

HOKLAS Supplementary Criteria No. 34

Accreditation Regulations Specific for HOKLAS – Proficiency Testing Provider

1 INTRODUCTION

- 1.1 This document provides specific regulations for accreditation of proficiency testing providers under the Hong Kong Laboratory Accreditation Scheme. All accredited proficiency testing providers shall conform with all the regulations stated in this document at all times. For an applicant proficiency testing provider, accreditation will only be granted after it has demonstrated to the satisfaction of HKAS Executive its competence and commitment to conforming with all the regulations stated in this document.
- 1.2 This document shall be used in conjunction with HKAS 002.
- 1.3 This document may be amended from time to time and the up-to-date version is uploaded to the HKAS website at the address of www.itc.gov.hk/hkas.

2 PROFICIENCY TESTING PROVIDER ACCREDITATION PROCEDURES

- 2.1 An assessment team may require a proficiency testing provider to demonstrate an activity as part of an assessment, or to participate in proficiency testing in order to evaluate its standard and competence. The specific activities to be demonstrated will be selected from those covered in the proposed scope of accreditation at the discretion of the assessment team.
- 2.2 HKAS Executive shall conduct a reassessment on the accredited activities of a proficiency testing provider:-
 - (a) twelve months after the date of the notification letter in which HKAS Executive granted the accreditation to the proficiency testing provider;
 - (b) every two years after the due date of the first reassessment;
 - (c) at such other times as may be specified in the terms of accreditation;

- (d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited proficiency testing provider, of any change in the structure and circumstances of the proficiency testing provider since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the proficiency testing provider's competence or conformity with the accreditation criteria; and
- (e) The reassessment schedule may be varied at the discretion of HKAS Executive.

- 2.3 HKAS Executive shall conduct a surveillance visit to an accredited proficiency testing provider if no reassessment, assessment for extension of accreditation, nor surveillance visit has been conducted for the past twelve months. HKAS Executive may, at its discretion, vary the surveillance visit schedule. The maximum interval between on-site visits shall not exceed 18 months.
- 2.4 Upon granting of accreditation to a proficiency testing provider, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for proficiency testing provider.

3 OBLIGATIONS OF ACCREDITED OR APPLICANT PROFICIENCY TESTING PROVIDERS

3.1 Accreditation Criteria

An accredited proficiency testing provider shall at all times comply with the following accreditation criteria:-

HKAS 002 - Regulations for HKAS Accreditation,

ILAC G13:2007 - Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes,

ISO/IEC Guide 43-1:1997 – Proficiency Testing by Interlaboratory Comparisons – Part 1 Development and Operation of Proficiency Testing Schemes,

HOKLAS 017 – Technical Criteria for Accrediting Proficiency Testing Providers,

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Relevant HOKLAS Supplementary Criteria, and

Relevant HKAS Supplementary Criteria

A list of HOKLAS and HKAS Supplementary Criteria and copies of such documents can be obtained from the office of HKAS Executive. These documents have also been uploaded to the website of HKAS.

- 3.2 An accredited proficiency testing provider shall not use its accreditation status in a way that may be interpreted by any person that any product, material or any other subject of an activity for which accreditation has been granted has been approved or disapproved by HKAS or HKAS Executive. It shall further endeavour to ensure that no person will use any certificate or report issued by it for such activity in a misleading manner.
- 3.3 An accredited proficiency testing provider shall afford its customers or their representatives reasonable cooperation to monitor its performance such as provision of information to demonstrate the correct operation of its proficiency testing programmes, or to arrange site visits (in so far as to their respective contracts are concerned).

For avoidance of doubt, the proficiency testing provider may also take reasonable steps to protect its proprietary information and agree with its customers the cost they have to pay to the proficiency testing provider for performing or taking part in such monitoring activities.

- 3.4 If an accredited proficiency testing provider intends to subcontract any conformity assessment activities which have significant impact on its accredited activities, it shall ensure that the activities of the organisation to which the activities will be subcontracted have been accredited by HKAS or an accreditation body recognised by HKAS under a mutual recognition arrangement/agreement. Where the subcontractor is not accredited for such activities, HKAS shall assess the competency of the subcontractor through on-site visits, and the subcontractor shall be required to carry out demonstration of the activities as requested by the assessment team. In the proficiency testing report, the accredited proficiency testing provider shall specify the activities performed and the results obtained by such subcontractor. The accredited proficiency testing provider shall not disclose the performance of any of its customers to any of its contractor without prior written approval from the customer. Some activities of an accredited proficiency testing provider shall not be subcontracted. They are specified in HOKLAS 017.

