



Hong Kong Laboratory Accreditation Scheme

HOKLAS 007

Assessment/Reassessment Questionnaire for Non-medical Laboratories

For initial applications for accreditation and applications 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.

For reassessments, the completion of this questionnaire is also required. The completed questionnaire and relevant documents should be provided to HKAS Executive and the assessor(s) one month before the scheduled reassessment date.

Fees payable for assessments are calculated in accordance with:

HOKLAS 006, Schedule of Accreditation Fees for Laboratories within the Hong Kong Special Administrative Region, or

HOKLAS 013, Schedule of Accreditation Fees for Laboratories outside of the Hong Kong Special Administrative Region.

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

HKAS 002, Regulations for HKAS Accreditation

HOKLAS Supplementary Criteria No. 33, Accreditation Regulations Specific for HOKLAS - Laboratory

HOKLAS 003, Technical Criteria for Laboratory Accreditation

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

The personal data received shall be used for accreditation purpose only.

Attachment Checklist

(Please tick the box or 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 fees in the form of a cheque payable to **The Government of the Hong Kong Special Administrative Region.**

Note : Application fees will be charged only for initial applications and applications for extension of accreditation. No application fees are required for reassessments. In addition to application fees, assessment fees will be charged. Applicants will be informed of the exact amounts when the on-site assessments have been arranged.

- Documents authenticating that the applicant laboratory is a legal entity or part of a legal entity
- Quality manual
- Operation procedure manual
- Latest audit schedule
- Summary of the findings of the latest quality and management system review
- Test/calibration procedure manual(s)
- Measurement uncertainty estimation
- CV's and copies of qualification documents for new nominees for signatory/operator approval
- Laboratory floor plan
- Laboratory organisation charts, with key positions clearly identified
- Sample test/calibration records (please refer to "Records" section on page 9 of this questionnaire for details)
- Sample test/calibration reports (please refer to "Reporting the Results" section of this questionnaire for details)
- Relevant proficiency test reports
- Scope of accreditation to be assessed
- Other documents (please specify)

Note : For reassessment, the required documents are listed in the AF07 form accompanying the letter to the laboratory which will normally be issued two months prior to the due date for the reassessment.

SCOPE OF ACCREDITATION

For applications for accreditation and applications for extension of scope of accreditation, the tests and calibrations proposed for accreditation shall be detailed in the “Scope of Accreditation Sought” table on page 4 and page 5.

For reassessments, the “Scope of Accreditation to be Reassessed” should have been sent to the laboratory together with the letter informing it of the forthcoming reassessment. The laboratory should check the scope carefully and minor changes should be annotated on it. The reviewed scope should then be signed for confirmation and returned to HKAS Executive together with this completed questionnaire. If major additions to the scope of accreditation are requested, the laboratory should consult HKAS Executive on whether an application for extension of scope of accreditation should be submitted.

Scope of Accreditation Sought (for application for accreditation or extension of scope of accreditation only)

Please specify as precisely as possible below the scope of accreditation sought. Specifications quoted in the fourth column should be of national or international standards or those published by reputable technical organisations or in relevant scientific texts or journals. In the absence of such standard specifications, documented and validated in-house methods may be quoted and the laboratory shall provide a copy of these documented methods to the HKAS Executive together with this completed questionnaire.

HOKLAS test category	Items, materials or products tested/calibrated	Specific tests, properties measured or ranges of measurement	Standard methods, specifications, or technique used (where appropriate)

Photocopy this sheet if required.

- Notes :
1. Please state the identification numbers of the laboratory internal technical procedures for the tests/calibrations listed in columns 3 and 4 on page 4.
 2. Please state the approximate frequency of performing the tests/calibrations in number per year
 3. Please state the approximate experience of the laboratory in performing the test/calibration, in total number of tests/calibrations performed per year
 4. Please state the identification numbers of the sample test/calibration records provided (see the "Records" section on page 9).
 5. Please state the identification numbers of the sample test/calibration reports provided (see the "Reporting the Results" section on page 16).

Best measurement capability expressed as an uncertainty or detection limits (where appropriate)	Test/Calibration procedure ¹	Frequency of performing ²	Experience ³	Sample test/calibration record ⁴	Sample test/calibration report/certificate ⁵

Photocopy this sheet if required.

General Information

Organisation name
(See Note 1)

Laboratory name
(See Note 2)

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

Signature

Date

Note 1 – Organisation is the legal identity of the owners of the laboratory. It may be a government department, instrumentality, company, person operating a laboratory or other legal entity.

Note 2 – The name used by the organisation to identify the laboratory.

