

HOKLAS Supplementary Criteria No. 33

Accreditation Regulations Specific for HOKLAS - Laboratory

1 INTRODUCTION

- 1.1 This document provides specific regulations for accreditation of laboratories under the Hong Kong Laboratory Accreditation Scheme. All accredited laboratories shall conform with all the regulations stated in this document at all times. For an applicant laboratory, 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 – Regulations for HKAS Accreditation.
- 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 LABORATORY ACCREDITATION PROCEDURES

- 2.1 An assessment team may require a laboratory to demonstrate a test, a calibration or other laboratory activities as part of an assessment, or to participate in proficiency testing in order to evaluate the laboratory's standard and competence. The specific laboratory 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 laboratory:-
 - (a) twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the laboratory;
 - (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;
and

(d) upon notification by the authorised representative, or in his absence, other responsible person of an accredited laboratory, of any change in the structure and circumstances of the laboratory since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the laboratory'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 laboratory if no reassessment nor assessment for extension of accreditation nor surveillance visit to it has been conducted for the past twelve months. HKAS Executive may, at its discretion, vary the surveillance visit schedule.

2.4 Upon granting of accreditation for a test category to a laboratory, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for such test category.

3 OBLIGATIONS OF ACCREDITED OR APPLICANT LABORATORIES

3.1 HOKLAS Accreditation Criteria

An accredited laboratory shall at all times comply with the following HOKLAS accreditation criteria:-

HKAS 002- Regulations for HKAS Accreditation,

Relevant HOKLAS Supplementary Criteria,

Relevant HKAS Supplementary Criteria, and

For non-medical laboratories:

HOKLAS 003 - Technical Criteria for Laboratory Accreditation
or its equivalent as specified and published by HKAS Executive, or

For medical laboratories:

HOKLAS 015 - Technical Criteria for Laboratory Accreditation
(Medical Laboratories)

or its equivalent as specified and published by HKAS Executive

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 laboratory 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 HOKLAS 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 A laboratory accredited under HOKLAS shall afford its customers or their representatives reasonable cooperation to monitor the laboratory's performance (in so far as to their respective contracts are concerned). This cooperation shall include:-
- (a) performing any reasonable check tests or calibrations or checks for other laboratory activities, including to prepare, pack and dispatch the test pieces, samples and other items for such check activities, which serve to verify its capability or standard of service as requested by the customer;
 - (b) allowing each of its customers or their representatives reasonable access to the laboratory in order to observe any test, calibration or other laboratory activity performed by it for the customer. However, the laboratory shall ensure that the confidentiality of its other customers will be protected and their information will not be divulged to any third party (subject to clause 5.10).

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

- 3.4 If an accredited laboratory intends to subcontract any part of its activities to which HOKLAS accreditation has been granted, it shall ensure that the activities of the laboratory 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. A list of such accreditation bodies is obtainable from HKAS Executive. The accredited laboratory shall notify its customer concerned in writing of its intention to subcontract the activities and the extent of such subcontract. It shall obtain agreement from the customer regarding such arrangement and shall further keep records of such agreement. In the report or certificate, the

accredited laboratory shall identify the activities performed and the results obtained by such subcontractor.

- 3.5 An accredited laboratory shall take part in proficiency testing programmes 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 laboratory in any proficiency testing activity relevant to its scope of accreditation shall be acceptable to HKAS Executive.
- 3.6 An applicant laboratory shall take part in at least one appropriate proficiency testing activity, where available, before accreditation will be granted. After accreditation has been granted, the laboratory shall take part in at least one appropriate proficiency testing activity, when available, which is related to each major sub-area of major disciplines of the accredited activities as specified in its scope of accreditation, every four years. The necessary level of participation in proficiency testing for a technical discipline may be defined in the HOKLAS Supplementary Criteria for that discipline. The assessment team shall determine the appropriateness of any proficiency testing activities and may, at its discretion, require the laboratory to participate in other forms of proficiency testing activity so as to evaluate its competence in performing specific tests, calibrations or other laboratory activities. Where an applicant or an accredited laboratory is unable to participate in any appropriate 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.
- 3.7 Where the performance of an applicant laboratory or an accredited laboratory in a proficiency testing activity is unsatisfactory, the laboratory shall investigate the cause and take effective remedial actions.
- 3.8 An applicant laboratory shall nominate persons to HKAS Executive for approval as approved signatories for signing HOKLAS endorsed reports and certificates for every test, calibration or other laboratory activity 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 laboratory shall maintain at least one approved signatory for each accredited activity. Additional persons may be nominated by an accredited laboratory to HKAS Executive for approval

as approved signatories at any time.

- 3.9 An accredited laboratory shall inform HKAS Executive forthwith of any change in the availability and duties of any of its HOKLAS 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 laboratory for a test, calibration or other laboratory activity if it does not have any approved signatory for such activity 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 activity.

