HOKLAS018 Annex II

Checklist

(Based on ISO / IEC 17043:2023)

The proficiency testing provider shall complete the following checklist which will be used for assessment of the proficiency testing provider's conformity with HKAS accreditation requirements.

The checklist consists of questions based on the requirements of ISO/IEC 17043:2023, HKAS PD003, HKAS 002 and HOKLAS Supplementary Criteria No. 34. For further information, please refer to the corresponding document and clause as listed in the second column.

The proficiency testing provider shall indicate in the 'MS Clause' column, for every question, the relevant clause(s) in its management system manual, operation procedures manual or other related document which can demonstrate the proficiency testing provider's conformity with the requirement.

The columns headed '*' and 'OK' are for internal use of HKAS Executive.

A softcopy of this completed checklist shall be provided to HKAS Executive by email or other means.

ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
4 General requirements					
4.1 Impartiality					
Are your proficiency testing (PT) activities undertaken impartially?	4.1.1		☐		
Is your PT provider and structured and managed so as to safeguard impartiality?	4.1.2		☐		
Is your PT provider responsible for the impartiality of your PT activities and does your PT provider prohibit commercial, financial or other pressures from compromising impartiality?	4.1.3		☐		
Does your PT provider monitor the activities and relationships (including personnel) to identify threats to impartiality?	4.1.4		☐		
If a threat to impartiality is identified, does your PT provider eliminate or minimize the effect so that the impartiality is not compromised?	4.1.5		☐		
Does your PT provider have top management commitment to impartiality?	4.1.6		☐		
4.2 Confidentiality					
Is your PT provider responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of PT provider activities?	4.2.1		☐		
Does your PT provider inform the customer in advance, of the information you intend to place in the public domain?	4.2.1		☐		
Except for information that the customer makes publicly available, or when agreed between your PT provider and the customer (e.g. for the purpose of responding to complaints), is all other information considered proprietary information and regarded as confidential?	4.2.1		☐		
NOTE The terms “proprietary” and “confidential” do not preclude publication for academic and new insights of information purposes, provided that neither clients nor participants can be identified, including by inference.					

* Assessors for technical operation should concentrate on items marked with a ●; other items will be checked by the assessor for management system operation or the assessment team leader.

ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
When your PT provider is required by law or authorised by contractual arrangements to release confidential information, is the customer or individual concerned, unless prohibited by law, notified of the information provided?	4.2.2		☐		
Is the information about the participant or customer obtained from a source other than the participant or customer (e.g. complainant or regulator) kept confidential by your PT provider? Is the identity of the source kept confidential by the PT provider and not to be shared with the participant or customer, unless agreed by the source?	4.2.3		☐		
Do your 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?	4.2.4		☐		
Shall the identity of participants in a PT scheme be dealt as confidential and known only to persons involved in the operation of the PT scheme? (unless the participant or the customer waives confidentiality.)	4.2.5		☐		
5 Structural requirements					
Is your PT provider a legal entity, or a defined part of a legal entity, that is legally responsible for your PT provider activities? NOTE For the purposes of ISO/IEC 17043:2023, a governmental PT provider is deemed to be a legal entity on the basis of its governmental status.	5.1		☐		
Does your PT provider identify management that has overall responsibility for the PT activities?	5.2		☐		
Does your PT provider define and document the PT schemes for which it conforms with ISO/IEC 17043:2023 and only claim conformity with ISO/IEC 17043:2023 for those PT schemes?	5.3		☐		
Are your PT activities carried out in such a way as to meet the requirements of ISO/IEC 17043:2023 and address the requirements of participants, customers, regulatory authorities, and organisations providing recognition? These requirements shall include PT provider activities performed in all your permanent facilities and any other facility or site.	5.4		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Does your PT provider	5.5				
- define the organisation and management structure of your PT provider, the place in any parent organisation, and the relationships between management, technical operations and support services?	5.5 a		☐		
- specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of the PT activities?	5.5 b		☐		
- document the procedures to the extent necessary to ensure the consistent application of the PT activities and the validity of the PT results?	5.5 c		☐		
Does your PT provider have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including					
- implementation, maintenance and improvement of your management system?	5.6 a		☐		
- identification of deviations from the management system or from the procedures for performing PT activities?	5.6 b		☐		
- initiation of actions to prevent or minimise such deviations?	5.6 c		☐		
- reporting to PT provider's management on the performance of the management system and any need for improvement?	5.6 d		☐		
- ensuring the effectiveness of PT activities?	5.6 e		☐		
Does your PT provider management ensure:					
- communication takes place regarding the effectiveness of your PT provider's management system and the importance of meeting the requirements of participants, customers, regulatory authorities and organisations providing recognition?	5.7 a		☐		
- the integrity of your management system is maintained when changes to the management system are planned and implemented?	5.7 b		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
6 Resource requirements					
6.1 General					
Does your PT provider have access to the personnel, facilities, equipment, systems and support services necessary to manage and perform its PT activities?	6.1.1	●	☐		
Do the measurements or tests conducted under the responsibility of the PT provider, related to PT item characterization or for assessing homogeneity and stability, be conducted in accordance with the relevant requirements of ISO/IEC 17025? Note 1 The relevant requirements are requirements that relate to the validity of the measurement or test results, which can impact the validity of PT activities (e.g. metrological traceability). They are not intended to include management system requirements or other requirements unrelated to the PT activities. Note 2 In the medical area, the relevant requirements of ISO 15189 apply in place of ISO/IEC 17025.	6.1.2	●	☐		
Does the PT item, a material that meets the definition of “reference material”, to be produced under conditions that meet the relevant requirements of ISO 17034? Note 1 Such materials include reference materials for quality control (e.g. chemical solutions with or without reference values) and reference materials with certified property values (CRMs). Note 2 The relevant requirements are requirements that relate to the validity of operations to produce a reference material that directly impacts the PT activities (e.g. mixing, or handling and storage). They are not intended to include management system requirements or other requirements not directly related to the PT activities (e.g. contents of certificates). Note 3 In the medical area, the relevant requirements of ISO 15194 can apply for CRMs in place of ISO 17034, when applicable.	6.1.3	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
6.2 Personnel					
Does your PT provider have access to a sufficient number of competent personnel to perform its PT activities?	6.2.1	●	☐		
Does your PT provider ensure that your personnel have the competence to?	6.2.2	●	☐		
- perform PT activities for which they are responsible?	6.2.2 a)	●	☐		
- evaluate the significance of deviations	6.2.2 b)		☐		
Does your PT provider have a process for managing competence of your personnel.?	6.2.3	●	☐		
Do all personnel of your PT provider (either internal or external) that can influence the PT activities act impartially.?	6.2.4	●	☐		
Does your PT provider have documented information demonstrating competence of your personnel, that can influence the results of its PT activities?	6.2.5	●	☐		
Does the documented information include requirements for education, qualification, training, technical knowledge, skills and experience?	6.2.5	●	☐		
Does your PT provider authorize personnel to perform specific activities within PT schemes, including but not limited to the following?	6.2.6	●	☐		
- plan PT schemes?	6.2.6 a)	●	☐		
- assess data/information to determine stability and homogeneity, if applicable, as well as assigned values and associated uncertainties of the properties or characteristics of the PT item?	6.2.6 b)	●	☐		
- evaluate the performance of PT participants?	6.2.6 c)	●	☐		
- give opinions and interpretations as well as advice to the participants?	6.2.6 d)	●	☐		
- review and authorize PT reports?	6.2.6 e)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Does your PT provider management communicate to all personnel their duties, responsibilities and authorities?	6.2.7	●	☐		
6.3 Facilities and environmental conditions					
Does your PT provider ensure that there are appropriate facilities for the operation of the PT scheme? Do the facilities adversely affect the validity of results?	6.3.1	●	☐		
Does your PT provider ensure that the environmental conditions do not compromise the PT activities, including operations that are undertaken at sites away from your PT provider's permanent facilities or that are undertaken by external service providers.?	6.3.2	●	☐		
Does your PT provider document environmental conditions that can influence the validity of the PT items and any measurements or tests carried out?	6.3.3	●	☐		
Does your PT provider consider environmental conditions that are required by relevant specifications and measurement or test methods?	6.3.3	●	☐		
Does your PT provider control, monitor and periodically review these conditions, and record all relevant monitoring activities?	6.3.3	●	☐		
Are the PT activities be halted, if environmental conditions compromise the validity of PT activities? (also see cl. 7.5.4 of ISO/IEC 17043:2023). EXAMPLE Examples of such conditions include biological sterility, dust, electromagnetic disturbances, radiation, illumination (light), humidity, electrical supply, temperature, sound and vibration levels, as appropriate to the technical activities concerned.	6.3.3	●	☐		
Does your PT provider have access control to, and use of, areas affecting the PT activities?	6.3.4	●	☐		
Does your PT provider determine the extent of access control based on its particular circumstances?	6.3.4	●	☐		
Is appropriate separation between neighbouring areas in which there are incompatible PT activities provided by your PT provider?	6.3.5	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Does your PT provider provide action to prevent cross-contamination, interference or adverse influences on PT activities?	6.3.5	●	☐		
6.4 Externally provided products and services					
Is your PT provider not use external service providers for the following activities:	6.4.1	●	☐		
- the design and planning of PT schemes?	6.4.1 a)	●	☐		
- the evaluation of performance?	6.4.1 b)	●	☐		
- the authorization of reports?	6.4.1 c)	●	☐		
NOTE This does not prevent the PT provider from using advice or assistance from any advisors, experts or steering groups.	-	●	☐		
Does your 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 your PT provider have procedures to ensure that the providers of external products and services comply with the relevant clauses of ISO/IEC 17043:2023 and other appropriate documents?	6.4.2	●	☐		
Does your 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?	6.4.3	●	☐		
Does your PT provider have a procedure and retain records for:	6.4.4	●	☐		
- defining, reviewing and approving the PT provider's requirements for externally provided products and services?	6.4.4 a)	●	☐		
- defining the criteria for selection of the external providers and for evaluating and monitoring their performance?	6.4.4 b)	●	☐		
- ensuring that externally provided products and services conform to your 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?	6.4.4 c)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- taking any actions arising from the performance monitoring and evaluation of the external providers?	6.4.4 d)	●	☐		
Does your PT provider communicate your requirements to external providers for:	6.4.5	●	☐		
- the products and services to be provided?	6.4.5 a)	●	☐		
- the acceptance criteria?	6.4.5 b)	●	☐		
- competence, including any required qualification of the organization or personnel involved?	6.4.5 c)	●	☐		
- PT activities that the PT provider or its customers intend to perform at the external provider's premises?	6.4.5 d)	●	☐		
Is your PT provider be responsible to the participants or customers for the externally provided products and services?	6.4.6	●	☐		
NOTE In cases where the customer or a regulatory authority specifies which external provider is to be used, being responsible can be interpreted as taking actions to minimize any undesired effects that directly affect the validity of PT activities.					
7 Process requirements					
7.1 Establishing, contracting and communicating the PT scheme objectives					
7.1.1 Review of requests, tenders and contracts					
Does your PT provider have a procedure for the review of requests, tenders and contracts to ensure that:	7.1.1.1	●	☐		
- the objectives of the PT scheme are sufficiently defined and in agreement with the customers' needs?	7.1.1.1 a)	●	☐		
- the requirements are adequately defined, documented and understood?	7.1.1.1 b)	●	☐		
- the PT provider has the capability and resources necessary to meet the requirements?	7.1.1.1 c)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- the PT scheme is technically appropriate taking into account the needs of the given application or field of application?	7.1.1.1 d)	●	☐		
NOTE 1 This review is particularly important when a customer requests a PT scheme to be created for a specific purpose or for a different level or frequency of participation from that normally offered.					
NOTE 2 This review can be simplified when the PT scheme is fully described in a catalogue or other notice and the participant is enrolling for a routine PT round.					
Does the review cover all aspects of the request, including any externally provided products and services?	7.1.1.2	●	☐		
Are the records of such reviews, including any significant changes, and pertinent discussions with the customer relating to their requirements, or the results of the PT activities retained?	7.1.1.3	●	☐		
Is the customer informed of any deviation from the contract?	7.1.1.4	●	☐		
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?	7.1.1.5	●	☐		
7.1.2 PT scheme communication					
Does your PT provider make detailed information available about the PT scheme to participants and customers? Do the information include the following items a) – g)?	7.1.2.1	●	☐		
- objectives and relevant details of the PT scheme;	7.1.2.1 a)	●	☐		
- criteria to be met for participation;	7.1.2.1 b)	●	☐		
- criteria for determining the assigned value and the evaluation of performance;	7.1.2.1 c)	●	☐		
- confidentiality arrangements;	7.1.2.1 d)	●	☐		
- critical timelines;	7.1.2.1 e)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- any fees for participation;	7.1.2.1 f)	●	☐		
- details of how to apply.	7.1.2.1 g)	●	☐		
Are the participants and customers advised in a timely manner by the PT provider of any changes in PT scheme design or operation?	7.1.2.2	●	☐		
Are the records of relevant communications maintained and retained by the PT provider, as appropriate?	7.1.2.3	●	☐		
7.2 Design and planning of a PT scheme			☐		
7.2.1 General			☐		
Does your PT provider identify, design and plan those activities which directly affect the validity of the PT scheme?	7.2.1.1	●	☐		
Does your PT provider ensure that activities are carried out in accordance with prescribed procedures?	7.2.1.1	●	☐		
NOTE When designing and planning the PT scheme, the relevant standards and requirements specific to the objectives of the PT scheme can be considered, e.g. ISO/IEC 17025, ISO 15189, ISO/IEC 17020. Safety and ethical issues can also be considered.					
When a PT provider intends to introduce significant changes to activities which can affect the validity of the PT scheme, does your PT provider identify and manage the risk to ensure the validity of the PT scheme is maintained?	7.2.1.2	●	☐		
NOTE Examples of significant changes are new approaches for PT item production, assessment of homogeneity and stability, determination of the assigned value, statistical analysis and new types of PT activities.					
Does your PT provider develop a documented plan before commencement of the PT scheme that addresses the objectives, purpose and basic design of the PT scheme?	7.2.1.3	●	☐		
Does the plan include the following information and, where appropriate, reasons for the selection or exclusion of the specific information?	7.2.1.3	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- the personnel involved in the design and operation of the PT scheme;	7.2.1.3 a)	●	☐		
- the activities to be undertaken by external providers of products and services and their contact details;	7.2.1.3 b)	●	☐		
- criteria to be met for participation in the PT scheme;	7.2.1.3 c)	●	☐		
- the number and type of expected participants in the PT scheme;	7.2.1.3 d)	●	☐		
- description of activities to be performed and results to be reported by participants;	7.2.1.3 e)	●	☐		
- a description of the range of values or characteristics, or both, to be expected for the PT items;	7.2.1.3 f)	●	☐		
- the potential major sources of errors involved in the area of PT offered;	7.2.1.3 g)	●	☐		
- requirements for the production, quality control, storage and distribution of PT items;	7.2.1.3 h)	●	☐		
- arrangements to prevent collusion between participants or falsification of results and procedures to be employed if collusion or falsification of results is suspected;	7.2.1.3 i)	●	☐		
- a description of the information which will be supplied to participants and the time schedule for the various phases of the PT scheme;	7.2.1.3 j)	●	☐		
- for continuous PT schemes, the frequency or dates upon which PT items will be distributed to participants, the deadlines for the return of results by participants and, where appropriate, the dates on which measurements or tests will be carried out by participants;	7.2.1.3 k)	●	☐		
- any information on methods or procedures which participants must use to store, handle, prepare, ship or dispose of the PT item and perform the measurements or tests;	7.2.1.3 l)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- procedures for the measurement or test methods to be used for the homogeneity and stability testing of PT items and, where applicable, to determine their biological viability;	7.2.1.3 m)	●	☐		
- preparation of any standardized reporting formats to be used by participants;	7.2.1.3 n)	●	☐		
- a detailed description of the statistical analysis to be used;	7.2.1.3 o)	●	☐		
- the origin, metrological traceability and uncertainty of any assigned values;	7.2.1.3 p)	●	☐		
NOTE Assigned values can have uncertainty contributions from sources in addition to the uncertainty of measurement results used for characterization, such as inhomogeneity and instability, and interlaboratory differences if more than one laboratory is used for characterization.					
- the treatment of results from different measurement or test methods, where permitted by the PT scheme;	7.2.1.3 q)	●	☐		
- criteria for the evaluation of the performance of participants;	7.2.1.3 r)	●	☐		
- a description of the data, interim reports or information to be returned to participants;	7.2.1.3 s)	●	☐		
- a description of the extent to which participant results, and the conclusions that will be based on the outcome of the PT scheme, will be made public or shared;	7.2.1.3 t)	●	☐		
- actions to be taken in the case of lost, delayed or damaged PT items.	7.2.1.3 u)	●	☐		
7.2.2 Statistical design					
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?	7.2.2.1	●	☐		
NOTE1 Statistical design covers the process of planning of the PT scheme and the collection, analysis and reporting of the PT scheme data. Statistical designs are often based on stated objectives for the PT scheme, such as detection of certain types of errors with specified power or determination of assigned values with a specified uncertainty.					

