

HOKLAS 017 (First Edition)

Technical Criteria for
Accrediting
Proficiency Testing Providers

Hong Kong Accreditation Service
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1. Introduction

- 1.1 Hong Kong Accreditation Service (HKAS) offers accreditation service for Proficiency Testing Providers under the test category of “Proficiency Testing Provider” of the Hong Kong Laboratory Accreditation Scheme (HOKLAS). Participation in this accreditation programme is voluntary. This programme is designed for proficiency testing scheme providers wishing to demonstrate their competence and compliance with relevant internationally acceptable requirements for the development and operation of proficiency testing schemes through obtaining accreditation.
- 1.2 This document establishes criteria for the competence of the proficiency testing providers.

2. Accreditation criteria

- 2.1 Accredited and applicant proficiency testing providers shall comply with the Regulations for HKAS Accreditation as documented in HKAS 002 and HOKLAS Supplementary Criteria No. 34. These regulations and criteria are applicable to all accredited and applicant proficiency testing providers, irrespective of its size and the proficiency testing schemes it offers.
- 2.2 Accredited and applicant proficiency testing providers shall also meet the requirements of the International Laboratory Accreditation Cooperation (ILAC) *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes* (ILAC-G13: 2007; ILAC Website: <http://www.ilac.org>). For information, ILAC-G13:2007 was established based on the ISO/IEC Guide 43 *Proficiency Testing by Interlaboratory Comparisons – Part 1: Development and Operation of Proficiency Testing Schemes* (ISO/IEC Guide 43-1:1997) and on the relevant elements of ISO/IEC 17025:2005 applicable to the management system requirements and the characterisation, homogeneity and stability testing of proficiency testing test items. Requirements from ISO 15189 regarding various uses of proficiency testing and the need for proficiency testing to cover other sources of error are accommodated in the 2007 version of ILAC G13. Additionally, relevant elements of ISO 9000:2005 are included in ILAC G13:2007 to eliminate the need for separate recognition of a provider’s management system.

2.3 It is the responsibility of an accredited or applicant proficiency testing provider to ensure that the requirements stipulated in ILAC G13:2007 and this document are met by it and its subcontractors at all times. Where there is any discrepancy in requirements described in ILAC G13:2007 and the other related documents including ISO/IEC Guide 43-1:1997, ISO/IEC 17025:2005 and ISO 15189:2007 (and other updated versions of relevant standards after their adoption by HKAS as accreditation criteria), the ILAC G13:2007 shall take precedence.

3. Scope of Accreditation

3.1 Proficiency testing providers may seek accreditation of proficiency testing schemes for technical disciplines covered by any HOKLAS test categories, which include

- Calibration Services
- Chemical Testing
- Chinese Medicine
- Construction Materials
- Electrical and Electronic Products
- Environmental Testing
- Food
- Medical Testing
- Miscellaneous
- Physical and Mechanical Testing
- Textiles and Garments
- Toys and Children's Products

An accredited proficiency testing provider is accredited only for the specific proficiency testing schemes and programmes listed in its scope of accreditation.

3.2 The application process is similar to the application procedure for HOKLAS accreditation and is detailed in Annex A of this document.

3.3 Accredited and applicant proficiency testing providers shall ensure that all tasks involved in the provision of a proficiency testing scheme included in its scope of accreditation are performed competently, whether they are carried out directly by itself or indirectly through collaboration with other parties.

4. Proficiency testing provider

- 4.1 An applicant or accredited proficiency testing provider shall be a legal entity and take responsibility for all activities involved in the operation of the proficiency testing scheme included in its scope of accreditation.
- 4.2 If a provider runs different proficiency testing programmes under a scheme, e.g. a proficiency testing scheme for construction materials testing may have a programme for chemical analysis and another for steel testing, it may seek accreditation for all or some of such programmes.
- 4.3 An accredited or applicant proficiency testing provider may use its own testing and measurement facility(ies) or those provided by its sub-contractor's (or collaborator's) laboratories.
- 4.4 If a provider subcontracts any of its activities for the production, testing, measurement, sampling, storage, and distribution of the proficiency test items (i.e. PT materials/samples or measurement artefacts), or for data processing and distribution of the proficiency testing reports, there shall be written agreements with each subcontractor to clearly document the work and responsibilities involved.
- 4.5 An accredited or applicant proficiency testing provider shall take part in proficiency testing for the laboratory activities relevant to its scope of accreditation. Relevant requirements are documented in HOKLAS Supplementary Criteria No. 34.
- 4.6 The following activities are expected to be carried out by an accredited or applicant proficiency testing provider itself and are NOT to be sub-contracted:
 - a. the design of a proficiency testing scheme, including all programmes included in the scope of accreditation;
 - b. the assessment and analysis of participants' performances; and
 - c. the final production, issue, and endorsement of interim or final reports of proficiency testing programmes under the scheme.
- 4.7 HKAS endorsed proficiency testing reports shall be signed by a signatory nominated by the proficiency testing provider and approved by HKAS in writing for signing such reports for specific proficiency testing programmes. Such a signatory is called an approved proficiency testing signatory. A nominee for signatory approval for a programme shall be the programme leader described in 5 below. He/she shall be authorized by the accredited proficiency testing provider

in writing to take overall responsibility for the conduct of the specified proficiency testing programmes and has in-depth understanding of the operation of the proficiency testing programmes and the relevant HKAS accreditation criteria. As approvals are granted in the context of the proficiency testing programmes operated by the proficiency testing provider, they shall not be considered as personal qualifications.