- 3.5 An applicant and accredited proficiency testing provider shall take part in proficiency testing programmes for laboratory activities which are relevant to its scope of accreditation organised or specified by HKAS Executive unless it can demonstrate to HKAS Executive that it has already participated in alternative programmes which are acceptable to HKAS Executive. The performance of an applicant or an accredited proficiency testing provider in any such proficiency testing activity shall be acceptable to HKAS Executive.
- 3.6 The minimum frequencies of participation in such activities shall be as follows:
- Before accreditation is granted
- Non-medical programmes
One activity relevant to its scope of accreditation
 - Medical programmes
One activity for every test area relevant to its scope of accreditation
- After accreditation has been granted
- Non-medical programmes
Once every four years for every major sub-area of major laboratory disciplines relevant to the proficiency testing programmes included in its scope of accreditation.
 - Medical programmes
Once a year for every test area relevant to the proficiency testing programmes included in its scope of accreditation.
If proficiency testing programmes are not organised in accordance with yearly schedules, the accredited proficiency testing provider shall take part in the relevant proficiency testing activity within 6 months before launching a programme.
- 3.7 The assessment team shall determine the appropriateness of any laboratory proficiency testing activities and may, at its discretion, require the proficiency testing provider to participate in other forms of laboratory proficiency testing activity so as to evaluate its competence in performing specific tests, calibrations or other laboratory activities. Where an applicant or an accredited proficiency testing provider is unable to participate in any appropriate laboratory proficiency testing activity because such activity is not available, it shall demonstrate to the satisfaction of the assessment team that it has taken all reasonable steps to identify such activity. In this clause, proficiency testing activity includes any international, regional and national interlaboratory comparisons as

well as measurement audits and check samples acceptable to HKAS. It is acceptable for a proficiency testing provider to organise proficiency testing activities to verify the correctness of its own laboratory activities.

- 3.8 Where the performance of an applicant or an accredited proficiency testing provider in an applicable laboratory proficiency testing activity is unsatisfactory, the proficiency testing provider shall investigate the cause and take effective remedial actions. If the concerned activity is subcontracted, the proficiency testing provider shall ensure that such investigation and remedial actions are undertaken by the subcontractor.
- 3.9 An applicant proficiency testing provider shall nominate persons to HKAS Executive for approval as approved signatories for signing endorsed proficiency testing reports for every proficiency testing programme for which it seeks accreditation. Accreditation for such activity will not be granted unless HKAS Executive is satisfied that at least one nominee meets the requirements for approved signatories as laid down in the accreditation criteria. An accredited proficiency testing provider shall maintain at least one approved signatory for each accredited programme. Additional persons may be nominated by an accredited proficiency testing provider to HKAS Executive for approval as approved signatories at any time.
- 3.10 An accredited proficiency testing provider shall inform HKAS Executive of any change in the availability and duties of any of its approved signatories. HKAS shall withdraw the approval concerning such approved signatory who no longer meets the requirements for approved signatories as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation of a proficiency testing provider for a proficiency testing programme if it does not have any approved signatory for such programme and has failed to obtain approval from HKAS Executive for a new signatory within three months from the date when it ceased to have any approved signatory for such programme.

4 SUSPENSION AND TERMINATION

- 4.1 The authorised representative of a proficiency testing provider, which has its accreditation suspended or terminated (voluntarily or by HKAS Executive) shall within 14 days from the effective date of such suspension or termination, identify the customers to whom the proficiency testing provider has issued results for proficiency testing programmes, which are found to be unreliable because of the deficiencies discovered during the investigation of the suspension and termination, and inform them that the results are unreliable.

