

Hong Kong Laboratory Accreditation Scheme

HOKLAS 007

Assessment/Reassessment Questionnaire for Non-medical Laboratories (Based on ISO/IEC 17025:2017)

For an initial application for accreditation or an application for extension of scope of accreditation, this questionnaire should be completed and returned to HKAS Executive together with the application form HOKLAS 005 and all relevant documents as listed in the checklist on page 2. HKAS Executive will only process an initial application for accreditation or an application for extension of scope of accreditation when completed forms (HOKLAS 005 and HOKLAS 007) and the required application fee are received.

For a reassessment, the accredited laboratory is also required to complete and submit this questionnaire together with 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)
HOKLAS 013 (for organisations outside of the Hong Kong Special Administrative Region)

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

HKAS 002 HKAS SC-06 HOKLAS SC-33 ISO/IEC 17025:2017 HKAS PD 001

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

Notes:

- 1. Any personal data provided in this form will be retained and used by HKAS for accreditation purpose and for dissemination of information in relation to its accreditation services. In addition, the personal data may be disclosed to members of the assessment team involved in the accreditation process.
- 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 Executive at the above address or via email at hkas@itc.gov.hk for access to and correction of your personal data.

List of documents to be submitted⁴

(Please tick the boxes below as appropriate)

This	s Questionnaire is for :			
	Initial Assessment Extension of Scope Reassessment			
List	t of attachments (for initial assessment and extension of scope only) Documents authenticating that the laboratory is a valid legal entity or part of a valid legal entity			
	Management system manual			
	Operation procedure manuals ⁵			
	Latest audit schedule			
	Summary of the findings of the latest management review			
	Records for identifying risks to the laboratory's impartiality			
	Test/calibration procedure manual(s), test/calibration standard(s) and normative reference, where applicable			
	Method verification/validation report, where applicable			
	Records of estimation of measurement uncertainty, where applicable (for 'Calibration Services' test category, a copy of the measurement uncertainty evaluation for each calibration to support the claimed CMC value is required)			
	Decision rules for reporting statement of conformity to specification/standard relevant to the scope of accreditation, where applicable			
	CV and a copy of the qualification documents for each nominee for signatory/operator approval ⁶			
	Laboratory floor plan and procedure for the control and monitoring of environmental conditions			
	Laboratory organisation chart(s) ⁷ , with names, positions and responsibilities of key personnel clearly identified			
	Sample test/calibration reports and corresponding test/calibration records ^{8,9}			
	Relevant proficiency testing (PT) reports and one-year PT participation plan			
	Code of conduct			
	Other documents (please specify)			
!	Payment method			
	Application fees ¹⁰ to be paid by			
	a cheque payable to The Government of the Hong Kong Special Administrative Region.			
	electronic payment methods ¹¹			

Notes:

- 4. For a reassessment, the required documents are listed in the AF07 form which will be provided to the organisation separately.
- 5. Operation procedure manuals refer to supporting procedures of the management system manual.
- 6. Specific requirements for an approved signatory/operator in a certain technical discipline are specified in the relevant HKAS/HOKLAS accreditation criteria or supplementary criteria.
- 7. Please provide a copy of the organisation chart(s) of the laboratory, including the division/unit in which the tests/calibrations to be assessed is performed. The chart should show the relationship between the laboratory and its parent and/or sister organisation(s), where applicable.
- 8. Please provide copies of representative reports/certificates and the associated raw test data records for the tests to be assessed. These records should preferably contain test results of real test samples and should be recent.
- 9. For application for accreditation and application for extension of scope of accreditation, the selection of sample records is at the discretion of the laboratory. It is not necessary to provide a separate sample record for every test/calibration. Tests/Calibrations with similar record formats may be represented by a common sample record. For each test/calibration, the identification number of the sample record selected should be entered in the 'Sample test record/report/certificate' columns in the 'Scope of Accreditation Sought' table in HOKLAS 007 Annex I.
- 10. An application fee will be charged for an initial application and 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 laboratory will be informed of the exact amount of assessment fee once the on-site assessment has been arranged.
- 11. Electronic payment methods include Automated Teller Machine (ATM), PPS, "Pay e-Cheque" portal and Faster Payment System (FPS). A demand note will be sent to the laboratory upon receipt of completed forms (HOKLAS 005 and HOKLAS 007) and all relevant documents as listed in the checklist on page 2.

SCOPE OF ACCREDITATION

For an initial application for accreditation or an application for extension of scope of accreditation, the tests and calibrations proposed for accreditation shall be detailed in HOKLAS 007 Annex I - Scope of Accreditation Sought.

For a reassessment, the 'Scope of Accreditation to be Reassessed' will have been sent to the laboratory together with the letter informing the laboratory of the forthcoming reassessment. The laboratory 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 of Accreditation to HKAS Executive together with this completed questionnaire.

For any voluntary suspension/termination of tests 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.

General Information			
Organisation name (See Note 12)			
Laboratory name (See Note 13)			
General description of the organisation and the laboratory including their major activities and history			
Laboratory physical address			
	Telephone	Fax	E-mail
Correspondence address			
	Hong Kong	☐ Kowloon	☐ N.T.
	Telephone	Fax	E-mail
Questionnaire completed by			
Name			
Position			
	Telephone	Fax	E-mail
Authorised representative			
Name			
Position			
Address (if different from the correspondence address)			
	Hong Kong	☐ Kowloon	☐ N.T.
	Telephone	Fax	E-mail
Notes:			
12 – The organisation's name should be the name department, instrumentality, company, person	operating a laboratory of		
13 – The name used by the organisation to identify	the laboratory.		

