

Hong Kong Laboratory Accreditation Scheme

HOKLAS 018

Assessment/Reassessment Questionnaire for Proficiency Testing Providers (Based on ISO/IEC 17043:2023)

For an initial application for accreditation or an application for extension of scope of accreditation, this questionnaire should be completed and returned to the HKAS Executive together with the application form HOKLAS 005 and all relevant documents as listed on page 2. HKAS Executive will only process an initial application for accreditation or an application for extension of scope of accreditation when the completed forms (HOKLAS 005 and HOKLAS 018) and the required application fee are received.

For a reassessment, the accredited proficiency testing (PT) provider is also required to complete and submit this questionnaire together with the relevant documents to HKAS Executive at least one month before the scheduled date of reassessment.

Fees payable for assessments are calculated in accordance with:

HOKLAS 006 (for organisations within the Hong Kong Special Administrative Region)

You should study the latest version of the following documents before completing this questionnaire:

HKAS 002 HKAS SC-06 HOKLAS SC-34 ISO/IEC 17043:2023 HKAS PD 003

HONG KONG ACCREDITATION SERVICE								
36/F., Immigration Tower, 7 Gloucester Road, Wanchai, Hong Kong.								
Tel: 2829 4840 Fax: 2824 1302 E-mail: hkas@itc.gov.hk								
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Notes: 1. Any personal data provided in this form will be retained and used by HKAS for accreditation purpose only. The personal data may be disclosed to members of the assessment team.

- 2. It is obligatory for you to provide all the personal data requested in this form. If you do not provide sufficient information, we may not be able to process the application.
- 3. The data subjects have the rights to obtain a printed copy of their own personal data held by HKAS and request for correction of their personal data. Please contact HKAS at the above address for access to and correction of the personal data.

This	Questionnaire is for :								
	Initial Assessment Extension of Scope Reassessment								
List	of Attachments (for initial assessment and extension of scope only)								
	Application fees ⁵ in the form of a cheque or an *e-Cheque payable to The Government of the Hong Kong Special Administrative Region .								
	*Application fees can be paid by e-Cheque through the 'Pay e-Cheque' portal <u>https://www.payecheque.gov.hk</u> . Please contact HKAS if special arrangement is required.								
	Documents authenticating that the PT provider is a valid legal entity or part of a valid legal entity								
	Management system manual or documentation								
	Operation procedure manual ⁶								
	Promotional material of the proficiency testing (PT) scheme (e.g. brochure, information for applicants)								
	Latest internal audit schedule and vertical and horizontal audit reports								
	Summary of the findings of the latest management review								
	Records for identifying risks to impartiality								
	CV's and copies of qualification documents for key personnel including any nominees for signatory approval as applicable								
	Copies of agreement with each external service provider and relevant sample records e.g. data analysis records, result forms, reports, etc. from them according to their role.								
	PT provider's organisation chart(s) ⁷ , with names, positions and responsibilities of key personnel clearly identified								
	Details of the proficiency testing scheme(s) to be assessed (including development history, design and validation of the PT scheme)								
	Agreed duties and responsibilities of each external service provider								
	Instructions to participants of each proficiency testing scheme								
	Sample result form submitted by participants of each scheme to be assessed								
	Sample reports ^{8,9} and the associated records of design and planning for each proficiency testing round of scheme(s) to be assessed								
	Proficiency testing scheme annual report, if applicable								
	Evidence of competence of the PT provider's testing or calibration facility (the organisation's or the external service provider's facility)								
	Records for identifying risks and opportunities								
	Code of conduct								
	Other documents, please specify								

Notes

- 4. For a reassessment, the required documents listed in the briefing notes will be provided to the organisation separately by HKAS Executive.
- 5. An application fee will be charged for an initial application and an application for extension of scope of accreditation. No application fee is required for a reassessment. In addition to the application fee, an on-site assessment fee will be charged. The PT provider will be informed of the exact amount of assessment fee once the on-site assessment has been arranged.
- 6. Operation procedure manuals refer to supporting procedures of the management system manual.
- 7. Please provide a copy of the organisation chart(s) of the PT provider, including the division/unit in which the activities to be assessed is performed. The chart(s) should show the relationship between the PT provider and its parent organisation, where applicable.
- 8. Please provide copies of representative interim and final reports for each proficiency testing round of scheme(s) to be assessed. These reports should contain results and information of real proficiency testing and should be recent.
- 9. For application for accreditation and application for extension of scope of accreditation, the selection of sample reports is at the discretion of the PT provider. It is necessary to provide a separate report for every round of each proficiency testing scheme. Proficiency testing rounds with similar report format may be represented by a common report.