5 USE OF HKAS ACCREDITATION SYMBOLS FOR PROFICIENCY TESTING PROVIDERS AND CLAIMS OF ACCREDITATION STATUS

- 5.1 An accredited proficiency testing provider may display the HKAS accreditation symbol for proficiency testing providers in a report issued by it for reporting the result of an accredited proficiency testing programme. Such a document is referred to hereafter as a HKAS endorsed proficiency testing report. A HKAS endorsed proficiency testing report shall contain the HKAS accreditation symbol for proficiency testing providers and other details as described in clause 5.2 below.
- 5.2 An accredited proficiency testing provider shall include in a HKAS endorsed proficiency testing report the following:-
- (a) the HKAS accreditation symbol for proficiency testing providers (which includes the proficiency testing provider's registration number) at the top right hand corner of the front page; and/or
 - (b) on the front page the following statement for:-

"Hong Kong Accreditation Service (HKAS) has accredited this proficiency testing provider under Hong Kong Laboratory Accreditation Scheme (HOKLAS) for specific proficiency testing programmes as listed in the HKAS directory of accredited proficiency testing providers. The results shown in this report were determined by this proficiency testing provider in accordance with its terms of accreditation."
- 5.3 The term "HKAS" and the HKAS accreditation symbol for proficiency testing providers shall not be used in any proficiency testing report of proficiency testing programme except in a HKAS endorsed proficiency testing report.
- 5.4 The form, size, colour and usage of the HKAS accreditation symbol for proficiency testing providers shall be in accordance with the HKAS Supplementary Criteria No.1.
- 5.5 A HKAS endorsed proficiency testing report shall be signed by an approved signatory of the issuing proficiency testing provider. The signature shall be made in hand-written form for printed report. If the report is in an electronic form, the signature shall be in the form of an electronic signature acceptable under the Electronic Transactions Ordinance (Cap. 553). The full name of the approved signatory (as in his/her identify document such as identity card or passport) shall be clearly shown alongside the signature.

Other arrangements of signing HKAS endorsed reports may be accepted subject to agreement from HKAS Executive. When determining the acceptability of such an arrangement, HKAS Executive will consider all pertinent factors such as the reliability of the arrangement in ensuring proper and traceable authorisation by approved signatories and the demand of users of the accredited service.

- 5.6 A HKAS endorsed proficiency testing report may contain signatures of others provided that the proficiency testing provider's HKAS approved signatory has signed the proficiency testing report.
- 5.7 A HKAS endorsed proficiency testing report shall only contain the results of proficiency testing activities for which the proficiency testing providers is holding valid HKAS accreditation unless otherwise approved in accordance with clause 5.8.
- 5.8 The results of any activity which has not been accredited (whether obtained by the proficiency testing providers or its subcontractor) can only be included in a HKAS endorsed proficiency testing report if HKAS Executive has explicitly approved such inclusion in writing. The HKAS endorsed proficiency testing report which contains the said results shall clearly state therein that the activities are not covered by the proficiency testing provider's HKAS accreditation.
- 5.9 An accredited proficiency testing provider shall keep at least one exact copy of the HKAS endorsed proficiency testing report issued by it for record. It shall also keep such copies, all original observations and records in relation to any accredited activity performed by it for a period of not less than three years or for a period specified by HKAS Executive.
- 5.10 Every HKAS endorsed proficiency testing report shall comply with all relevant accreditation criteria as specified by HKAS Executive from time to time.
- 5.11 A HKAS endorsed proficiency testing report shall bear either:-
- (a) a statement indicating that such report shall not be reproduced except in full, or
 - (b) a statement indicating the conditions under which such report may be reproduced either in full or in part.

Any extract or abstract of a HKAS endorsed proficiency testing report shall not contain the HKAS accreditation symbol for proficiency testing providers nor other details as specified in clause 5.2 above unless the

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Authorised Representative of the accredited proficiency testing provider which issues the report has approved in writing of such inclusion in the extract or abstract. The Authorised Representative, if granting approval under this clause, shall ensure that such extract or abstract will not be used for any purpose which HKAS Executive may consider it as having misleading effect.

- 5.12 Opinions or interpretations for which a proficiency testing provider is not accredited for providing can only be included in a HKAS endorsed proficiency testing report if HKAS Executive has given its approval for such inclusion in writing. An endorsed proficiency testing report containing such opinions or interpretations shall in all cases clearly state that the proficiency testing provider is not accredited for providing such opinions or interpretations.

6 FORMS

- 6.1 Application for any HKAS service from HKAS shall be made in appropriate forms. These forms are obtainable from the office of HKAS Executive and have been uploaded to the HKAS website.