General Requirements (ISO/IEC 17025:2017, Section 4)			
Impartiality (ISO/IEC 17025:2017, S	ection 4.1.4)		
	laboratory arising from its activities, from its relationships, or from the partiality is identified, please demonstrate how the laboratory eliminates		
Confidentiality (ISO/IEC 17025:2017	, Section 4.2)		
Please explain how the laboratory protects in activities.	nformation obtained or created during the performance of laboratory		
Structural Requirements (ISC	D/IEC 17025:2017, Section 5)		
Organisation (The organisation under which accreditation is §	granted or sought)		
Legal status			
Is your organisation:	If the laboratory is a part of the organisation, please give details of the line of authority and the relationship of other parts within the same organisation.		
a government department?	same organisation.		
a statutory body?			
a company incorporated in or outside Hong Kong?			
a sole-proprietorship or partnership organisation?			
other? (please specify)			

Does your organisation activities.	conduct other activities in	addition to laboratory ope	eration? If yes, please give details on th
ictivities.			
Customers			
D 4 . 1 . 1	Marca to		D
Does the laboratory pro			Percentage of work
internally?	☐ Yes ☐ No		
to the public?	☐ Yes ☐ No		
I abanatamy aire			
Laboratory size			
What is the total number	er of staff members?		
What is the floor area of	eccupied ?		
			d improvement of the managen
system (ISO/IEC	17025:2017, Section 5.	6)	
		Position	Area of responsibility
Name	l l		

Resource Requirements (ISO/IEC 17025:2017, Section 6)

Personnel (ISO/IEC 17025:2017, Section 6.2)

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 laboratory and shown in the organisation chart. The staff members shall include those in the management that have overall responsibility for the laboratory.

	Key Personnel				
Name	Position	Date appointed	Qualifications and experience	Responsible technical area(s), if applicable	

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.

s, if any

Resource Requirements (cont'd) (ISO/IEC 17025:2017, Section 6)

Personnel (cont'd) (ISO/IEC 17025:2017, Section 6.2)

Nominees for signatory approval

Please list below the person(s) to be considered by HKAS Executive as approved signatories of HOKLAS endorsed reports/certificates. Please also provide the name of the person(s) in Chinese for test areas under the test category of 'Testing Required by the China Compulsory Certification System (CCC)'.

Name	Test area	Existing approved signatory? (Y/N)

Nominees for operator approval (applicable to specific test areas only)

Please list below the persons to be considered by HKAS Executive as approved operators. (Please refer to corresponding HOKLAS supplementary criteria for areas where approved operator is required).

Name	Test area	Existing approved operator? (Y/N)

Resource Requirements (cont'd) (ISO/IEC 17025:2017, Section 6)

Equipment and metrological traceability (ISO/IEC 17025:2017, Sections 6.4 and 6.5)

Please provide below or in separate page(s) a list of reference equipment, reference materials and major testing/calibration equipment, including its calibration and verification schedules for the tests/calibrations to be assessed.

Description, make, model, range	Code#	Calibration/ verification interval	Last calibration/ verification date	Internal*/ External [@]

*	For equipment calibrations/verifications performed internally by laboratory staff, the HKAS Executive may require the laboratory
	to provide a copy of the internal calibration/verification procedures.

Code: RE = reference equipment; RM = reference materials; TE = major testing equipment

Please list the name of the calibration laboratory and the accreditation body which accredits the calibration laboratory where applicable.

Process Requirements (ISO/IEC 17025:2017, Section 7)		
Ensuring the validity of results (ISO/IEC 17025:2017, Section 7.7) Please briefly describe the protocol used to demonstrate the laboratory's competence in performing tests/calibrations under its scope of accreditation and provide details on the internal check conducted to ensure the validity of the est/calibration results.		
Management System Requirements (ISO/IEC 17025:2017, Section 8)	
Options (ISO/IEC 17025:2017, Section 8.3	1)	
Please indicate the approach of the laboratory in finiso/IEC 17025:2017	ulfilling the management system requirements of	
Option A – to maintain a management system that addresses Clause 8.2 to 8.9 of ISO/IEC 17025:2017 and capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025:2017 and	Option B – to maintain a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of ISO/IEC	

For option B, certification to ISO 9001 is not mandatory. However, if property copy of the ISO 9001 certificate for reference if it is available. Any further stated below.					
Any other supplementary information should be provided below.					

Proficiency Testing Activities

For the tests/calibrations to be assessed, please provide details of all relevant proficiency testing (PT) activities (including both PT and inter-laboratory comparison (ILC)) that your laboratory has participated in the **last four years and a 1-year PT participation plan**. The HOKLAS requirements on PT activities are specified in 3.5 to 3.11 of HOKLAS Supplementary Criteria No. 33 and relevant HOKLAS supplementary criteria.

Name of the PT/ILC scheme and, if relevant, the PT/ILC item	For PT, is the PT provider accredited to ISO/IEC 17043? (Y/N)	Date of participation	Date of PT report issued	Performance of y Number of satisfactory results	our laboratory Number of reported results	Remark, including any corrective action taken

Replicate this sheet if required.

HOKLAS 007 (November 2025)

Annex I - Scope of Accreditation Sought

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

Annex II – Checklist