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
NOTE2 Data analysis methods can vary from the very simple (e.g. descriptive statistics) to the complex, using statistical models with probabilistic assumptions or combinations of results for different PT items. NOTE3 In cases where the PT scheme design is mandated by a specification given by, for example, a customer or regulatory authority, the statistical design and data analysis methods can be taken directly from the specification. NOTE4 In the absence of reliable information needed to produce a statistical design, a preliminary interlaboratory comparison can be used.					
Does your PT provider document the statistical design and data analysis methods to be used to determine the assigned value and to evaluate the participant results?	7.2.2.2	●	☐		
Does your 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 your PT provider able to demonstrate that statistical assumptions are reasonable and that statistical analyses are carried out in accordance with prescribed procedures?	7.2.2.2	●	☐		
In designing a statistical analysis, does your PT provider give careful consideration to the following items a) – j):	7.2.2.3	●	☐		
- the accuracy, as well as the uncertainty, required or expected for the assigned value for each property or characteristic in the PT scheme;	7.2.2.3 a)	●	☐		
- the minimum number of participants in the PT scheme needed to meet the objectives of the statistical design. In cases where there is an insufficient number of participants to meet these objectives or to produce statistically meaningful analysis of participant results, the PT provider shall document, and provide to participants, details of the alternative approaches used to assess participant performance;	7.2.2.3 b)	●	☐		
- the relevance of significant figures to the reported participant result, including the number of decimal places;	7.2.2.3 c)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- 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;	7.2.2.3 d)	●	☐		
- the procedures used to establish the standard deviation for proficiency assessment or other evaluation criteria;	7.2.2.3 e)	●	☐		
- 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;	7.2.2.3 f)	●	☐		
- whether the measurement uncertainty of participant results shall be reported and how it will be used to evaluate the participant's performance;	7.2.2.3 g)	●	☐		
- the procedures to be used to identify or handle outliers, or both;	7.2.2.3 h)	●	☐		
- where relevant, the procedures for the evaluation of values excluded from statistical analysis;	7.2.2.3 i)	●	☐		
- where appropriate, the objectives to be met for the design and the frequency of PT rounds.	7.2.2.3 j)	●	☐		
7.2.3 Determination of assigned values					
Does your PT provider document the procedure for determining the assigned values for the properties or characteristics in a particular PT scheme?	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?	7.2.3.1	●	☐		
NOTE ISO 13528 provides statistical methods for the determination of the assigned value.					
For PT schemes in the area of calibration, are the assigned values provisioned with metrological traceability?	7.2.3.2	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
For PT schemes in areas other than calibration, have the relevance, need and feasibility for the establishment of metrological traceability and the associated uncertainty of the assigned value been determined by taking into account the purpose of the PT scheme? NOTE The required metrological traceability chain can differ depending on the type of PT item, the property or characteristic and the availability of traceable calibrations and reference materials.	7.2.3.3	●	☐		
When a consensus value is used as the assigned value, does your PT provider provide an estimate of the uncertainty of the assigned value [see Note to 7.2.1.3 item p of ISO/IEC 17043:2023)] as described in the plan for the PT scheme?	7.2.3.4	●	☐		
Does your 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?	7.2.3.5	●	☐		
7.3 Production and distribution of PT items					
7.3.1 Production of PT items					
Does your PT provider establish and implement procedures to ensure that PT items are produced in accordance with the plan described in cl. 7.2 of ISO/IEC 17043:2023 and are fit for the PT scheme's purpose?	7.3.1.1	●	☐		
Does your PT provider establish and implement procedures to ensure appropriate selection, acquisition, collection, identification, preparation, handling, storage and, where required, disposal of all PT items? NOTE PT items usually match the type of items or materials encountered in routine laboratory activities.	7.3.1.2	●	☐		
In PT schemes that require participants to sample, prepare or manipulate the PT item and submit it to the PT provider, does your PT provider issue appropriate instructions for preparation, environmental conditions (where applicable), packaging, handling, storage and shipping of the PT item?	7.3.1.3	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
7.3.2 Homogeneity and stability assessment of PT items					
Do the criteria for suitable homogeneity and stability to be established and to be based on the risks that inhomogeneity and instability can impact the evaluation of the performance of participants?	7.3.2.1	●	☐		
Have your PT laboratory documented the procedures for the assessment of homogeneity and stability?	7.3.2.2	●	☐		
Where applicable, have your PT laboratory conducted assessment of homogeneity and stability and in accordance with appropriate statistical designs?	7.3.2.2	●	☐		
Is the assessment of homogeneity and stability performed for every PT round after the PT items have been packaged in their final form?	7.3.2.3	●	☐		
NOTE 1 Homogeneity can be demonstrated prior to packaging where no influence of packaging is reasonably expected or when stability studies indicate that the material is preferably stored in bulk form.					
NOTE 2 Different approaches for the assessment of homogeneity and stability, including situations where experimental study is not feasible, are described in Annex B of this document, in ISO 13528 and ISO Guide 35.					
Where experimental evidence is needed to assess homogeneity or stability of the PT item (or both), does your PT provider use appropriate methods to assess the homogeneity and stability of the PT item?	7.3.2.4	●	☐		
Have the PT items demonstrated to be sufficiently stable to ensure that they will not undergo any significant change throughout the conduct of the PT round, including storage and transport?	7.3.2.5	●	☐		
When this is not possible, have 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?	7.3.2.5	●	☐		
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 your PT provider prior to distribution?	7.3.2.6	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
7.3.3 Handling and storage of PT items					
From the time of production to their distribution to participants, does your PT provider ensure that PT items are appropriately identified and stored to prevent contamination, damage or deterioration?	7.3.3.1	●	☐		
Does your PT provider have appropriate procedures for dispatch to, and receipt from, storage?	7.3.3.2	●	☐		
Are the condition of stored PT items be properly assessed at specified intervals or prior to distribution in order to detect possible deterioration?	7.3.3.3	●	☐		
Where potentially hazardous PT items are used, are the facilities available to ensure their safe handling, decontamination and disposal?	7.3.3.4	●	☐		
7.3.4 Packaging, labelling and distribution of PT items					
Does your PT provider control packaging and labelling processes to the extent necessary to ensure conformity with relevant national, regional, or international safety and transport requirements?	7.3.4.1	●	☐		
Does your PT provider document relevant environmental conditions for the transport of PT items?	7.3.4.2	●	☐		
If necessary, are environmental conditions monitored during transport?	7.3.4.2	●	☐		
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?	7.3.4.3	●	☐		
Does your PT provider ensure that labels are securely attached to the packaging of individual PT items?	7.3.4.4	●	☐		
Does your PT provider ensure that the labels are designed to remain legible and intact throughout the PT round?	7.3.4.4	●	☐		
Does your PT provider follow a procedure to enable the confirmation of delivery of the PT items?	7.3.4.5	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
7.3.5 Instructions for participants					
Does your PT provider give participants sufficient notice before sending PT items?	7.3.5.1	●	☐		
Unless the design of the PT scheme makes it inappropriate to do so, does your PT provider provide the date on which the PT items are likely to arrive or to be dispatched?	7.3.5.1	●	☐		
Does your PT provider give detailed documented instructions to all participants?	7.3.5.2	●	☐		
Does the instructions to participants include:					
- 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;	7.3.5.2 a)	●	☐		
- 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;	7.3.5.2 b)	●	☐		
- 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;	7.3.5.2 c)	●	☐		
- any appropriate instructions on handling the PT items, including any safety requirements;	7.3.5.2 d)	●	☐		
- 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;	7.3.5.2 e)	●	☐		
- 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	7.3.5.2 f)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
uncertainty shall include the coverage factor and the coverage probability; NOTE This instruction usually includes parameters such as the units of measurement, the number of significant figures or decimal places, and the reporting basis (e.g. on "dry weight" or "as received").					
- 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;	7.3.5.2 g)	●	☐		
- instructions on return or forwarding of the PT items, when applicable;	7.3.5.2 h)	●	☐		
- the last date for the PT provider to receive the results from the participants;	7.3.5.2 i)	●	☐		
- information on the contact details of the PT provider for enquiries.	7.3.5.2 j)	●	☐		
7.4 Evaluation and reporting of PT scheme results					
7.4.1 Data analysis					
Have your PT provided recorded results received from participants and analysed the results by using appropriate methods?	7.4.1.1	●	☐		
Have your PT provider established and implemented procedures to check the validity of data entry, data transfer, statistical analysis, and reporting?	7.4.1.1	●	☐		
Does data analysis generate summary statistics, performance statistics, and associated information consistent with the statistical design of the PT scheme?	7.4.1.2	●	☐		
Have your laboratory adopted an appropriate statistical approach to minimize the influence of outliers on summary statistics?	7.4.1.3	●	☐		
Where the PT scheme allows participants to use different measurement or test methods, does your PT provider have procedures for treatment of results from different measurement or test methods?	7.4.1.4	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Does your PT provider have documented criteria and procedures for dealing with measurement or test results that are inappropriate for statistical evaluation?	7.4.1.5	●	☐		
e.g. because of calculation errors, transpositions and other gross errors.					
Does your PT provider have documented criteria and procedures to identify and manage situations where PT items that have been distributed and the collected data are subsequently found to be unsuitable for performance evaluation?	7.4.1.6	●	☐		
e.g. because of inhomogeneity, instability, damage or contamination.					
7.4.2 Evaluation of performance					
Does your PT provider use valid methods of evaluation which meet the objectives of the PT scheme?	7.4.2.1	●	☐		
Have your PT provider documented the methods, including a description of the basis for the evaluation?	7.4.2.1	●	☐		
NOTE Examples of valid methods of evaluation are described in ISO 13528.					
Where applicable for the objectives of the PT scheme, does your PT provider provide expert commentary on the performance of participants with regard to the following items a) – h)?	7.4.2.2	●	☐		
- overall performance against prior expectations, taking measurement uncertainties into account;	7.4.2.2 a)	●	☐		
- variation within and between participants, and comparisons with any previous PT rounds, similar PT schemes, or published data;	7.4.2.2 b)	●	☐		
- variation between measurement or test methods;	7.4.2.2 c)	●	☐		
- possible sources of error (with reference to outliers or poor performance) and suggestions for improving performance;	7.4.2.2 d)	●	☐		
- advice and feedback to participants as part of the continuous improvement procedures of participants;	7.4.2.2 e)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- situations where unusual factors make evaluation of results and commentary on performance impossible;	7.4.2.2 f)	●	☐		
- any other suggestions, recommendations or general comments;	7.4.2.2 g)	●	☐		
- conclusions.	7.4.2.2 h)	●	☐		
NOTE It can be useful to provide individual summary sheets for participants periodically during or after completion of a particular PT round. These can include updated summaries of performance for individual participants over successive PT rounds of a continuous PT scheme. Such summaries can be further analysed and trends highlighted, if required.					
7.4.3 PT reports					
Do the PT reports clear, accurate, objective and comprehensive and include data covering the results of all participants, together with an indication of the performance of individual participants?	7.4.3.1	●	☐		
NOTE When it is not practical to report all original data to participants, a summary of the results, e.g. in tabulated or graphical form, can be supplied.					
Unless it is not applicable or the PT provider has valid reasons for not doing so does the PT reports include the following items a) – s),:	7.4.3.2	●	☐		
- the name and contact details of the PT provider;	7.4.3.2 a)	●	☐		
- identification of person(s) authorizing the report;	7.4.3.2 b)	●	☐		
- 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;	7.4.3.2 c)	●	☐		
- the date of issue and status (e.g. preliminary, interim, or final) of the report;	7.4.3.2 d)	●	☐		
- unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;	7.4.3.2 e)	●	☐		
- a statement of the extent to which results are confidential;	7.4.3.2 f)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- a unique identification of the report and the PT scheme;	7.4.3.2 g)	●	☐		
- a clear description of the PT items used, including necessary details of the PT item's production and homogeneity and stability assessment;	7.4.3.2 h)	●	☐		
- the results of participants, including the reported measurement uncertainties;	7.4.3.2 i)	●	☐		
- procedures used to statistically analyse the data;	7.4.3.2 j)	●	☐		
- statistical data and summaries, including assigned values, range of acceptable results and graphical displays;	7.4.3.2 k)	●	☐		
- details of the metrological traceability, and uncertainty of any assigned value;	7.4.3.2 l)	●	☐		
- procedures used to establish any assigned value and its uncertainty;	7.4.3.2 m)	●	☐		
- 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);	7.4.3.2 n)	●	☐		
- procedures used to establish the standard deviation for proficiency assessment, or other criteria for evaluation;	7.4.3.2 o)	●	☐		
- comments on the performance of participants;	7.4.3.2 p)	●	☐		
- information about the design and implementation of the PT scheme;	7.4.3.2 q)	●	☐		
- advice on the interpretation of the statistical analysis;	7.4.3.2 r)	●	☐		
- comments or recommendations based on the outcomes of the PT round.	7.4.3.2 s)	●	☐		
NOTE For continuous PT schemes, it can be sufficient to have simpler reports, such that many of the elements in this clause can be excluded from routine reports but included in the PT scheme procedures or in periodic summary reports that are available to participants.					