SCOPE OF ACCREDITATION

For an initial application for accreditation or an application for extension of scope of accreditation, the proficiency testing scheme proposed for accreditation should be detailed in HOKLAS 018 Annex I – 'Scope of Accreditation Sought' table.

For a reassessment, the 'Scope of Accreditation to be Reassessed' should have been sent to the proficiency testing provider together with the letter informing the proficiency testing provider of the forthcoming reassessment. The proficiency testing provider should check the scope carefully, mark minor changes to the scope with justification, sign to confirm the 'Scope of Accreditation to be Reassessed' and return the confirmed scope to HKAS Executive together with this completed questionnaire.

For any voluntary suspension/termination of activities from the Scope of Accreditation, a copy of HKAS 009 – Notification of Changes shall be completed and returned together with the confirmed scope of accreditation to be reassessed to HKAS Executive.

rganisation's name (Both English and Chinese) See Note 10)			
oficiency testing provider's name, if different om above			
eneral description of the organisation and the oficiency testing provider including their majo tivities, history and relationship	r		
uvities, instory and relationship			
nysical address of the proficiency testing ovider			
	Hong Kong	Kowloon	N.T.
	Telephone	Fax	E-mail
		·	
orrespondence address different from the physical address)			
	Hong Kong	Kowloon	N.T.
	Telephone	Fax	E-mail

Questionnaire completed by				
Name				
Position				
	Telephone	Fax		E-mail
Authorised Representative		J L		
Name				
Name				
Position				
Address (if different from the correspondence address)				
(
	Hong Kong	Kowloo	n 🗌	N.T.
	Telephone	F	Fax	E-mail
Information on the Proficiency Testing Scho	ma			
Name of the Proficiency Testing Provider				
[i.e. Name of the provider used in information provided to participants]				
Proficiency Testing Scheme Category (Please include all schemes offered by	Accreditation Status Please indicate wheth	her the scheme is	Number of Round(s)	Total Number of Participants
the Proficiency Testing Provider)	(a) seeking accreation (a) applic	ditation in this cation;	operated (in the past two	
	(b) already accr MM/Y	redited since	years)	
	(c) not acc			
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Regulations for HKAS Accreditation (HKAS 002)
The Obligations of an Applicant or Accredited Organisation (HKAS 002, Section 5)

Was there any convicted case of unlawful act related to integrity and impartiality of your organisation, management and/or staff in the past 24 months?

 \square No.

☐ Yes. Details are provided below. (Please use additional sheet if necessary)

Declaration of the Authorised Representative

I, the undersigned, declare that the information given in this questionnaire is correct to the best of my knowledge and belief.

Signature of the Authorised Representative

Date

General Requirements (ISO/IEC 17043:2023, Section 4)

Impartiality (ISO/IEC 17043:2023, Section 4.1.4)

Please identify threats to the impartiality of the PT provider, arising from its activities, from its relationships, or from the relationships of its personnel. If a threat to impartiality is identified, please demonstrate how the PT provider eliminates or minimizes such threat.

Confidentiality (ISO/IEC 17043:2023, Section 4.2)

Please explain how the PT provider protects information obtained or created during the performance of proficiency testing activities.

