

# HOKLAS Supplementary Criteria No. 34

## Accreditation Regulations Specific for HOKLAS - Proficiency Testing Providers

### 1 INTRODUCTION

- 1.1 This document provides specific regulations for accreditation of proficiency testing (PT) providers under the Hong Kong Laboratory Accreditation Scheme. An accredited PT provider shall conform to all the regulations stated in this document at all times. For an applicant PT provider, accreditation will only be granted after it has demonstrated to the satisfaction of HKAS Executive its competence and commitment to conforming to all the requirements 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 [www.hkas.gov.hk](http://www.hkas.gov.hk).

### 2 PROFICIENCY TESTING PROVIDERS ACCREDITATION PROCEDURES

- 2.1 An assessment team may require a PT provider to demonstrate an activity as part of an assessment 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 PT provider:-
  - (a) within twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the PT provider;
  - (b) every two years after the due date of the first reassessment or at such time intervals as specified for the Monitoring Plan adopted by the PT provider (refer to HKAS SC-04 for details);
  - (c) at such other times as may be specified in the terms of accreditation;

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(d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited PT provider, of any change in the structure and circumstances of the PT provider since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the PT provider's competence or conformity with the accreditation criteria; and

(e) HKAS Executive may, at its discretion, vary the reassessment schedule.

2.3 HKAS Executive shall conduct a surveillance visit to an accredited PT provider if neither reassessment, assessment for extension of accreditation nor surveillance visit to it has been conducted within the past twelve months' period or at such time intervals as specified for the Monitoring Plan adopted by the PT provider. HKAS Executive may, at its discretion, vary the surveillance visit schedule.

2.4 Upon granting of accreditation to a PT provider, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for PT provider.

### **3 OBLIGATIONS OF ACCREDITED OR APPLICANT PROFICIENCY TESTING PROVIDERS**

#### **3.1 Accreditation Criteria**

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

HKAS 002 - Regulations for HKAS Accreditation;

HOKLAS 017:2016 - Technical Criteria for Accrediting Proficiency Testing Providers

or its equivalent as specified by HKAS Executive, such as HKAS Policy Document No. 3 and ISO/IEC 17043:2023;

Relevant HKAS Supplementary Criteria; and

Relevant HOKLAS Supplementary Criteria.

HOKLAS and HKAS publications relevant to the accreditation of PT providers are listed in a HOKLAS application package 'HOKLAS AP012 -

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Accreditation of Proficiency Testing Providers' which is available at the website of HKAS. All documents mentioned in the package except HOKLAS 017:2016 and ISO/IEC 17043:2023 can be downloaded from the same website.

3.2 An accredited PT 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 has been approved or disapproved by HKAS or HKAS Executive. It shall further endeavour to ensure that no person will use any certificate, report, statement or documentation issued by it for such an activity in a misleading manner.

3.3 An accredited PT 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 PT schemes, or to arrange site visits (in so far as to their respective contracts are concerned).

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

3.4 If a PT report contains results from a subcontractor, the accredited PT provider shall identify such results in the report. The accredited PT provider shall not disclose the performance of any of its customers to any of its subcontractor without prior written approval from the customer. Some activities of an accredited PT provider shall not be subcontracted. They are specified in HOKLAS 017:2016 or ISO/IEC 17043:2023.

3.5 An applicant PT provider shall nominate person(s) to HKAS Executive for signing endorsed PT reports for each PT scheme in the scope of application. Accreditation for such an 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 PT provider shall maintain at least one approved signatory for each PT scheme in its scope of accreditation. An accredited PT provider may nominate additional signatories to HKAS Executive for approval at any time.

3.6 A person nominated for approved signatory shall:

3.6.1 be familiar with the management system and operation of the PT

provider;

3.6.2 have sufficient contact with the PT provider to enable him/her to have an in-depth understanding on the operation of its PT schemes and have confidence in the validity of the PT results which are obtained in accordance with the PT provider's documented procedures;

3.6.3 be fully aware of the HOKLAS Accreditation Criteria as specified in clause 3.1;

Note: Signatory approval may be limited to specific PT schemes or may be granted for all PT schemes for which the PT provider is accredited.

3.7 As signatory approval is granted in the context of the work being performed in a particular PT provider, such approval shall not be considered as a personal qualification.

3.8 A nominee for signatory approval for a PT scheme may not necessarily be the same person as the coordinator as described in 4.2.H. of HOKLAS 017:2016 or Cl 5(d) of HKAS Policy Document No. 3. The coordinator, if different from the approved signatory, shall participate in the preparation and drafting of the report and shall communicate closely with the approved signatory for the final authorisation of the PT report.

3.9 An accredited PT provider shall inform HKAS Executive forthwith of any change in the availability and duties of any of its approved signatories. HKAS shall withdraw the approval concerning such an approved signatory who no longer meets the requirements as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation of a PT provider for a PT scheme if it does not have any approved signatory for such a scheme 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 a scheme.

3.10 An applicant PT provider shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, if the applicant PT provider intentionally provides false information or if the applicant PT provider conceals information, HKAS Executive shall reject the application or terminate the assessment process. The resulting application and assessment fees paid are not refundable.