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Does the PT Reports made available to participants within planned timescales?	7.4.3.3	●	☐		
In sequential PT schemes, e.g. where the turn-around time can be very long, and in PT schemes involving perishable materials, are preliminary or anticipated results provided before final results are disclosed?					
NOTE Preliminary or anticipated results allow for early investigation of possible errors.					
Does your PT provider have a policy for the use of reports by participants and customers?	7.4.3.4	●	☐		
When it is necessary to issue a new or amended report for a PT scheme or PT round, do the report include the following items a) – c):	7.4.3.5	●	☐		
- a unique identification;	7.4.3.5 a)	●	☐		
- a reference to the original report that it replaces or amends;	7.4.3.5 b)	●	☐		
- identification of the amendment and a statement concerning the reason for the amendment or re-issue.	7.4.3.5 c)	●	☐		
When it is necessary to issue an amended report to a subset of participants, to ensure there is no influence on the general performance of the other participants, does your PT provider perform an analysis of the potential impact on the other participants for that PT scheme and/ or PT round?	7.4.3.6	●	☐		
If the PT provider issues a statement of participation or performance in addition to the PT report, is the statement be misleading?	7.4.3.7	●	☐		
7.5 Control of the PT scheme process					
7.5.1 Technical records					
Does your PT provider ensure that technical records for each PT activity contain the results, reports and sufficient information to facilitate, if possible, identification of factors affecting the PT performance evaluation and its associated characteristics?	7.5.1.1	●	☐		
Does your PT provider ensure that technical records for enabling the repetition of	7.5.1.1	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
the PT activity under conditions as close as possible to the original?					
Does the technical records include the date and the identity of personnel responsible for each PT activity and for checking data and results?	7.5.1.1	●	☐		
Are all the data used to verify the PT items, instructions to participants, the original responses of participants and any other information included in reports recorded at the time they are made and identifiable with the specific task?	7.5.1.2	●	☐		
Does your PT provider ensure that amendments to technical records can be tracked to previous versions or to original information submitted by participants?	7.5.1.3	●	☐		
Are the original and amended data and files retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations?	7.5.1.3	●	☐		
7.5.2 Control of data and information management					
Does your PT provider have access to the data and information needed to perform your PT activities?	7.5.2.1	●	☐		
Is your PT provider information management system used for the collection, processing, recording, reporting, storage or retrieval of data validated for functionality, including the proper functioning of interfaces before introduction?	7.5.2.2	●	☐		
Whenever there are any changes, including PT provider software configuration or modifications to commercial off-the-shelf software used for PT activities, are they authorised, documented and validated before implementation?	7.5.2.2	●	☐		
NOTE 1 In this document, a PT provider information management system includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.					
NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered sufficiently validated.					
Is your PT provider information management system(s):	7.5.2.3	●	☐		
- protected from unauthorised access?	7.5.2.3 a)	●	☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- safeguarded against tampering and loss?	7.5.2.3 b)	●	☐		
- operated in an environment that complies with the system supplier or PT provider specifications or, in the case of non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription?	7.5.2.3 c)	●	☐		
- maintained in a manner that ensures the integrity of the data and information?	7.5.2.3 d)	●	☐		
- capable of recording system failures and the appropriate immediate and corrective actions?	7.5.2.3 e)	●	☐		
When the PT provider information management system is managed and maintained off-site or through an external service provider, does your PT provider ensure that the provider or operator of the system complies with all applicable requirements of ISO/IEC 17043:2023?	7.5.2.4	●	☐		
Does your PT provider ensure that instructions, manuals and reference data relevant to the PT provider information management system(s) are made readily available to personnel?	7.5.2.5	●	☐		
Are calculations and data transfers checked in an appropriate and systematic manner?	7.5.2.6	●	☐		
7.5.3 Surveillance of the process					
Does your PT provider have a procedure to ensure the validity of the PT scheme?	7.5.3		☐		
Do surveillance activities planned and reviewed [see also 8.9.2 item n of ISO/IEC 17043:2023)]?	7.5.3		☐		
Are the resulting data recorded for your PT provider continuous improvement process?	7.5.3		☐		
NOTE Depending on the PT scheme, surveillance activities can include:					
- evaluation of externally provided products and services;					
- use of reference materials or other control items;					

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- 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					
Does your PT provider have a procedure that is implemented when any aspect of its PT scheme do not conform to its own procedures or the agreed requirements of the participants or customers?	7.5.4.1	●	☐		
Does the procedure ensure that:					
- the responsibilities and authorities for the management of nonconforming work are defined?	7.5.4.1 a)	●	☐		
- actions (including halting work of ongoing PT schemes, and/or PT rounds and withholding PT schemes and/or PT round reports, as necessary) are defined and are based upon the risk levels established by the PT provider?	7.5.4.1 b)	●	☐		
- an evaluation of the significance of the nonconforming work, including an impact analysis on previous PT activities?	7.5.4.1 c)	●	☐		
- a decision on the need for action and timescale is taken immediately, together with any decision about the acceptability of the nonconforming work?	7.5.4.1 d)	●	☐		
- PT scheme participants and customers as appropriate, are informed and the nonconforming PT items or PT reports already sent to participants are recalled or disregarded?	7.5.4.1 e)	●	☐		
- the responsibility for authorising the resumption of work is defined?	7.5.4.1 f)	●	☐		
NOTE Identification of nonconforming work or problems with the management system or with technical activities can occur at various places within the management system and technical operations. Examples are participant or customer complaints, management reviews					

