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HOKLAS Information Notes No. 3

Application Procedures for HOKLAS Accreditation (*Informative*)

This document provides a summary of the procedures for accreditation of laboratories, proficiency testing providers and reference material producers under HOKLAS. Detailed accreditation procedures are given in Chapter 4 of HKAS 002 ‘Regulations for HKAS Accreditation’.

STEP 1 - SUBMISSION OF APPLICATION

- (i) A potential applicant organisation contacts HKAS Executive in writing.
- (ii) For an initial application for accreditation, HKAS Executive provides an appropriate HKAS accreditation criteria document as shown below to the potential applicant organisation upon request:
 - HOKLAS 017 Technical Criteria for Accrediting Proficiency Testing Providers
 - HOKLAS 022 Technical Criteria for Accreditation of Reference Material Producers

For accreditation criteria document directly adopted from an accreditation standard (e.g. ISO/IEC 17025 or ISO 15189), the applicant organisation is required to purchase the standard from the standards body. Other HKAS published documents are available at HKAS website (www.hkas.gov.hk) for free download.

- (iii) The applicant organisation submits an application including the following documents to HKAS Executive:
 - (a) A completed HOKLAS 005 ‘Application for Accreditation of a Laboratory, Proficiency Testing Providers (PTP) or Reference Material Producers(RMP) / Extension of Scope of Accreditation of a Laboratory, PTP or RMP’;
 - (b) A completed Assessment/Reassessment Questionnaire together with the required documents:
 - HOKLAS 007 for a non-medical laboratory,
 - HOKLAS 016 for a medical laboratory,
 - HOKLAS 018 for a proficiency testing provider, or
 - HOKLAS 023 for a reference material producer; and
 - (c) An appropriate application fee as stated in HOKLAS 006 or HOKLAS 013.

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STEP 2 - PRELIMINARY VISIT [For an initial application only]

- (i) After reviewing the documents submitted by the applicant organisation, HKAS Executive arranges a preliminary visit to the organisation to:
 - (a) answer any query regarding HKAS accreditation requirements and procedures,
 - (b) identify any obvious nonconformity with the accreditation criteria,
 - (c) evaluate the organisation's readiness for a HOKLAS assessment visit,
 - (d) determine an appropriate schedule for the initial assessment visit to the organisation.
- (ii) Where necessary, the applicant organisation submits additional/revised documents as required by HKAS Executive after the preliminary visit.

STEP 3 - PREPARATION FOR ASSESSMENT

- (i) The assessment team leader may ask the applicant organisation for further information during document review. HKAS Executive may decide not to proceed with the initial assessment visit if the team leader has identified a critical or significant nonconformity during document review and/or the preliminary visit. HKAS will then inform the applicant organisation in writing.
- (ii) HKAS Executive selects suitable technical assessor(s)/expert(s) to undertake the initial assessment of the organisation.
- (iii) The assessment team leader proposes the date(s) of initial assessment visit for the applicant organisation's agreement. Such date(s) should be convenient to the organisation's subcontractor(s) in case the applicant organisation is a proficiency testing provider or reference material producer.

NOTE: An applicant organisation may object to the appointment any assessment team member only if it can provide a valid reason.

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STEP 4 -ON-SITE ASSESSMENT VISIT

- (i) The assessment team conducts the assessment visit to the organisation including its subcontractor(s) where appropriate.

*NOTE: 1. All key personnel shall be available for interview during the assessment visit.
2. An applicant laboratory shall demonstrate certain tests during the assessment visit.
3. An applicant proficiency testing provider or reference material producer shall demonstrate the competence of its testing facility(ies).*

- (ii) Upon completion of the assessment visit, the assessment team provides the management of the organisation an assessment report which includes:
- the assessment team’s recommendation on granting accreditation to the applicant organisation for all or part of the activities shown in the scope of accreditation sought;
 - a list of actions, where applicable, to be undertaken by the applicant organisation before HKAS Executive makes a decision on granting accreditation to the applicant organisation.; and
 - details of follow-up actions to be taken by HKAS Executive.

STEP 5 - ASSESSMENT OUTCOME

- (i) For an assessment visit under a new test category or a new technical discipline, the assessment report will be reviewed by HKAS Executive as well as Accreditation Advisory Board (AAB). After review, HKAS Executive will issue the assessment results to the organisation through an outcome letter.
- (ii) For an assessment visit for extending the scope of accreditation under a test category for which the organisation is already accredited, the assessment report will normally be reviewed by HKAS Executive only. Any amendment to the assessment report will be issued to the accredited organisation within 10 working days of the assessment visit.
- (iii) In most cases, specific matters which require the applicant/accredited organisation’s attention before accreditation can be further considered are listed in the assessment report and/or in the outcome letter.

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STEP 6 - REMEDIAL ACTIONS (if required)

- (i) Upon receipt of a written reply from an applicant/accredited organisation that all required actions have been taken, HKAS Executive will take an appropriate follow-up action. The actions undertaken by the applicant/accredited organisation may be confirmed through reviewing documents submitted by the applicant/accredited organisation and, where necessary, a follow-up visit by the assessment team. Under certain circumstances, a full on-site assessment visit will be conducted by the assessment team.
- (ii) Once all actions undertaken by the applicant/accredited organisation are acceptable, HKAS Executive will make a decision on granting accreditation to the organisation through a formal notification letter which includes the scope of accreditation. HKAS Executive will issue a certificate of accreditation to the organisation if accreditation is granted under a new test category.

STEP 7 - AFTER GRANTING ACCREDITATION

- (i) After accreditation is granted to a new accredited organisation, such an organisation will be reassessed in the following year and thereafter in accordance with its monitoring plan. Surveillance visits will also be conducted to ensure that the accredited organisation maintains its competence for performing specific activities in accordance with the accreditation criteria.
- (ii) An accredited organisation may apply to HKAS Executive for extending or reducing its scope of accreditation. It may also nominate its staff member(s) for inclusion in the list of HOKLAS approved personnel and such nomination will normally be processed during an on-site assessment visit.
- (iii) An organisation is required to participate in proficiency testing activities from time to time as required by HKAS Executive.
- (iv) Under HKAS Regulations, an applicant/accredited organisation is required to notify HKAS Executive immediately in writing of any change in the organisation's circumstances which may affect the organisation's continued compliance with HKAS accreditation requirements. Examples of such changes are given in Clause 5.9 of HKAS 002.

END