Management Requirements (HOKLAS 003, Section 4)

Organisation (HOKLAS 003, Section 4.1)

(The organisation under which accreditation is granted or sought)

Legal status

Is your organization:

- a government department?
- a statutory body?
- a limited company?
- an unlimited company?
- a sole proprietor?
- other? (please specify)

Please give details of the relationship
between the laboratory and the organisation

Activities

Are there other major activities involved apart
from laboratory operation ?

- Yes No

If yes, please give details on the additional activities

Customers

Does the laboratory provide service to

- the parent organization ? Yes No
- the public ? Yes No

Percentage of work

Laboratory size

What is the total number of laboratory staff ?

What is the size of the floor area occupied ?

Management Requirements (cont'd)

Organisation (cont'd)(HOKLAS 003, Section 4.1)

Technical management

(Please refer to 4.1.5h of HOKLAS 003 for requirements for technical management)

Please give a general description of technical management structure relevant to the scope of accreditation

--

Please provide below details of the members of the technical management team

Name	Position	Area of responsibility

Quality Manager

(Please refer to 4.1.5i of HOKLAS 003 for requirements for quality manager)

Name

--

Position

--

Deputy management

(Please give a general description of the deputy arrangements for the members of the technical management team and for the quality manager)

--

Scope and function

(Please describe the scope and function of the laboratory)

--

Management Requirements (cont'd)

Management System (HOKLAS 003, Section 4.2)

Quality Manual

Please provide a copy of the quality manual and related quality documents such as operation procedure manuals. Any further comments should be given below or on separate sheets.

Records (HOKLAS 003, Section 4.13)

Please provide copies of representative raw test/calibration data records for the tests/calibrations to be assessed. These records should be obtained from real samples. For confidentiality, the identities of the customers and the products under test/calibration should be blanked out.

For applications for accreditation and applications 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 report/certificate" column in the "Scope of Accreditation Sought" table on page 5.

For reassessments, sample records are selected by HKAS Executive. The selected tests/calibrations are marked with a tick in the "Sample test report/certificate" column in the "Scope of Accreditation to be Reassessed" accompanying this questionnaire. For identification, the laboratory should also enter the identification numbers of the sample records provided by the side of the ticks.

Internal audits (HOKLAS 003, Section 4.14)

(Please refer to HOKLAS Supplementary Criteria No.7) Please provide a copy of the latest audit schedule. Any further comments should be given below.

Management review (HOKLAS 003, Section 4.15)

(Please refer to HOKLAS Supplementary Criteria No.7 on Quality Audits and Quality System Reviews) Please provide a copy of the latest management system review record. Any further comments should be given below.

Technical Requirements (HOKLAS 003, Section 5)

Personnel (HOKLAS 003, Section 5.2)

Officer-in-charge of the division/unit in which the work to be assessed is performed.

Name	<input type="text"/>
Position	<input type="text"/>
Qualifications	<input type="text"/>
Experience	<input type="text"/>
Date appointed to division/unit	<input type="text"/>

Deputy

Name	<input type="text"/>
Position	<input type="text"/>
Qualifications	<input type="text"/>
Experience	<input type="text"/>
Date appointed to division/unit	<input type="text"/>

The person to whom officer-in-charge reports

Name	<input type="text"/>
Position	<input type="text"/>

Organisation chart

Please provide a copy of the organisation charts of the division/unit in which the work to be assessed is performed. The charts should show the position of the division/unit within the organisation structure of the laboratory and any parent organisation. The key positions with respect to the work to be assessed should be clearly identified. Any further comments should be given below.

Technical Requirements (cont'd) (HOKLAS 003, Section 5)

Personnel (cont'd) (HOKLAS 003, Section 5.2)

Other key staff (Please attach additional sheets if necessary)

Please provide below the names, qualifications, experience, current position of and date of appointment for the staff members occupying key positions as shown in the organisation charts of the division/unit

Key Personnel				
Name	Position	Date appointed	Qualifications	Experience

Nominated HOKLAS approved signatories

Who is/are the key staff member(s) listed above required to be considered by HKAS Executive for approval as signatories of HOKLAS endorsed test/calibration reports? (Please refer to HOKLAS Supplementary Criteria No. 33 and HOKLAS 003 for requirements for HOKLAS endorsed test/calibration reports and approved signatories).

Name	Test area	New / Existing

Note : Please provide copies of qualification documents (degrees, diplomas, certificates, etc.) for new nominees.

Technical Requirements (cont'd) (HOKLAS 003, Section 5)

Personnel (cont'd) (HOKLAS 003, Section 5.2)

Personnel changes (applicable only for reassessments)

Please give details of any changes in laboratory personnel relevant to the work to be reassessed since the last assessment/reassessment.