5. Programme leader

- 5.1 An applicant or accredited proficiency testing provider shall nominate an individual as the programme leader for each of the programmes under a scheme included in its scope of accreditation.
- 5.2 The responsibility of the programme leader shall be clearly documented. There shall be written agreement between the programme leader and the proficiency testing provider defining the tasks the leader shall be responsible for. In such a case, the programme leader shall report directly to the proficiency testing provider and is not considered a subcontractor.
- 5.3 The programme leader shall participate in the preparation of the report(s) for the particular programmes he/she is responsible.
- 5.4 The nominated leader shall have appropriate training, qualifications and experience in the field of the specific programme. Before appointing a potential programme leader, the applicant or accredited proficiency testing provider shall assess and confirm the competence of the candidate. Such assessments and their results shall be recorded.

6. The subcontractors

When an applicant or accredited proficiency testing provider subcontracts work relating to a proficiency testing programme included in its scope of accreditation, the subcontractor shall meet the relevant requirements of ILAC G13: 2007 and ISO/IEC Guide 43: 1997 Part 1.

- 6.1 The applicant or accredited proficiency testing provider shall ensure that the subcontractor operates a quality control system and carries out the subcontracted activity according to well-defined documented procedures.
- 6.2 The applicant or accredited proficiency testing provider shall ensure that there is no further subcontracting of the testing/measuring activities by the provider's subcontractor.

- 6.3 If the work to be subcontracted is a test or measurement, a subcontractor holding current accreditation by HKAS or a mutual recognition arrangement partner of HKAS for the relevant test or measurement is accepted as having adequately demonstrated its competence. Where the subcontractor is not accredited for such activities, HKAS will assess, reassess and monitor the competency of the subcontractor through on-site visits as part of the assessment or surveillance activity for the proficiency testing provider. Relevant requirements are documented in HOKLAS Supplementary Criteria No. 34.
- 6.4 When evaluating a laboratory's competence, HKAS will take into consideration all relevant factors, including the performance of the laboratory in external proficiency testing programmes for relevant activities. Where an accredited proficiency testing scheme is not available for such activities, the laboratory is expected to demonstrate its competence through other forms of interlaboratory comparison.

7. On-site assessment

- 7.1 HKAS will appoint an assessment team to conduct on-site assessments at the proficiency testing provider's own facility and where appropriate, also at its subcontractors' facilities.
- 7.2 Before seeking accreditation from HKAS, an application proficiency testing provider shall ensure that prior written consent has been obtained from all its subcontractors regarding on-site visits by the HKAS assessment team for the relevant activity. For the assessment of the relevant activities, the proficiency testing provider shall through agreement with the subcontractor, ensure that the obligations of an accredited or applicant organisation stated in Chapter 5 of HKAS 002 are fulfilled. In particular, the proficiency testing shall ensure that its subcontractors will provide necessary cooperation and support to the assessment team, including but not limited to test demonstration, provision of any documents and data related to the subcontracted activities and access to files and records during the on-site visits and other assessment activities.
- 7.3 Any nonconformity identified in the work of the subcontractor will be considered as nonconformity of the applicant or accredited proficiency testing provider.
- 7.4 On-site visits, whether as part of the reassessments or surveillance activities, will be conducted at a frequency as documented in HOKLAS Supplementary Criteria No. 34.

References

1. ILAC-G13: 2007, Guidelines for the requirements for the competence of providers of proficiency testing schemes.
2. ISO/IEC Guide 43: 1997, Proficiency testing by inter-laboratory comparisons – Part 1 : Development and operation of proficiency testing schemes.
3. ISO/IEC 17025: 2005, General requirements for the competence of calibration and testing laboratories.
4. ISO 15189: 2007, Medical laboratories – Particular requirements for quality and competence.
5. ISO 13528: 2005, Statistical methods for use in proficiency testing by interlaboratory comparisons.
6. HOKLAS Supplementary Criteria No. 34, Accreditation regulations specific for HOKLAS – Proficiency Testing Provider

Annex A

Application Process

Procedures for HOKLAS Accreditation

Full details of the processes involved in achieving HOKLAS accreditation are given in Chapter 4 of HKAS 002 - Regulations for HKAS Accreditation. A brief summary of the main features is given below:

Step1- Initial Contact

- A. An organisation interested in seeking accreditation contacts HKAS Executive in writing.
- B. Documents relevant to application for accreditation of proficiency testing providers are available on the HKAS website at <http://www.itc.gov.hk/hkas>. These include:

