



## Hong Kong Laboratory Accreditation Scheme

### HOKLAS 023

#### Assessment/Reassessment Questionnaire for Reference Material Producer (Based on HOKLAS 022:2017)

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 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 023) and the required application fee are received.

For a reassessment, the accredited reference material producer (RMP) is also required to complete and return 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

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

HKAS 002

HKAS SC-06

HOKLAS SC-39

HOKLAS 022:2017

Please note that testing and calibration activities of an accredited RMP will be assessed on its adequacy to support the operation of the RMP. Such activities will not be considered as accredited laboratory activities. If an RMP wants to obtain laboratory accreditation for such activities, it shall apply for laboratory accreditation separately.

#### 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](mailto: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<sup>4</sup>

(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<sup>5</sup> in the form of a cheque or an \*e-Cheque payable to **The Government of the Hong Kong Special Administrative Region**.

\*Fees can be paid by e-Cheque through “Pay e-Cheque” portal <https://www.payechequer.gov.hk>. Please contact HKAS if special arrangement is required.

- Documents authenticating that the RMP is, or is part of, a valid legal entity.
- Management system manual
- Operation procedure manuals<sup>6</sup>
- RMP’s organisation chart(s)<sup>7</sup>, with names, positions and responsibilities of key personnel clearly identified
- RMP’s floor plan and procedure for the control and monitoring of environmental conditions
- CV and a copy of the qualification documents for each nominee for signatory approval
- Latest internal audit schedule and sample audit reports
- Records of the latest management review
- Records of risk identified to the RMP’s impartiality
- Code of conduct and confidentiality arrangement
- Production plan, procedure and quality control, and means of establishing metrological traceability of certified values for each certified reference material (CRM) included in the proposed scope of accreditation
- Evidence of conformity with relevant requirements of ISO/IEC 17025 for the producer’s testing facility, if testing and calibration subcontractors are not used. Examples are testing, calibration and sampling procedures, method validation report, list of measurement equipment and their calibration schedules, sample handling procedures and quality assurance procedures
- Copies of agreements with each subcontractor for testing and calibration, if used, with details of each subcontractor and the evidence of subcontractors’ competence (e.g. accreditation to ISO/IEC 17025 for the tests and/or calibrations concerned)
- Technical standards/protocols that are used for the production of each reference material (RM) included in the proposed scope of accreditation
- Sample certificates for CRMs and/or sample product information sheets for other RMs<sup>8,9</sup>
- Sample technical records of homogeneity assessment, stability assessment and monitoring, characterisation, property value assignment, measurement uncertainty evaluation of RMs, where applicable<sup>8,9</sup>
- Records of performance in proficiency testing for test and/or calibration involved, if applicable
- Other documents, please specify

Notes:

4. For a reassessment, the required documents are listed in the AF16 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 RMP 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 RMP, including the division/unit in which the activities to be assessed is performed. The chart should show the relationship between the RMP and its parent organisation, where applicable.
8. Please provide copies of representative certificates/product information sheets and the associated raw data records for the RMs to be assessed.
9. For application for accreditation and application for extension of scope of accreditation, the selection of sample records is at the discretion of the RMP. It is not necessary to provide a separate sample record for every RM. Similar record formats may be represented by a common sample record.

# **SCOPE OF ACCREDITATION**

**For an initial application for accreditation or an application for extension of scope of accreditation, the reference materials proposed for accreditation should be detailed in HOKLAS 023 Annex I – ‘Scope of Accreditation Sought’.**

**For a reassessment, the ‘Scope of Accreditation to be Reassessed’ should have been sent to the RMP together with the letter informing it of the forthcoming reassessment. The RMP should check the scope carefully, mark minor changes to the scope with justification, sign to confirm the ‘Scope of Accreditation to be Reassessed’ and returned the confirmed scope to HKAS Executive together with this completed questionnaire. If major additions to the scope of accreditation are requested, the RMP should consult HKAS Executive on whether an application for extension of scope of accreditation should be submitted.**

**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.**

## General Information

Organisation name  
(See Note 10)

Name of RMP  
(See Note 11)

General description of the organisation and the RMP including their major activities, history and any trade name(s) used by the RMP.

Physical address of RMP

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: 10 – The organisation name should be the name of the legal entity that owns the RMP. It may be a government department, instrumentality, company, person operating an RMP or other types of legal entity.

11 – The name used by the organisation to identify the RMP e.g. Reference Material Division.

## 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 (HOKLAS 022, Section 4)

#### Impartiality (HOKLAS 022, Clause 4.2)

Please identify risks to the impartiality of the RMP 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 RMP eliminates or minimizes such risk.

#### Confidentiality (HOKLAS 022, Clause 4.3)

Please explain how the RMP protects information obtained from another individual or body during the RM production activities.

## Structural Requirements (HOKLAS 022, Section 5)

### Legal Status

Please give details of the legal status of your organisation (i.e. the organisation under which accreditation is granted or sought).

- 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 RMP is a part of the organisation, please give details of the line of authority and the relationship of other parts within the same organisation.

### Activities

The RMP is

- an organisation with activities in addition to production of reference materials?
- are these 'additional activities' the main activities?

Yes/No	If yes, please describe

### Customers

The RMP provide service

- to the public
- internally

Yes/No	Percentage of work

### Size of RMP

- number of people working for the RMP

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(Note: If the RMP is part of an organisation, include only the number of people that contribute to the production of reference materials. Please indicate full time or part-time involvement)

- floor size occupied

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## Structural Requirements (cont'd)

### Technical management (HOKLAS 022, Clause 5.3e)

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

### Personnel responsible for the implementation of the management system (HOKLAS 022, Clause 5.3f)

Name

Position

### Deputy arrangement

Please give a general description of the deputy arrangements for the members of the technical management team and for the personnel responsible for the implementation of the management system below.



## Resource Requirements (HOKLAS 022, Section 6)

### Personnel (HOKLAS 022, Clause 6.1) (Please attach additional sheets if necessary)

#### Key personnel

Please provide below the name, qualifications, experience, current position and date of appointment for each staff member occupying key positions as defined by the RMP and shown in the organisation chart.

Key Personnel				
Name	Position	Date appointed	Qualifications	Experience

#### Changes in key personnel (applicable to a 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

#### Nominees for signatory approval

Please list below the persons to be considered by HKAS Executive as approved signatories of HOKLAS endorsed RM certificates/documents.

Name	Area	Existing approved signatory? (Y/N)

#### Advisory group

If any advisory group is formed for providing technical expertise to the RMP, please state the membership of the advisory group and describe the role and responsibility of each member below.

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## Technical and Production Requirements (cont'd)

### Distribution service (HOKLAS 022, Clause 7.15)

Please briefly describe below how the RMs are distributed.

## Management Requirements (HOKLAS 022, Section 8)

### Options (HOKLAS 022, Clause 8.1)

The RMP adopts **Option A / Option B** (please delete where appropriate) when fulfilling the requirements of the International Standard.

If Option B is adopted, please describe below how clause 8.1.3 of HOKLAS 022 is fulfilled and provided documented evidence where relevant, e.g. a copy of the ISO 9001 certificate.

## 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**