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 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 your personal data.

List of Documents to be submitted[4]

(Please tick the boxes below as appropriate)

This Questionnaire is for :

☐ Initial Assessment ☐ Extension of Scope ☐ Reassessment

List of Attachments (for initial assessment and extension of scope only)

☐ Application fee[5] in the form of a cheque or an *e-Cheque payable to **The Government of the Hong Kong Special Administrative Region**.

*Application fee can be paid by e-Cheque through "Pay e-Cheque" portal https://www.payecheque.gov.hk. Please contact HKAS if special arrangement is required.

☐ Documents authenticating that the laboratory is a valid legal entity or part of a valid legal entity

☐ Management system manual

☐ Operation procedure manuals[6]

☐ 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)

☐ CV and a copy of the qualification documents for each nominee for signatory/operator approval[7]

☐ Laboratory floor plan and procedure for the control and monitoring of environmental conditions

☐ Laboratory organisation chart(s)[8], with names, positions and responsibilities of key personnel clearly identified

☐ Sample test/calibration records[9, 10]

☐ Sample test/calibration reports[9, 10]

☐ Relevant proficiency testing (PT) reports and one-year PT participation plan

☐ Code of conduct

☐ Other documents (please specify)

Notes:

4. For a reassessment, the required documents are listed in the AF07 form which will be provided to the organisation separately.

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 laboratory 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. Specific requirements for an approved signatory/operator in a certain technical discipline are specified in the relevant HKAS/HOKLAS accreditation criteria or supplementary criteria.

8. 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 organisation, where applicable.

9. 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. To protect the confidentiality of the customers, the identity of the customers and the products under test should be blanked out.

10. 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.

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' table.

For a reassessment, the 'Scope of Accreditation to be Reassessed' should 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 11)

Laboratory name
(See Note 12)

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:
11 – The organisation's name should be the name of the legal entity that owns the laboratory. It may be a government department, instrumentality, company, person operating a laboratory or other types of legal entity.
12 – The name used by the organisation to identify the laboratory.

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?

☐ 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 17025:2017, Section 4)

Impartiality (ISO/IEC 17025:2017, Section 4.1.4)

Please identify risks to the impartiality of the laboratory arising from its activities, from its relationships, or from the relationships of its personnel. If a risk to impartiality is identified, please demonstrate how the laboratory eliminates or minimizes such risk.

Confidentiality (ISO/IEC 17025:2017, Section 4.2)

Please explain how the laboratory protects information obtained or created during the performance of laboratory activities.

Structural Requirements (ISO/IEC 17025:2017, Section 5)

Organisation

(The organisation under which accreditation is granted or sought)

Legal status

Is your organisation:

- ☐ a government department?
- ☐ a statutory body?
- ☐ a company incorporated in or outside Hong Kong?
- ☐ a sole-proprietorship or partnership organisation?
- ☐ other? (please specify)

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.

Other activities

Does your organisation conduct other activities in addition to laboratory operation? If yes, please give details on those activities.

Customers

Does the laboratory provide service	Percentage of work
- internally? ☐ Yes ☐ No	
- to the public ? ☐ Yes ☐ No	

Laboratory size

What is the total number of staff members?	
What is the floor area occupied ?	

Personnel in charge of the implementation, maintenance and improvement of the management system (ISO/IEC 17025:2017, Section 5.6)

Name	Position	Area of responsibility

Technical personnel

Please provide below details of the key technical personnel

Name	Position	Area of responsibility

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	Experience

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)

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

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

Nominees for operator approval (applicable to certain 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)

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

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 test/calibration results.

Management System Requirements (ISO/IEC 17025:2017, Section 8)

Options (ISO/IEC 17025:2017, Section 8.1)

Please indicate the approach of the laboratory in fulfilling the management system requirements of ISO/IEC 17025:2017

☐ 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 assuring the quality of the laboratory results

☐ Option B – to maintain a management system, in accordance with the requirements of ISO 9001, and that and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of ISO/IEC 17025:2017, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9 of ISO/IEC 17025:2017

For option B, certification to ISO 9001 is not mandatory. However, if possible, please provide a copy of the ISO 9001 certificate for reference if it is available. Any further comments should be 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 interlaboratory comparisons and proficiency testing activities that your laboratory has participated in the **last four years and a 1-year proficiency testing participation plan**. The HOKLAS requirements on proficiency testing activities are specified in 3.5 to 3.10 of HOKLAS Supplementary Criteria No. 33 and relevant HOKLAS supplementary criteria.

Name of the PT scheme, if relevant, and test item	Date of participation	Date of PT report issued	Performance of your laboratory		Remark, including any corrective action taken
			Number of satisfactory results	Number of reported results	

Replicate this sheet if required.

Annex I - Scope of Accreditation Sought

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

Annex II – Checklist