed should be incorporated into the quality manual after an initial assessment of the laboratory may be arranged.

Example 2: The manual requires revision and re-submission for evaluation after which an initial assessment of the laboratory may be arranged.

Example 3: The deviations listed require a submission of additional documents or information to conclude the Document review process after which an Initial assessment may be arranged.

Signed by Team Leader		**Date:**

REVIEW OF ADDITIONAL DOCUMENTS				
Comments on adequacy:				
Reviewer Name:			Date:	
Review Signature:				
Document Review Report Checked by (SC/TM)			**Date**:	
Signed by Checker			**Comments of Checker**:	