Structural Requirements (ISO/IEC 17043:2023, Section 5)

Organisation

(The organisation under which accreditation is granted or sought)

Legal status

Is your organisation:		If the PT provider is a part of an organisation, please give details of the line of authority and the relationship of other parts within the same organisation.
🗌 a	government department?	
🗌 a	statutory body?	
	company incorporated in or outside long Kong?	
	sole-proprietorship or partnership organisation?	
0	ther? (please specify)	

Other activities		
Does your organisation conduct other activities in additidetails on those activities.	tion to profi	ciency testing related operation? If yes, please give
Customers		
Does the PT provider provide service		Percentage of work
- internally?		
- to the public?		
Office size		
What is the total number of staff members?		
What is the floor area occupied ?		
Participants		
The Proficiency Testing Scheme is available to	Yes/No	Expected number of participants
- local participants only		
- local and overseas participants		
Size of PT provider		
- what is the total number of staff members working for the PT provider		
<i>Note</i> If the PT provider is part of an organisation, include only the number of staff members that contribute to the implementation of the PT programmes, please indicate full time or part-time involvement		
- number of external services / products provider		

Scope and function

Please describe the scope and function of the PT provider

Personnel in charge of the implementation, maintenance and improvement of the management system (ISO/IEC 17043:2023, Section 5.6)

Name	Position	Area of responsibility

Technical personnel

Please provide below details of the key technical personnel

Position	Area of responsibility

Resource Requirements (ISO/IEC 17043:2023, Section 6)

Personnel (ISO/IEC 17043, Section 6.2)

Nominees for signatory approval

Please list below the person(s) to be considered by HKAS Executive as approved signatories of HKAS endorsed proficiency testing reports.

NAME (as on HKID card)	PT SCHEME NOMINATED TO BE APPROVED SIGNATORY	POSITION IN PROFICIENCY TESTING PROVIDER'S ORGANISATION	EXPERIENCE IN ORGANISING PROFICIENCY TESTING SCHEMES	NEW APPLICANT OR EXISTING SIGNATORY OF AN ACCREDITED SCHEME

Information on the contact details of the person-in-charge of the Proficiency Testing Scheme

PT SCHEME	PERSON	AE OF N-IN-CHA GE	AFFIL	IATION	QUALI	FICATIONS	ERIENCE IN /ANT TESTING FIELD	C	PERIENCE IN DRGANISING ROFICIENCY TESTING

Resource Requirements (ISO/IEC 17043:2023, Section 6) (Cont'd)

Personnel (ISO/IEC 17043, Section 6.2) (Cont'd)

Key personnel (Please attach additional sheets if necessary)

Please provide below the name, qualifications, experience, current position and date of appointment for each staff member occupying key positions as defined by the proficiency testing provider and shown in the organisation chart. The staff members shall include those in the management that have overall responsibility for the proficiency testing provider.

Key Personnel									
Name	Position	Date appointed	Qualifications	Experience					

Changes in key personnel (applicable to reassessment only)

Please give details of any change in key personnel relating to the scope of accreditation to be reassessed since the initial assessment or the last reassessment. If there is any change(s) in approved personnel from those listed in the last notification letter, please also submit HKAS 009 – Notification of Changes.

Name	Current or Last Position	Details of changes	Effective Date	Follow up actions, if any

Process Requirements (ISO/IEC 17043:2023, Section 7)

Design and planning of Proficiency Testing Schemes (ISO/IEC 17043:2023, Section 7.2)

Please provide details of the proficiency testing scheme(s) to be assessed (including development history, design and validation of the PT scheme). Any further comment should be given below.

Please explain the PT provider's access to technical expertise, for example, formation of an advisory group. If any advisory group is formed for this function, please state the membership of the advisory group for each scheme, where applicable, and describe the role and responsibility of each member.

Process Requirements (Cont'd)

Evaluation and reporting of PT Scheme Results (ISO/IEC 17043:2023, Section 7.4)

Please describe the data processing system (including equipment and software) and the statistical methods used.

Evaluation of performance (ISO/IEC 17043:2023, Section 7.4.2)

Please give a brief description of the methods for assessing the performance of participants.

Surveillance of the processes (ISO/IEC 17043:2023, Section 7.5.3)

Please give a brief description of the surveillance activities to ensure the validity of the PT scheme.

Management System Requirements (ISO/IEC 17043:2023, Section 8)

Quality Management

Please list the personnel responsible for establishing, documenting, implementing, maintaining and improving the management system.

Name	Position	Area of responsibility

Other Information

Any other supplementary information should be provided below.

Annex I - Scope of Accreditation Sought

(For an initial application or extension of scope of accreditation application only)

Annex II – Checklist