HKAS 002	Regulations for HKAS Accreditation
HOKLAS 005	Application Form for Accreditation of Laboratory or Proficiency Testing Provider
HOKLAS 006	Schedule of Accreditation Fees for Hong Kong Laboratories
HOKLAS 017	Technical Criteria for Accrediting Proficiency Testing Providers
HOKLAS 018	Application Questionnaire (Proficiency Testing Scheme Providers)
	Relevant HKAS and HOKLAS Supplementary Criteria and Information Notes

- C. The organisation lodges the application by providing the following to HKAS Executive
 - (a) A completed Application Form for Accreditation of Laboratory or Proficiency Testing Provider (HOKLAS 005)
 - (b) A completed Application Questionnaire for Proficiency Testing Provider (HOKLAS 018)
 - (c) The documents specified in the Application Questionnaire
 - (d) Appropriate application fees as stated in HOKLAS 006

Step 2 – Preliminary Advice to Organisation

- A. Following examination of the documentation submitted by the organisation, HKAS Executive arranges a pre-assessment visit to :
 - (a) answer any questions relating to technical criteria and regulations;
advise on any obvious improvements to existing practice necessary;
advise on probable technical validity for the areas for which accreditation is sought;
comment on the acceptability of the organisation's quality manual.

Step 3 – Preparation for Assessment

- A. The organisation submits the final copies of its quality manual and operation procedures.
- B. HKAS Executive seeks any further information required from the organisation.
- C. HKAS Executive selects suitable expert assessors to undertake on-site assessment of the organisation.
- D. Arrangements are made with the organisation for a mutually convenient date or dates for an on-site assessment of the organisation and its subcontractors.

NOTE : Applicant organisations may object on reasonable grounds to the assessors nominated for the assessment of their organisations.

Step 4 – Assessment of Organisation

- A. An on-site assessment is undertaken at the organisation and where necessary, also at its subcontractors.

NOTES : All key organisation personnel shall be available for interview during the on-site assessment.

The organisation may be asked to undertake typical procedures as part of the assessment process.

The provider shall be able also to demonstrate the competence of its testing facility(ies).

- B. On completion of the on-site assessment, the organisation management is provided with an assessment report by the assessment team which
 - (a) includes the assessment team's recommendation regarding granting of accreditation for all or part of the areas sought by the applicant organisation;
 - (b) lists any action which may be necessary before accreditation for all or part of the areas can be further considered;
 - (c) details follow-up action.

Step 5 – Advice of Assessment Outcome

Generally, for reassessments and assessments for extension of accreditation within a specific category of proficiency testing for which the organisation is already accredited, the assessment report will be reviewed by HKAS Executive. Any amendment to the assessment report will be issued to the organisation within 10 working days of the assessment.

For initial assessment for a specific category of proficiency testing, the assessment will be reviewed by HKAS Executive as well as the Accreditation Advisory Board. The reviewed assessment results will be issued to the organisation in the form of an outcome letter.

In most cases, there are specific matters requiring attention by the organisation before accreditation can be considered further, and these are listed in the assessment report or in the outcome letter.

Step 6 – Remedial Actions (if required)

- A. On receipt of formal advice from an applicant organisation that all required actions have been taken, HKAS Executive will take the necessary follow-up action. If the matters are of a minor nature, corrective actions may be confirmed through submission of supporting documents or through a brief visit by a member of HKAS Executive and where necessary with an assessor, but in some cases, a further on-site assessment may be needed.

- B. Assuming the remedial actions are found acceptable, a recommendation for accreditation will normally follow. A formal notification letter and a Certification of Accreditation will be issued.
- C. If an organisation does not agree with the decision made by HKAS Executive or AAB, it has the right to appeal (See Disputes, Complaints and Appeals in HKAS 002).

Step 7 – After Accreditation

- A. After accreditation has been granted, organisations are reassessed the following year and thereafter at intervals not exceeding two years. Surveillance visits will also be conducted. The purpose is to ensure that the standards required for continued accreditation are being maintained.

For the purpose of on-going surveillance, accredited organisations are required to provide the following information to HOKLAS on an annual basis for review:

- (a) details of the planned proficiency testing programmes for the next twelve months;
- (b) details of any subcontractors used in the past twelve months and any forward plans for the use of subcontractors;
- (c) an example of at least one report for a proficiency testing programme recently conducted;
- (d) results in any external quality assurance programme relevant to the scope of accreditation that the provider's laboratory (or subcontractors') has participated, together with the results of investigations into outliers;
- (e) details of customer complaints received and the resolution of these complaints.

The organisation will be informed about the outcome of the review. There may require on-site assessment, depending on the outcome of the review.

- B. Organisations may seek to have their scope of accreditation extended or reduced or they may seek changes to their subcontracting laboratories. Such changes may require on-site assessment.

- C. Organisations are required under HOKLAS regulations to advise HKAS Executive immediately in writing of any changes in the provider's circumstances which may affect their continued compliance with HOKLAS requirements. In addition to those specified in Chapter 5 of HKAS 002, the accredited Proficiency Testing Provider shall also notify HKAS Executive if there is any change of its subcontractors or the contractual agreement with its subcontractors.