4 SUSPENSION AND TERMINATION

- 4.1 The authorised representative of a laboratory, 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 laboratory has issued results for tests, calibrations or other laboratory activities, 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 AND CLAIMS OF ACCREDITATION STATUS

- 5.1 An accredited laboratory may display the appropriate HOKLAS accreditation symbol in a report or certificate issued by it for reporting the result of an activity accredited under HOKLAS. The claiming of accreditation in such a report or certificate for internal use may also be made in the form of a statement specified by HKAS Executive. Such a document is referred to hereafter as a HOKLAS endorsed report or certificate. A HOKLAS endorsed report or certificate shall contain the HOKLAS accreditation symbol and other details as described in clause 5.2 below.
- 5.2 An accredited laboratory shall include in a HOKLAS endorsed report or certificate the following:-
- (a) the HOKLAS accreditation symbol (which includes the laboratory's registration number) at the top right hand corner of the front page. For reports and certificates issued for internal use and where it is

technically not possible or very difficult to display the accreditation symbol on a report or certificate, endorsement may be made with the statements in (b) below without displaying the accreditation symbol. Such endorsement without displaying the accreditation symbol is subject to prior written agreement by the HKAS Executive, and

(b) on the same page the following statements:-

(i) for non-medical laboratories

“Hong Kong Accreditation Service (HKAS) has accredited this laboratory under Hong Kong Laboratory Accreditation Scheme (HOKLAS) for specific laboratory activities as listed in the HOKLAS directory of accredited laboratories. The results shown in this report (or certificate, where appropriate) were determined by this laboratory in accordance with its terms of accreditation.”

reports and certificates showing calibration results, the following statement shall be appended to the above statement.

“Such terms of accreditation stipulate that the results shall be traceable to the International System of Units (S.I.) or recognised measurement standards.”

(ii) for medical laboratories

accredited for performing examinations and, in some cases, giving clinical interpretations of examination results:

"Hong Kong Accreditation Service (HKAS) has accredited this laboratory under Hong Kong Laboratory Accreditation Scheme (HOKLAS) for performing examinations and, in some cases, for providing clinical interpretation as listed in its scope of accreditation. The examinations are conducted in accordance with the terms of accreditation for this laboratory."

accredited for performing examinations only:

"Hong Kong Accreditation Service (HKAS) has accredited this laboratory under Hong Kong Laboratory Accreditation Scheme (HOKLAS) for performing examinations as listed in its scope of accreditation. The examinations are conducted in accordance with the terms of accreditation for this laboratory."

The word “this laboratory” in the first sentence of the above endorsement statement may be replaced by the full organisation name of the laboratory.

When the endorsement statement is used alone to endorse a report or certificate without displaying the accreditation symbol, the same words shall be replaced by the full organisation name and registration number (in form of e.g., ABC Testing Limited, Registration Number 999).

- 5.3 The term “HOKLAS” and the HOKLAS accreditation symbol shall not be used in any report or certificate of laboratory activities except in a HOKLAS endorsed report or certificate.
- 5.4 The form, size, colour and usage of the HOKLAS accreditation symbol shall be in accordance with the HKAS Supplementary Criteria No.1.
- 5.5 A HOKLAS endorsed report or certificate shall be signed by a HOKLAS approved signatory of the issuing laboratory. For printed reports or certificates, such signature shall be made in hand-written form. For reports or certificates 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 HOKLAS endorsed reports or certificates 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 HOKLAS endorsed report or certificate may contain signatures of others provided that the laboratory’s HOKLAS approved signatory has signed the report or certificate.
- 5.7 A HOKLAS endorsed report or certificate shall only contain the results of the tests, calibrations or other laboratory activities for which the laboratory is holding valid HOKLAS 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 laboratory or its subcontractor) can only be included in a HOKLAS endorsed report or certificate if HKAS Executive has explicitly approved such inclusion in writing. The HOKLAS endorsed report and certificate which contains the said results shall clearly state therein that the activities are not covered by the laboratory’s HOKLAS accreditation.
- 5.9 An accredited laboratory shall keep at least one exact copy of the HOKLAS endorsed report or certificate 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 HOKLAS endorsed report or certificate shall comply with all relevant accreditation criteria as specified by HKAS Executive from time to time.

5.11 A HOKLAS endorsed report or certificate shall bear either:-

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

Any extract or abstract of a HOKLAS endorsed report or certificate shall not contain the HOKLAS accreditation symbol nor other details as specified in clause 5.2 above unless the authorised representative of the accredited laboratory which issues the report or certificate 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 An accredited laboratory may issue a HOKLAS endorsed report or certificate which extends the results of a test, a calibration or another laboratory activity on a sample or samples to the properties or qualities of the inspected lot, batch or consignment from which the sample(s) was drawn provided that:-

- (a) the accredited laboratory's scope of accreditation covers the sampling involved; and
- (b) the sample or samples concerned were taken by staff of the accredited laboratory using the accredited sampling procedure.

5.13 A HOKLAS endorsed report or certificate may include statements in amplification of results reported therein provided that:-

- (a) where a sample, batch or consignment is tested, calibrated or examined to specification requirements such statements shall be limited to information as to whether or not the sample, batch or consignment conforms with the specification requirements and the

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manner or degree in which it departs from such specification requirements;

- (b) where a sample is not tested, calibrated or examined to specification requirements such statements shall be limited to explanation of the results as is necessary for interpretation of their meaning; and
- (c) where an instrument or measuring device is calibrated such statements shall be limited to:-
 - (i) the uncertainty to be associated with its use, or
 - (ii) the information referred to in (a) or (b) above as appropriate.

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

6 FORMS

6.1 Application for any HOKLAS 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.

7 SAMPLE HOKLAS ENDORSED REPORT BEARING THE HOKLAS ACCREDITATION SYMBOL

7.1 An example of a HOKLAS endorsed test report is provided on page 10. It is provided for reference only. An accredited laboratory shall submit its letterhead and formats of HOKLAS endorsed report and certificate to HKAS Executive for approval before use.

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Sample Endorsed Test Report

Refer to HKAS Supplementary Criteria No. 1 for specification of appropriate HOKLAS accreditation symbols for different programmes

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TEST REPORT

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Date of Issue:	16 February 2007

Approved signatory : _____

CHAN Tai Man

Refer to clauses 5.2 (b) and 5.11 of this Supplementary Criteria for the appropriate statement to be included.