SADCAS Ref. No:											

TECHNICAL 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.
6	**Resource Requirement**			
6.1	***General***			
6.1.1	Does the PT provider have access to the personnel, facilities, equipment, systems and support services necessary to manage and perform its PT activities?			
6.1.2	Are the measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability, conducted in accordance with the relevant requirements of ISO/IEC 17025?			
6.1.3	Is the PT item, a material that meets the definition of "reference material", produced under conditions that meet the relevant requirements of ISO 17034?			
7.2.2	**Statistical design**			
7.2.2.1	Are the statistical designs developed to meet the objectives of the PT scheme, based on the type of data (quantitative or qualitative, including ordinal and nominal), statistical assumptions, the type of errors and the expected number of results?			
7.2.2.2	Does the PT provider document the statistical design and data analysis methods to be used to determine the assigned value and to evaluate the participant results?			

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7.2.2.2	Does the PT provider document the reasons for the selection and the assumptions upon which the statistical design and data analysis methods are based?			
7.2.2.2	Is the PT provider being able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures?			
7.2.2.3	In designing a statistical analysis, does the PT provider consider the following:			
a)	the accuracy, as well as the uncertainty, required or expected for the assigned value for each property or characteristic in the PT scheme?			
b)	the minimum number of participants in the PT scheme needed to meet the objectives of the statistical design. In cases where there is an insufficient number of participants to meet these objectives or to produce statistically meaningful analysis of participant results, is the PT provider documenting, and provide to participants, details of the alternative approaches used to assess participant performance?			
c)	the relevance of significant figures to the reported participant result, including the number of decimal places?			

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d)	the number of PT items to be measured or tested and the number of repeat measurements or tests to be conducted on each PT item or for each determination?			
e)	the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria?			
f)	the procedures to be used to treat participant results from different measurement or test methods which are not technically equivalent, where permitted by the PT scheme?			
g)	whether the measurement uncertainty of participant results is being reported and how it will be used to evaluate the participant's performance?			
h)	the procedures to be used to identify or handle outliers, or both?			
i)	where relevant, the procedures for the evaluation of values excluded from statistical analysis?			
j)	where appropriate, the objectives to be met for the design and the frequency of PT rounds?			
7.2.3	**Determination of assigned values**			
7.2.3.1	Does the PT provider document the procedure for determining the assigned values for the properties or characteristics in a particular PT scheme?			

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7.2.3.1	Where applicable, does the procedure take into account the metrological traceability and uncertainty required to demonstrate that the PT scheme is fit for its purpose?			
7.2.3.2	For PT schemes in the area of calibration, are the assigned values provisioned with metrological traceability?			
7.2.3.3	For PT schemes in areas other than calibration, was the relevance, need and feasibility for the establishment of metrological traceability and the associated uncertainty of the assigned value determined by taking into account the purpose of the PT scheme?			
7.2.3.4	When a consensus value is used as the assigned value, does the PT provider provide an estimate of the uncertainty of the assigned value as described in the plan for the PT scheme?			
7.2.3.5	Does the PT provider have a policy regarding the disclosure of assigned values?			
7.2.3.5	Does the policy ensure that participants cannot gain advantage from early disclosure?			
7.3.2	**Homogeneity and stability assessment of PT items**			

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7.3.2.1	Are the criteria for suitable homogeneity and stability to be established based on the risks that inhomogeneity and instability can impact the evaluation of the performance of participants?			
7.3.2.2	Has the PT provider documented the procedures for the assessment of homogeneity and stability?			
7.3.2.2	Where applicable, has the PT provider conducted an assessment of homogeneity and stability in accordance with appropriate statistical designs?			
7.3.2.3	Is the assessment of homogeneity and stability performed for every PT round after the PT items have been packaged in their final form?			
7.3.2.4	Where experimental evidence is needed to assess homogeneity or stability of the PT item (or both), does the PT provider use appropriate methods to assess the homogeneity and stability of the PT item?			
7.3.2.5	Have the PT items demonstrated sufficient stability to ensure that they will not undergo any significant change throughout the conduct of the PT round, including storage and transport?			
7.3.2.5	When this is not possible, has the stability been quantified and considered as an additional component of the uncertainty associated with the assigned value of the PT item and/or taken into account in the evaluation criteria?			

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7.3.2.6	When PT items from previous PT rounds are retained for another PT round, are the property values or characteristics to be determined in the PT scheme confirmed again by the PT provider prior to distribution?			
7.3.3	**Handling and storage of PT items**			
7.3.3.1	From the time of production to their distribution to participants, does the PT provider ensure that PT items are appropriately identified and stored to prevent contamination, damage or deterioration?			
7.3.3.2	Does the PT provider have appropriate procedures for dispatch to, and receipt from, storage?			
7.3.3.3	Are the conditions of stored PT items properly assessed at specified intervals or prior to distribution in order to detect possible deterioration?			
7.3.3.4	Where potentially hazardous PT items are used, are facilities available to ensure their safe handling, decontamination and disposal?			
7.3.4	**Packaging, labelling and distribution of PT items**			
7.3.4.1	Does the PT provider control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements?			

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7.3.4.2	Does the PT provider document relevant environmental conditions for the transport of PT items?			
7.3.4.2	If necessary, are environmental conditions monitored during transport?			
7.3.4.3	In PT schemes where participants are required to transport the PT items to other participants, or return them to the PT provider, have the documented instructions for this transport, to ensure the validity of the PT item, been supplied?			
7.3.4.4	Does the PT provider ensure that labels are securely attached to the packaging of individual PT items?			
7.3.4.4	Is the PT provider label designed to remain legible and intact throughout the PT round?			
7.3.4.5	Does the PT provider follow a procedure to enable the confirmation of delivery of the PT items?			

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

Technical Assessor's Signature:		**Date:**	
Team Leader Signature:		**Date**	