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
and internal or external audits, surveillance of the processes, production of PT items, homogeneity and stability assessments, data analysis, instructions to participants and materials handling and storage.					
Does your PT provider retain records of nonconforming work and actions as specified in cl. 7.5.4.1 items b) to f) of ISO/IEC 17043:2023?	7.5.4.2	●	☐		
Where the evaluation indicates that the nonconforming work can recur, or that there is doubt about the compliance of the PT provider with your own procedures, does your PT provider promptly follow your corrective action procedure?	7.5.4.3	●	☐		
7.6 Handling of complaints					
Does your PT provider have a documented procedure for handling complaints and that include the following details?	7.6.1		☐		
- a description of the process for receiving, substantiating and investigating the complaint and deciding what actions to be taken in response?	7.6.1 a)		☐		
- tracking and recording complaints, including actions undertaken to resolve them?	7.6.1 b)		☐		
- ensuring that any appropriate action is taken?	7.6.1 c)		☐		
Is a description of the process for handling complaints publicly available?	7.6.2		☐		
Upon receipt of a complaint, does your PT provider confirm whether the complaint relates to PT activities that it is responsible for and, if so, proceed to resolve it?	7.6.3		☐		
Is your PT provider responsible for gathering all necessary information to determine whether the complaint is substantiated?	7.6.4		☐		
Whenever possible, does your PT provider acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports?	7.6.5		☐		
Does our laboratory ensure that the investigation and resolution of complaints would not result in any discriminatory actions?	7.6.6		☐		
Is the resolution of complaints made by, or reviewed and approved by, persons not	7.6.7		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
involved in the subject of the complaint in question?					
Where resources do not permit this, does your laboratory have any alternative approach that would not compromise impartiality?	7.6.7		☐		
Whenever possible, does your PT provider give formal notice of the end of the complaint handling to the complainant?	7.6.8		☐		
Is your PT provider responsible for all decisions at all levels of the handling process for complaints?	7.6.9		☐		
7.7 Handling of appeals					
Does your PT provider have a documented procedure for handling appeals and that include at the following details?:	7.7.1		☐		
- description of the process for receiving, validating, investigating the appeals, and deciding what actions are to be taken in response to it?	7.7.1 a)		☐		
- tracking and recording the appeals, including actions undertaken to resolve them?	7.7.1 b)		☐		
- ensuring that any appropriate action is taken?	7.7.1 c)		☐		
NOTE PT providers that only have PT schemes using purely statistically derived evaluation procedures do not usually handle appeals. Appeals concerning performance evaluations can be addressed as a complaint.					
Is a description of the process for handling appeals publicly available?	7.7.2		☐		
Does your PT provider acknowledge receipt of the appeal and provide the appellant with the outcome and, if applicable, progress reports?	7.7.3		☐		
Is your PT provider responsible for gathering and verifying all necessary information to validate the appeal received?	7.7.4		☐		
Is your PT provider responsible for all decisions during the handling process for appeals?	7.7.5		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Is the decision on the appeal made by, or reviewed and approved by, persons not involved in the subject of the appeal in question?	7.7.6		☐		
Does our laboratory ensure that the investigation and decision on appeals would not result in any discriminatory actions?	7.7.7		☐		
8 Management system requirements					
8.1 General requirements					
Does your PT provider establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17043:2023 and assuring the quality of the PT activities?	8.1.1		☐		
As a minimum, does the management system of your PT provider include the following items?	8.1.2		☐		
- policies;	8.1.2		☐		
- responsibilities;	8.1.2		☐		
- management system documentation (see 8.2 of ISO/IEC 17043:2023);	8.1.2		☐		
- control of management system documents (see 8.3 of ISO/IEC 17043:2023);	8.1.2		☐		
- control of records (see 8.4 of ISO/IEC 17043:2023);	8.1.2		☐		
- actions to address risks and opportunities (see 8.5 of ISO/IEC 17043:2023);	8.1.2		☐		
- improvement (see 8.6 of ISO/IEC 17043:2023);	8.1.2		☐		
- corrective actions (see 8.7 of ISO/IEC 17043:2023);	8.1.2		☐		
- internal audits (see 8.8 of ISO/IEC 17043:2023);	8.1.2		☐		
- management reviews (see 8.9 of ISO/IEC 17043:2023);	8.1.2		☐		
Does your PT provider meet 8.1.2 of ISO/IEC 17043:2023 by establishing,	8.1.3		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
implementing and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001)?					
Does your PT provider's quality management system support and demonstrate the consistent fulfilment of the requirements of ISO/IEC 17043:2023?	8.1.3		☐		
Does your PT provider management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?	8.1.4		☐		
8.2 Management system documentation					
Do the policies and objectives address the competence, impartiality and consistent operation of your PT provider?	8.2.1		☐		
Are all documentation, processes, systems, records, related to the fulfilment of the requirements of ISO/IEC 17043:2023 included in, referenced from, or linked to the management system?	8.2.2		☐		
Do all personnel involved in PT provider activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?	8.2.3		☐		
8.3 Control of management system documents					
Does your PT provider control the documents (internal and external) that relate to the fulfilment of ISO/IEC 17043:2023?	8.3.1		☐		
Does your PT provider ensure that:					
- documents are approved for adequacy prior to issue by authorised personnel?	8.3.2 a		☐		
- documents are periodically reviewed, and updated as necessary?	8.3.2 b		☐		
- changes and the current revision status of documents are identified?	8.3.2 c		☐		
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled?	8.3.2 d		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- documents are uniquely identified?	8.3.2 e		☐		
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose?	8.3.2 f		☐		
8.4 Control of records					
Does your PT provider establish and retain legible records to demonstrate fulfilment of the requirements in ISO/IEC 17043:2023?	8.4.1		☐		
Does your PT provider implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records?	8.4.2		☐		
Does your PT provider retain records for a period consistent with its contractual obligations?	8.4.3		☐		
Is the access to these records consistent with the confidentiality commitments, and are the records readily available?	8.4.3		☐		
NOTE Additional requirements regarding technical records are given in 7.5.1 of ISO/IEC 17043:2023.					
8.5 Actions to address risks and opportunities					
Does your PT provider consider the risks and opportunities associated with the PT activities in order to:					
- give assurance that the management system achieves its intended results?	8.5.1 a		☐		
- enhance opportunities to achieve the purpose and objectives of the PT provider?	8.5.1 b		☐		
- prevent, or reduce, undesired impacts and potential failures in the PT activities?	8.5.1 c		☐		
- achieve improvement?	8.5.1 d		☐		
Does your PT provider plan:					

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
- actions to address these risks and opportunities?	8.5.2 a		☐		
- how to:					
■ integrate and implement these actions into its management system?	8.5.2 b		☐		
■ evaluate the effectiveness of these actions?	8.5.2 c		☐		
NOTE Although ISO/IEC 17043:2023 specifies that the PT provider plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. PT providers can decide whether or not to develop a more extensive risk management methodology, e.g. through the application of other guidance or standards.					
Are the actions taken to address risks and opportunities proportional to the potential impact on the validity of PT scheme?	8.5.3		☐		
NOTE 1 Examples of addressing risks include developing strategies for preventing collusion between participants and performing a feasibility study to evaluate the best transport conditions for the PT items of a PT scheme.					
NOTE 2 Opportunities can lead to expanding the scope of the PT activities, increasing the number of participants in a PT scheme, making a PT scheme more cost effective for the PT provider as well as the participants (customers), and reducing the time required to produce the PT items.					
8.6 Improvement					
Does your PT provider identify and select opportunities for improvement and implement any necessary actions?	8.6.1		☐		
NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data and external assessments.					
Does your 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?	8.6.2		☐		
NOTE Examples of the types of feedback include participant or customer satisfaction					

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
surveys, communication records and review of reports with participants and customers.					
8.7 Corrective actions					
When a nonconformity occurs, does your PT provider:					
- react to the nonconformity and, as applicable:					
■ take action to control and correct it?	8.7.1 a		☐		
■ address the consequences?	8.7.1 a		☐		
- evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:					
■ reviewing and analysing the nonconformity?	8.7.1 b		☐		
■ determining the causes of the nonconformity?	8.7.1 b		☐		
■ determining if similar nonconformities exist, or could potentially occur?	8.7.1 b		☐		
- implement any action needed?	8.7.1 c		☐		
- review the effectiveness of any corrective action taken?	8.7.1 d		☐		
- update risks and opportunities determined during planning, if necessary?	8.7.1 e		☐		
- make changes to the management system, if necessary?	8.7.1 f		☐		
Are corrective actions appropriate to the effects of the nonconformities encountered?	8.7.2		☐		
Does your PT provider retain records as evidence of:					
- the nature of the nonconformities, cause(s) and any subsequent actions taken?	8.7.3 a		☐		
- the effectiveness of any corrective action?	8.7.3 b		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
8.8 Internal audits					
Does your PT provider conduct internal audits at planned intervals to provide information on whether the management system:	8.8.1		☐		
- conforms to:					
■ your PT provider's own requirements for its management system, including the PT activities?	8.8.1 a		☐		
■ the requirements of ISO/IEC 17043:2023?	8.8.1 a		☐		
- is effectively implemented and maintained?	8.8.1 b		☐		
Does your PT provider:	8.8.2				
- plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which take the importance of the PT activities concerned, changes affecting the PT provider, and the results of previous audits into consideration?	8.8.2 a		☐		
- ensure that internal audits are performed by personnel knowledgeable in conducting PT activities and auditing and the requirements of this document and that these personnel are independent of activities being audited, wherever resources permit?	8.8.2 b		☐		
- define the audit criteria and scope for each audit?	8.8.2 c		☐		
- ensure that the results of the audits are reported to relevant management?	8.8.2 d		☐		
- implement appropriate correction and corrective actions without undue delay?	8.8.2 e		☐		
- retain records as evidence of the implementation of the audit programme and the audit results?	8.8.2 f		☐		
NOTE ISO 19011 provides guidelines for auditing management systems.					
8.9 Management reviews					

* Assessors for technical operation should concentrate on items marked with a ●; other items will be checked by the assessor for management system operation or the assessment team leader.

ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Does your PT provider management review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of ISO/IEC 17043:2023?	8.9.1		☐		
Are the inputs to management review recorded and do they include information related to the following items:	8.9.2				
- changes in internal and external issues that are relevant to the PT provider?	8.9.2 a		☐		
- fulfilment of objectives?	8.9.2 b		☐		
- suitability of policies and procedures?	8.9.2 c		☐		
- status of actions from previous management reviews?	8.9.2 d		☐		
- outcome of recent internal audits?	8.9.2 e		☐		
- corrective actions?	8.9.2 f		☐		
- assessments by external bodies?	8.9.2 g		☐		
- changes in the volume and type of the work or in the range of PT activities?	8.9.2 h		☐		
- customer and personnel feedback?	8.9.2 i		☐		
- complaints and appeals?	8.9.2 j		☐		
- effectiveness of any implemented improvements?	8.9.2 k		☐		
- adequacy of resources?	8.9.2 l		☐		
- results of risk identification?	8.9.2 m		☐		
- outcomes of the surveillance of the processes?	8.9.2 n		☐		
- other relevant factors, such as training?	8.9.2 o		☐		

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ISO/IEC 17043:2023 Requirements	Clause	*	OK	MS Clause	Remarks / Questions to be asked at PT provider
Do the outputs from the management review record all decisions and actions related to at least:	8.9.3				
- the effectiveness of the management system and its processes?	8.9.3 a		☐		
- improvement of the PT activities related to the fulfilment of the requirements of ISO/IEC 17043:2023?	8.9.3 b		☐		
- provision of required resources?	8.9.3 c		☐		
- any need for change?	8.9.3 d		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
The obligations of an accredited organisation After obtaining accreditation, will your PT provider at all times:-					
- conform with the accreditation criteria, including accreditation regulations specified in HKAS 002, technical and non-technical requirements and other conditions as specified by HKAS Executive under your terms of accreditation?	HKAS 002 5.1 a		☐		
- represent honestly and truthfully to any person concerned that it is only accredited for activities stated in the scope of accreditation?	HKAS 002 5.1 b		☐		
- pay the fees and charges as determined by HKAS Executive?	HKAS 002 5.1 c		☐		
- endeavour to ensure the accreditation granted by HKAS is not used in a misleading manner?	HKAS 002 5.1 d		☐		
- be a legal entity?	HKAS 002 5.1 e		☐		
- conform to the Business Registration Ordinance (Cap. 310) and provide a copy of its business registration certificate to HKAS Executive if such legislation is applicable to the organisation?	HKAS 002 5.1 f		☐		
- If your accredited organisation is incorporated or registered outside HKSAR, does a copy of official document showing its name and registered address under the laws of its place of incorporation or registration provided to HKAS Executive?	HKAS 002 5.1 f		☐		
- For each location (except location of on-site activities) where accredited activities are performed, is your accredited organisation provide proof that your organisation has the right to access and perform accredited activities at that permanent location?	HKAS 002 5.1 f		☐		
For any customers for which your PT provider performs any accredited activity, does your PT provider maintain for such activity a quality standard which is in conformity with the accreditation criteria as set by HKAS?	HKAS 002 5.2		☐		
Will your PT provider maintain the same quality standard at all times, no matter	HKAS 002		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
whether or not the HKAS accreditation symbol is used in the report or certificate covering the result of such activity?	5.2				
When making any statement in relation to your PT provider's accreditation status in situation where non-accredited activities are mentioned, will your PT provider ensure that such a statement is accompanied by a statement indicating which activities are not accredited?	HKAS 002 5.3		☐		
Is your PT provider aware of the following accreditation regulation: 'Upon termination of accreditation for all activities of an organisation as specified in a certificate of accreditation, the organisation shall return such certificate of accreditation to HKAS Executive forthwith.'?	HKAS 002 5.4		☐		
Will your PT provider cooperate with HKAS Executive and its assessment teams and provide them with full support during an on-site assessment and in any other situation such as to provide all necessary information for assessment of the PT provider's competence and its conformity with the accreditation criteria?	HKAS 002 5.5		☐		
Upon the request of HKAS Executive, will your PT provider provide HKAS Executive with a copy of the documentary standard for which it seeks HKAS accreditation for use during the assessment?	HKAS 002 5.5		☐		
Does your PT provider ensure that it will use its accreditation status only in a manner that will not bring HKAS or any of its accreditation schemes into disputes and will not make any statement regarding its accreditation status that HKAS Executive may reasonably consider it to be misleading?	HKAS 002 5.6		☐		
Does your PT provider maintain complete integrity and impartiality in all circumstances?	HKAS 002 5.7		☐		
Does your PT provider issue and implement a pertinent code of conduct for all its directors, officers, employees and other personnel involved in its operation?	HKAS 002 5.7		☐		
Will the authorised representative further report immediately any corrupt practice to the ICAC (or similar authority or the police when outside the jurisdiction of the HKSAR)?	HKAS 002 5.7		☐		
Will the authorised representative further report any impropriety or unlawful act of	HKAS 002 5.7		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
the organisation or any iniquitous management and/or staff to HKAS Executive?					
Will your PT provider notify HKAS Executive within one calendar month if a new authorised representative has been appointed?	HKAS 002 5.8		☐		
Will the authorised representative or in his absence, other responsible person of the PT provider inform HKAS Executive in writing immediately of any changes or intended changes in the PT provider's circumstances which may affect its conformity with relevant accreditation criteria?	HKAS 002 5.9		☐		
Does your PT provider implement the following HKAS regulation on confidentiality:	HKAS 002 5.10		☐		
'An applicant or accredited organisation shall pay due regard to the confidentially of its customer's information and shall make internal rules and guidelines in order to ensure protection of its customer's information. Confidential information about a particular customer shall not be disclosed to a third party without the consent of the customer, except where the law requires such information to be so disclosed. However, an applicant organisation or an accredited organisation shall allow HKAS Executive to examine all its records which are relevant to the scope of accreditation in order to assess its competence and compliance with the relevant accreditation criteria. An applicant or accredited organisation shall obtain consent from their customers for the disclosure of any relevant information to HKAS.'?					
Does your PT provider ensure that no unofficial contact with assessors, technical experts and/or AAB members will be made on any matter relating to or in connection with the assessment of any activity for the purpose of granting or maintaining accreditation?	HKAS 002 5.11		☐		
Are all communications concerning the PT provider's assessment make between the authorised representative or his/her representative or its chief executive or his/her representative and HKAS Executive?	HKAS 002 5.11		☐		
Does your PT provider have a clear policy in writing concerning offering, solicitation and acceptance of advantages as stipulated in the Prevention of Bribery Ordinance by its personnel?	HKAS 002 5.12		☐		
Does the policy document contain a statement notifying its personnel of the law	HKAS 002 5.12		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
under Section 9 of the Prevention of Bribery Ordinance (Cap. 201)?					
Does your PT provider further ensure that the policy is made known to all its personnel?	HKAS 002 5.12		☐		
Does your PT provider have a policy and procedure in writing for handling and resolving complaints, disputes and appeals made to it by its customers or other parties?	HKAS 002 5.13		☐		
Does your PT provider keep records of all complaints, disputes and appeals and actions taken for a minimum of 3 years and make available to HKAS Executive for inspection upon request?	HKAS 002 5.13		☐		
Where a complaint, dispute or appeal received from your customers or other parties raise any doubt on your compliance with your PT provider's polices or procedures, will your PT provider ensure that the relevant areas of its accredited activities are promptly audited?	HKAS 002 5.14		☐		
If a complaint, dispute or appeal received from your customers or other parties relating to any of your accredited activities is not satisfactorily resolved within 60 days from the date of receipt, will your PT provider notify HKAS Executive in writing of this matter?	HKAS 002 5.15		☐		
Is your PT provider aware that any concerned party may lodge complaints with HKAS on any of your accredited activities?	HKAS 002 5.16		☐		
Is your PT provider aware of the following HKAS regulation? 'Upon the request of HKAS Executive, an accredited organisation shall confirm the authenticity or otherwise of a report, certificate or other document purporting to have been issued by it for an accredited activity. Where such a report, certificate or document is found to be a forged document, the organisation shall cooperate with HKAS Executive in the investigation of its cause and taking mutually agreeable steps to prevent recurrence.'	HKAS 002 5.17		☐		
Is your PT provider aware of the following HKAS regulation? 'An applicant or accredited organisation shall not provide certification service to any other party for any standard used by HKAS as accreditation criteria. HKAS Executive will take immediate action to suspend the accreditation of an accredited	HKAS 002 5.18		☐		

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Regulations for HKAS Accreditation	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
organisation in violation of this requirement.'					