Accommodation and Environmental Conditions (HOKLAS 003, Section 5.3)

Please provide a floor plan of the laboratory and indicate the use of different areas. Any further comment should be given below.

Please state whether any of the tests/calibrations to be assessed require specific environmental conditions and describe how the environmental conditions in the laboratory are controlled and monitored to meet the requirements.

Technical Requirements (cont'd) (HOKLAS 003, Section 5)

Test and calibration methods and method validation (HOKLAS 003, Section 5.4)

Test and calibration procedures

Please provide a copy of the technical procedures for the tests / calibrations to be assessed. The identification numbers of the procedures should be entered into the "Test/Calibration procedure" column in the "Scope of Accreditation Sought" on page 5 against the relevant tests/calibrations.

Any further comments should be given below.

Validation of method (HOKLAS 003, Section 5.4.5)

Please describe the procedures used for validating the test/calibration methods listed in the proposed scope of accreditation

Estimation of uncertainty of measurement (HOKLAS 003, Section 5.4.6)

Please give a brief account of the methods for estimation of the measurement uncertainty for the tests/calibrations included in the proposed scope of accreditation. For "Calibration Services" test category, a copy of the measurement uncertainty evaluation for each calibration to support the claimed BMC value is required. For other test categories, HKAS may request the laboratory to provide copies of the estimation of measurement uncertainty for the tests to be assessed.

Computer and automated equipment (HOKLAS 003, Section 5.4.7.2)

For the tests/calibrations to be assessed, please describe below the extent to which computers and other types of automated equipment are used for the capture, processing, manipulation, recording, reporting, storage and retrieval of the test/calibration data.

Technical Requirements (cont'd) (HOKLAS 003, Section 5)

Equipment and measurement traceability (HOKLAS 003, Sections 5.5 and 5.6)

Please provide below or where necessary 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	Traceability®

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

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

® Please name the organisation which conducts the calibration or provides the traceability link and the accreditation body which accredits it, if any.

Technical Requirements (cont'd) (HOKLAS 003, Section 5)

Handling of test and calibration items (HOKLAS 003, Section 5.8)

Please briefly describe any special precautions taken in the reception, registration, transportation, storage and where appropriate disposal of the test / calibration items.

Assuring the quality of test and calibration results (HOKLAS 003, Section 5.9)

Please briefly describe the quality control procedures for monitoring the validity of tests / calibrations to be assessed.

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. The HOKLAS requirements on proficiency testing activities are detailed in 3.5 to 3.7 of HOKLAS Supplementary Criteria No. 33 and relevant HOKLAS Supplementary Criteria.

Name, title, frequency and other relevant information	Year & Month of participation	Performance of your laboratory	Remark, including any remedial action taken (to be completed by laboratory)	Assessor comments

Technical Requirements (cont'd) (HOKLAS 003, Section 5)

Internal Checks

Please provide details on the internal checks conducted to ensure the quality of results for the tests/calibrations to be assessed.

Reporting the Results (HOKLAS 003, Section 5.10)

How many reports on average are issued per year on the tests/calibrations to be assessed?

What is the percentage of the above total which are HOKLAS endorsed?

Please provide copies of representative reports/certificates for the tests/calibrations to be assessed. These reports should be based on real samples. For confidentiality, the identities of the customers and the products under test/calibration should be blanked out.

For applications for accreditation and applications for extension of scope of accreditation, the selection of sample reports is at the discretion of the laboratory. It is not necessary to provide a separate sample report for every test/calibration. Tests/Calibrations with similar report formats may be represented by a common sample report. For each test/calibration, the identification number of the sample report selected should be entered in the "Sample test report/certificate" column in the "Scope of Accreditation Sought" table on page 5.

For reassessment, sample reports are selected by HKAS Executive. The selected tests/calibrations are marked with a tick in the "Sample test report/certificate" column in the "Scope of Accreditation to be Reassessed" accompanying this questionnaire. For identification, the laboratory should also enter the identification numbers of the sample reports provided by the side of the ticks.

Any further comments on records should be provided below.

Quality System Checklist

The applicant laboratory or laboratory to be reassessed must complete the following checklist. It will be used to assess conformity with HOKLAS requirements.

The checklist consists of questions based on the requirements of HKAS 002, HOKLAS Supplementary Criteria No. 33 and HOKLAS 003. For further information, please refer to the corresponding document and clause as listed in the second column.

The laboratory should indicate in the “QM Clause” column, for every question, the clause(s) in its quality manual, operation procedures manual or other related documents which cover the requirement.

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

A softcopy of this checklist should be provided to HKAS Executive through email or other means.