#### **4 SUSPENSION AND TERMINATION OF ACCREDITATION**

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- 4.1 The authorised representative of a PT provider shall identify and inform its customers within 14 days from the effective date of suspension or termination (whether voluntarily or by HKAS Executive) of the accreditation of a PT scheme, if any PT reports with unreliable results associated with such a PT scheme had been issued before the suspension/termination and were discovered during the investigation. For voluntary suspension, the effective date shall be advised by the PT provider or the same as the issue date of the notification letter confirming the suspension if the PT provider does not provide an effective date. For suspension imposed by HKAS Executive, the effective date shall be the issue date of the relevant notification letter. The PT provider shall provide to HKAS Executive an action plan to resolve the concerns related to the suspended PT scheme(s) within four weeks from the date of notice of suspension. Such actions shall be taken to the satisfaction of HKAS Executive within one year from the effective date of suspension.

## **5 USE OF HOKLAS ACCREDITATION SYMBOLS FOR PROFICIENCY TESTING PROVIDERS AND CLAIMS OF ACCREDITATION STATUS**

- 5.1 An accredited PT provider may display the HOKLAS accreditation symbol for PT providers in a report issued by it for reporting the result(s) of a PT scheme in its scope of accreditation. Such a report is referred to hereafter as a HOKLAS endorsed PT report, which shall contain the details as described in clause 5.2 below.

- 5.2 A HOKLAS endorsed PT report shall contain the following:-

- (a) the HOKLAS accreditation symbol (which includes the PT provider's registration number and the identification code of the accreditation program) at the top right hand corner of the front page; and

- (b) on the front page the following statement:-

‘HKAS has accredited this proficiency testing provider (Reg. No. HOKLAS 999) under HOKLAS for specific proficiency testing schemes as listed in the scope of accreditation.’

The word ‘this proficiency testing provider’ in the first sentence of the above endorsement statement may be replaced by the full identity of the PT provider as it appears on the scope of accreditation.

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- 5.3 The form, size, colour and usage of the HOKLAS accreditation symbol for PT providers shall be in accordance with the HKAS SC-01.
- 5.4 An accredited PT provider may also claim its accreditation status by including the statement described in 5.2 (b) in a PT report of an accredited scheme, but such a report is not considered as a HOKLAS endorsed PT report. The HOKLAS accreditation symbol shall not be used alone to claim the accreditation status.
- 5.5 The terms ‘HKAS’/‘HOKLAS’, the HOKLAS accreditation symbol and/or a statement claiming accreditation status under HOKLAS shall not be used in a report of any PT scheme except as described above in clauses 5.2 and 5.4.
- 5.6 Claiming of accreditation status without displaying the accreditation symbol is subject to prior written agreement by HKAS Executive. The PT provider should also note that if it selects to claim the accreditation status with the statement described in 5.2(b) without displaying the accreditation symbol, requirements that govern the issue of HOKLAS endorsed report as detailed in this document and HKAS 002 shall also apply to such reports.
- 5.7 A HOKLAS endorsed PT report or a report with its accreditation status claimed by a statement shall be signed by an approved signatory of the issuing PT provider. The signature shall be made in hand-written form for printed report. If the report is in an electronic form, the electronic signature shall be in a form acceptable under the Electronic Transactions Ordinance (Cap. 553). The full name of the approved signatory (as in his/her identity document such as identity card or passport) shall be clearly shown alongside the signature.

Other arrangements of signing HOKLAS endorsed reports may be acceptable 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.

- 5.8 A HOKLAS endorsed PT report may contain signatures of others provided that an HKAS approved signatory of the accredited PT provider has signed the PT report. Where signatures other than the approved signatory also appear on the report, the capacity of the one who signed (such as his

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capacity as reviewer) shall appear on the report.

5.9 A HOKLAS endorsed PT report shall only contain the results of PT activities for which the PT provider is holding valid HKAS accreditation unless otherwise approved in accordance with clause 5.10.

5.10 The results of any activity which has not been accredited (whether obtained by the PT provider or its subcontractor) can only be included in a HOKLAS endorsed PT report if HKAS Executive has explicitly approved such inclusion in writing. The HOKLAS endorsed PT report which contains the said results shall clearly state therein that the activities are not covered by the PT provider's HKAS accreditation.

5.11 An accredited PT provider shall keep at least one exact copy of each PT report issued by it within its scope of accreditation 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 specified by HKAS Executive in HOKLAS 017:2016, HKAS Policy Document No. 3 or relevant HOKLAS Supplementary Criteria, as applicable.

5.12 Each HOKLAS endorsed PT report or any PT report with the accreditation status claimed shall comply with all relevant accreditation criteria as specified by HKAS Executive from time to time.

5.13 A HOKLAS endorsed PT report shall also bear either:-

- (a) a statement indicating that such a report shall not be reproduced except in full, or
- (b) a statement indicating the conditions under which such a report may be reproduced either in full or in part.

Any extract or abstract of a HOKLAS endorsed PT report shall not contain the HOKLAS accreditation symbol for PT providers nor other details as specified in clause 5.2 above unless the authorised representative of the accredited PT 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.

5.14 When technical comments other than those on the performance of participants are made in PT reports, they are not covered under the scope

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of accreditation of the PT provider. Those comments, and other opinions or interpretations for which a PT provider is not accredited for providing, can only be included in a HOKLAS endorsed PT report if HKAS Executive has given its approval for such inclusion in writing. Where such comments, opinions or interpretations are included in an endorsed PT report, a clear and explicit disclaimer shall be given in the report that they are not covered under the scope of accreditation.

- 5.15 An accredited PT provider shall not issue any PT report containing any logo, symbol or statement that may be interpreted by any person that the activities or results reported are covered by certification which does not convey any information on technical competence.

## **6 FORMS**

- 6.1 Application for any accreditation service from HKAS shall be made in appropriate forms. These forms can be downloaded at the HKAS website.