Use of HKAS accreditation symbols and claims of accreditation status	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
Does your PT provider conform with the following HKAS regulation:-			☐		
'An accredited organisation may use the relevant HKAS accreditation symbols and claim its accreditation status as described in HKAS Supplementary Criteria No. 1 – "Use of HKAS accreditation symbols and claims of accreditation status' provided that the following conditions are conformed with:-					
(a) all advertising and promotional materials (including letterheads) shall not, in the opinion of HKAS Executive, give a false or misleading impression regarding the accreditation status of the organisation;	HKAS 002 8.1 a		☐		
(b) HKAS Supplementary Criteria No. 1 – 'Use of HKAS accreditation symbols and claims of accreditation status' and requirements relevant to the accreditation scheme concerned as described in the relevant specific regulations, are conformed with at all times; and	HKAS 002 8.1 b		☐		
(c) any statement made by the organisation in connection with its accreditation status shall not, in the opinion of HKAS Executive, give a false or misleading impression to any third party of its accreditation status.'?	HKAS 002 8.1 c		☐		
Is your PT provider aware of that an accredited organisation shall not allow its accreditation be used to imply that any subject of its accredited activities, for example, a product, process, system or person is approved by HKAS or HKAS Executive and shall take suitable actions to stop any incorrect reference to accreditation.	HKAS 002 8.2		☐		
Does your PT provider ensure that its customers, on receiving any HKAS endorsed report, are aware that the subject of the activity (e.g. the sample, instrument, product, design or system tested, calibrated, certified or inspected) as referred to in such report or certificate is in no way approved nor disapproved by HKAS or HKAS Executive?	HKAS 002 8.2		☐		
Upon suspension or termination of the accreditation of any activities carried out by an organisation, regardless of whether it is voluntarily made, will your organisation discontinue to make reference to the accreditation in any report, certificate, and	HKAS 002 8.3		☐		

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Use of HKAS accreditation symbols and claims of accreditation status	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
other document reporting conformity assessment results, letterhead, brochure, advertising material, stationery, and Internet websites, etc., immediately?					

Specific regulations for HKAS (Code of Conduct)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
Has your PT provider documented the code of conduct within its management system for stating its policies on impartiality, confidentiality, professionalism, integrity, conflict of interest, and the organisation's commitment to complying with the Prevention of Bribery Ordinance (Cap 201) of Hong Kong or applicable laws and regulations of the country where the accredited organisation is located?	HKAS SC-06 2.1		☐		
Does the code of conduct cover at least the following aspects:					
- Solicitation and acceptance of advantage	HKAS SC-06 2.2 a		☐		
- offer of advantage?	HKAS SC-06 2.2 b		☐		
- entertainment?	HKAS SC-06 2.2 c		☐		
- compliance with laws of Hong Kong or of relevant jurisdictions?	HKAS SC-06 2.2 d		☐		
- compliance with relevant requirements of applicable professional standards?	HKAS SC-06 2.2 e		☐		
- conflict of interest?	HKAS SC-06 2.2 f		☐		
- use of company assets?	HKAS SC-06 2.2 g		☐		
- confidentiality of company information?	HKAS SC-06 2.2 h		☐		

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Specific regulations for HKAS (Code of Conduct)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
- outside employment?	HKAS SC-06 2.2 i		☐		
- relationship with customers, suppliers and contractors?	HKAS SC-06 2.2 j		☐		
- procedures for reporting suspected violation and established mechanism for the prompt and fair adjudication of alleged violations?	HKAS SC-06 2.2 k		☐		
- disciplinary actions to be taken against violations?	HKAS SC-06 2.2 l		☐		
Does your PT provider determine the contents of the code of conduct in accordance with its circumstances to ensure that all personnel working for it act lawfully, ethically, professionally, and honestly and protect the impartiality, independence and integrity of the organisation?	HKAS SC-06 2.3		☐		
Does your PT provider ensure that all personnel including its directors, staff and other personnel working for it understand and practise the code of conduct?	HKAS SC-06 3.1		☐		
Has your PT provider provided training to all personnel as part of the orientation training when they join the organisation and refresher training to all personnel periodically thereafter?	HKAS SC-06 3.2		☐		
Does your PT provider periodically remind all personnel working for it the code of conduct?	HKAS SC-06 3.3		☐		
Is the code of conduct accessible to all personnel working for the organisation?	HKAS SC-06 3.4		☐		
Is the authorised representative aware that he/she shall report any impropriety or unlawful act of the organisation or any iniquitous management and/or staff to HKAS Executive in accordance with clause 5.7 of HKAS 002?	HKAS SC-06 3.5		☐		
Does your PT provider periodically review the code's suitability and adequacy; and implement improvement as appropriate?	HKAS SC-06 3.6		☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
Is your PT provider aware of the following accreditation regulation on accreditation procedure: 'An assessment team may require a PT provider to demonstrate a test, a calibration or other PT provider activities as part of an assessment. It may also require the PT provider to participate in proficiency testing in order to evaluate its standard and competence. The specific PT provider activities to be demonstrated will be selected from those covered in the proposed scope of accreditation at the discretion of the assessment team.'?	HOKLAS SC-34 2.1		☐		
Is your PT provider aware of the following accreditation regulation on accreditation procedure: 'HKAS Executive shall conduct a reassessment on the accredited activities of a PT provider:-					
(a) within twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the PT provider;	HOKLAS SC-34 2.2 a		☐		
(b) every two years after the due date of the first reassessment or at such time intervals as specified for the Monitoring Plan adopted by the PT provider;	HOKLAS SC-34 2.2 b		☐		
(c) at such other times as may be specified in the terms of accreditation;	HOKLAS SC-34 2.2 c		☐		
(d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited PT provider, of any change in the structure and circumstances of the PT provider since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the PT provider's competence or conformity with the accreditation criteria; and	HOKLAS SC-34 2.2 d		☐		
(e) HKAS Executive may, at its discretion, vary the reassessment schedule.'?	HOKLAS SC-34 2.2 e		☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
Is your PT provider aware of the following accreditation regulation on surveillance visit: 'HKAS Executive shall conduct a surveillance visit to an accredited PT provider if neither reassessment, assessment for extension of accreditation, nor surveillance visit to it has been conducted within the past twelve months' period or at such time intervals as specified for the Monitoring Plan adopted by the PT provider. HKAS Executive may, at its discretion, vary the surveillance visit schedule.'?	HOKLAS SC-34 2.3		☐		
Is your PT provider aware of the following accreditation regulation on accreditation procedure: 'Upon granting of accreditation for a test category to a PT provider, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for such test category.'?	HOKLAS SC-34 2.4		☐		
Does your PT provider at all times comply with the following HOKLAS accreditation criteria? HKAS 002, ISO/IEC 17043:2023, HKAS Policy Document No. 3, relevant HKAS Supplementary Criteria and relevant HOKLAS Supplementary Criteria. HOKLAS and HKAS publications relevant to the accreditation of PT providers are listed in a HOKLAS application package 'HOKLAS AP012 - Accreditation of Proficiency Testing Providers' which is available at the website of HKAS.	HOKLAS SC-34 3.1		☐		
Does your PT provider ensure that you shall not use its accreditation status in a way that may be interpreted by any person that any product, material or any other subject of an activity has been approved or disapproved by HKAS or HKAS Executive? Will your PT provider further endeavour to ensure that no person use any certificate, report, statement or documentation issued by it for such activity in a misleading manner?	HOKLAS SC-34 3.2		☐		
Is your PT provider aware of the following HKAS regulation on cooperation: 'A PT provider accredited under HOKLAS shall afford its customers or their representative reasonable cooperation to monitor the PT provider's performance such as provision of information to demonstrate the correct operation of its PT schemes, or to arrange site visits (in so far as to their respective contracts are concerned).'?	HOKLAS SC-34 3.3		☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
'For avoidance of doubt, the PT provider may also take reasonable steps to protect its proprietary information and agree with its customers the cost they have to pay to the PT provider for performing or taking part in such monitoring activities.'?	HOKLAS SC-34 3.3		☐		
Is your PT provider aware of the following HKAS regulation on subcontracting: 'If a PT report contains results from a subcontractor, the accredited PT provider shall identify such results in the report. The accredited PT provider shall not disclose the performance of any of its customers to any of its subcontractor without prior written approval from the customer. Some activities of an accredited PT provider shall not be subcontracted. They are specified in ISO/IEC 17043:2023.'?	HOKLAS SC-34 3.4		☐		
Is your PT provider aware of the following HKAS regulation on approved signatory: 'An applicant PT provider shall nominate person(s) to HKAS Executive for signing endorsed PT reports for each PT scheme in the scope of application. Accreditation for such an activity will not be granted unless HKAS Executive is satisfied that at least one nominee meets the requirements for approved signatories as laid down in the accreditation criteria. An accredited PT provider shall maintain at least one approved signatory for each PT scheme in its scope of accreditation. An accredited PT provider may nominate additional signatories to HKAS Executive for approval at any time.'?	HOKLAS SC-34 3.5		☐		
'A person nominated for approved signatory shall: - be familiar with the management system and operation of the PT provider; - have sufficient contact with the PT provider to enable him/her to have an in-depth understanding on the operation of its PT schemes and have confidence in the validity of the PT results which are obtained in accordance with the PT provider's documented procedures; - be fully aware of the HOKLAS Accreditation Criteria as specified in clause 3.1 of HOKLAS SC-34; Note: Signatory approval may be limited to specific PT schemes or may be granted for all PT schemes for which the PT provider is accredited.	HOKLAS SC-34 3.6		☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
Is your PT provider aware of the following HKAS regulation on approved signatory: 'As signatory approval is granted in the context of the work being performed in a particular PT provider, such approval shall not be considered as a personal qualification.'?	HOKLAS SC-34 3.7		☐		
'A nominee for signatory approval for a PT scheme may not necessarily be the same person as the coordinator as described in Cl 5(d) of HKAS Policy Document No. 3. The coordinator, if different from the approved signatory, shall participate in the preparation and drafting of the report and shall communicate closely with the approved signatory for the final authorisation of the PT report.'?	HOKLAS SC-34 3.8		☐		
'An accredited PT provider shall inform HKAS Executive forthwith of any change in the availability and duties of any of its approved signatories. HKAS shall withdraw the approval concerning such an approved signatory who no longer meets the requirements as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation of a PT provider for a PT scheme if it does not have any approved signatory for such a scheme and has failed to obtain approval from HKAS Executive for a new signatory within three months from the date when it ceased to have any approved signatory for such a scheme.'?	HOKLAS SC-34 3.9		☐		
Is your PT provider aware of the following HKAS regulation on integrity: 'An applicant PT provider shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, if the applicant PT provider intentionally provides false information or if the applicant PT provider conceals information, HKAS Executive shall reject the application or terminate the assessment process. The resulting application and assessment fees paid are not refundable.'?	HOKLAS SC-34 3.10		☐		
Is your PT provider aware of the following HKAS regulation on suspension and termination of accreditation: 'The authorised representative of PT provider shall identify and inform its customers within 14 days from the effective date of suspension or termination (whether voluntarily or by HKAS Executive) of the accreditation of a PT scheme, if any PT reports with unreliable results associated with such a PT scheme had been issued before the suspension/termination and were discovered during the investigation.'?	HOKLAS SC-34 4.1		☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
'For voluntary suspension, the effective date shall be advised by the PT provider or the same as the issue date of the notification letter confirming the suspension if the PT provider does not provide an effective date. For suspension imposed by HKAS Executive, the effective date shall be the issue date of the relevant notification letter.'?	HOKLAS SC-34 4.1		☐		
'The PT provider shall provide to HKAS Executive an action plan to solve the concerns related to the suspended activity(ies) within four weeks from the date of notice of suspension. Such actions shall be taken to the satisfaction of HKAS Executive within one year from the effective date of suspension'?	HOKLAS SC-34 4.1		☐		
'HKAS Executive may publish information relating to any suspension and termination of accreditation granted by HKAS in any HKAS publications and in the website of HKAS.'?	HKAS 002 2.10		☐		
Is your PT provider aware of the following HKAS regulation on HOKLAS accreditation symbol: 'An accredited PT provider may display the HOKLAS accreditation symbol for PT providers in a report issued by it for reporting the result(s) of a PT scheme in its scope of accreditation. Such a report is referred to hereafter as a HOKLAS endorsed PT report, which shall contain the details as described in clause 5.2 of HOKLAS SC-34.'?	HOKLAS SC-34 5.1		☐		
Is your PT provider aware of the following HKAS regulation on HOKLAS accreditation symbol: 'An accredited PT provider shall issue a HOKLAS endorsed PT report containing the following:-					
(a) the HOKLAS accreditation symbol (which includes the PT provider's registration number and the identification code of the accreditation program) at the top right hand corner of the front page;	HOKLAS SC-34 5.2 a		☐		
(b) on the front page the following statements:-					
'HKAS has accredited this proficiency testing provider (Reg. No. HOKLAS 999) under HOKLAS for specific proficiency testing schemes as listed in the scope of accreditation.'	HOKLAS SC-34 5.2 b		☐		
The word 'this proficiency testing provider' in the first sentence of the above endorsement statement may be replaced by the full identity of the PT provider as it			☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
appears on the scope of accreditation.					
Does your PT provider ensure that the form, size, colour and usage of the HOKLAS accreditation symbol for PT providers are in accordance with HKAS SC-01?	HOKLAS SC-34 5.3				
Is your PT provider aware of the following HKAS regulation on claiming its accreditation status: 'An accredited PT provider may also claim its accreditation status by including the statement described in 5.2 (b) of HOKLAS SC-34 in a PT report of an accredited scheme, but such a report is not considered as a HOKLAS endorsed PT report. The HOKLAS accreditation symbol shall not be used alone to claim the accreditation status.'	HOKLAS SC-34 5.4		☐		
Does your PT provider ensure that the term 'HKAS'/'HOKLAS', the HOKLAS accreditation symbol and/or a statement claiming accreditation status under HOKLAS shall not be used in a report of any PT scheme except as described above in clauses 5.2 and 5.4 of HOKLAS SC-34.?	HOKLAS SC-34 5.5		☐		
'Claiming of accreditation status without displaying the accreditation symbol is subject to prior written agreement by HKAS Executive. The PT provider should also note that if it selects to claim the accreditation status with the statement described in 5.2(b) of HOKLAS SC-34 without displaying the accreditation symbol, requirements that govern the issue of HOKLAS endorsed report as detailed in this document and HKAS 002 shall also apply to such reports.?'	HOKLAS SC-34 5.6		☐		
Is your PT provider aware of the following HKAS regulation on HOKLAS endorsed PT report: 'A HOKLAS endorsed PT report or a report with its accreditation status claimed by a statement shall be signed by an approved signatory of the issuing PT provider. The signature shall be made in hand-written form for printed report. If the report is in an electronic form, the electronic signature shall be in a form acceptable under the Electronic Transactions Ordinance (Cap. 553). The full name of the approved signatory (as in his/her identity document such as identity card or passport) shall be clearly shown alongside the signature. Other arrangements of signing HOKLAS endorsed reports may be acceptable	HOKLAS SC-34 5.7		☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
subject to agreement from HKAS Executive. When determining the acceptability of such an arrangement, HKAS Executive will consider all pertinent factors such as the reliability of the arrangement in ensuring proper and traceable authorisation by approved signatories and the demand of users of the accredited service.'?					
'A HOKLAS endorsed PT report may contain signatures of others provided that an HKAS approved signatory of the accredited PT provider has signed the PT report. Where signatures other than the approved signatory also appear on the report, the capacity of the one who signed (such as his capacity as reviewer) shall appear on the report.'?	HOKLAS SC-34 5.8		☐		
Does HOKLAS endorsed PT report issued by your PT provider contain the results of PT activities for which your PT provider is holding valid HKAS accreditation unless otherwise approved in accordance with clause 5.10 of HOKLAS SC-34?	HOKLAS SC-34 5.9		☐		
Is your PT provider aware of the following HKAS regulation on reporting results of any activity which has not been accredited: 'The results of any activity which has not been accredited (whether obtained by the PT provider or its subcontractor) can only be included in a HOKLAS endorsed PT report if HKAS Executive has explicitly approved such inclusion in writing. The HOKLAS endorsed PT report which contains the said results shall clearly state therein that the activities are not covered by the PT provider's HKAS accreditation.'?	HOKLAS SC-34 5.10		☐		
Is your PT provider aware of the following HKAS regulation on HOKLAS endorsed PT report: Does your PT provider keep at least one exact copy of each PT report issued by it within its scope of accreditation for record?	HOKLAS SC-34 5.11		☐		
Does your PT provider also keep such copies, all original observations and records in relation to any accredited activity performed by it for a period specified by HKAS Executive in HKAS Policy Document No. 3 or relevant HOKLAS Supplementary Criteria, as applicable?	HOKLAS SC-34 5.11		☐		
Does your PT provider ensure that each HOKLAS endorsed PT report or any PT report with the accreditation status claimed shall comply with all relevant	HOKLAS SC-34 5.12		☐		

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Specific regulations for HOKLAS (as required under HOKLAS Supplementary Criteria No. 34)	Clause	*	OK	QM Clause	Remarks / Questions to be asked at PT provider
accreditation criteria as specified by HKAS Executive from time to time?					
'A HOKLAS endorsed PT report shall also bear either:-'	HOKLAS SC-34 5.13				
(a) 'a statement indicating that such a report shall not be reproduced except in full', or	HOKLAS SC-34 5.13 a		☐		
(b) 'a statement indicating the conditions under which such a report may be reproduced either in full or in part'?	HOKLAS SC-34 5.13 b		☐		
'Any extract or abstract of a HOKLAS endorsed PT report shall not contain the HOKLAS accreditation symbol for PT providers nor other details as specified in clause 5.2 of HOKLAS SC-34 unless the authorised representative of the accredited PT provider which issues the report has approved in writing of such inclusion in the extract or abstract. The authorised representative, if granting approval under this clause, shall ensure that such extract or abstract will not be used for any purpose which HKAS Executive may consider it as having misleading effect.'	HOKLAS SC-34 5.13		☐		
Is your PT provider aware of the following HKAS regulation on technical comments: 'When technical comments other than those on the performance of participants are made in PT reports, they are not covered under the scope of accreditation of the PT provider. Those comments, and other opinions or interpretations for which a PT provider is not accredited for providing, can only be included in a HOKLAS endorsed PT report if HKAS Executive has given its approval for such inclusion in writing. Where such comments, opinions or interpretations are included in an endorsed PT report, a clear and explicit disclaimer shall be given in the report that they are not covered under the scope of accreditation.'?	HOKLAS SC-34 5.14		☐		
Is your PT provider aware that you shall not issue any PT report containing any logo, symbol or statement that may be interpreted by any person that the activities or results reported are covered by certification which does not convey any information on technical competence?	HOKLAS SC-34 5.15		☐		

End

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