# 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 (HOKLAS). An accredited laboratory shall conform to 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 to 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 www.hkas.gov.hk.

### 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. It may also require the laboratory to participate in proficiency testing in order to evaluate its 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. The laboratory shall have, where applicable, legally enforceable arrangements with their customers that commit the customers to provide, on request, access to HKAS assessment teams to assess the laboratory's performance when carrying out laboratory activities at their customers' site.

2.2 HKAS Executive shall conduct a reassessment on the accredited activities of a laboratory:-

(a) within 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 or at such time intervals as specified for the Monitoring Plan adopted by the laboratory (refer to HKAS Supplementary Criteria No. 4 for details);

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

2.3 HKAS Executive shall conduct a surveillance visit to an accredited laboratory if neither reassessment, assessment for extension of scope 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 laboratory. 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 accreditation criteria:

HKAS 002 - Regulations for HKAS Accreditation,

Relevant HOKLAS Supplementary Criteria [Note: All existing HOKLAS Supplementary Criteria applicable to accreditation of laboratories according to ISO 15189:2012 are equally applicable to the accreditation of laboratories according to ISO 15189:2022, unless it is otherwise specified in the HOKLAS Supplementary Criteria concerned],

Relevant HKAS Supplementary Criteria,

and

For non-medical laboratories:
HKAS Policy Document No. 1 and ISO/IEC 17025:2017

For medical laboratories:
HOKLAS 015 (Fifth Edition) - Technical Criteria for Laboratory Accreditation (Medical Laboratories)
or its equivalent as specified by HKAS Executive, such as HKAS Policy Document No. 2 and ISO 15189:2022

HOKLAS and HKAS publications relevant to the accreditation of laboratory are listed in HOKLAS Application Packages which are available at the website of HKAS. All HKAS and HOKLAS policy and criteria documents mentioned in the packages can be downloaded from the same website.

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 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 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 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 of HKAS 002).

For avoidance of doubt, the laboratory may also take reasonable steps to protect its proprietary information and agree with its customers the cost they 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 for 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. A list of such accreditation bodies is available at the HKAS website. The accredited laboratory shall also:

3.4.1 document its policy and procedures for subcontracting;

3.4.2 require its subcontractor to perform the subcontracted test or calibration by itself, and not to further subcontract the test or calibration to another laboratory;

3.4.3 notify its customer concerned in writing of its intention to subcontract the activities and the extent of such subcontracting and obtain agreement from the customer regarding such arrangement and shall further keep records of such agreement;

3.4.4 identify the activities performed and the results obtained by such subcontractor in the report or certificate.

Note: HKAS will grant accreditation to a laboratory only for those activities which the laboratory itself is competent to carry out and which it normally performs itself.

3.5 An applicant or accredited laboratory shall participate in proficiency testing (PT) activities which are relevant to its scope of accreditation. The PT activities participated shall be either PT or inter-laboratory comparison (ILC) other than PT, if PT is not available. The outcome of the laboratory's risk assessment shall be taken into consideration in determining the participation. The performance of an applicant or an accredited laboratory in any PT activity relevant to its scope of accreditation shall be acceptable to HKAS Executive.

3.6 An applicant laboratory shall have taken part in appropriate PT activities, representative of each test area of the laboratory's scope of accreditation to demonstrate its competence in each test area, and obtain satisfactory result before initial accreditation or accreditation extended to a new test area will be granted.

3.7 The laboratory shall maintain appropriate evidence of the competence of its PT providers and ILC organisers.

Note 1: Competence of a PT provider can be demonstrated through either accreditation to ISO/IEC 17043 by an ILAC MRA signatory for PT providers (e.g. HKAS), or provision of appropriate evidence for demonstrating its conformity with ISO/IEC 17043 if it is not accredited.

Note 2: Competence of an ILC organiser can be demonstrated through provision of appropriate evidence for demonstrating its conformity with the relevant requirements of ISO/IEC 17043. Such evidence should include, but not limited to, the competence of its personnel, the proper design, planning and implementation of its ILCs, actions taken to prevent collusion, measures to ensure homogeneity and stability for quantitative comparisons, correct statistical design and data analysis, proper handling of ILC items, keeping of appropriate records and proper reporting of results. The document EA-4/21 INF: 2018, published by the European co-operation for Accreditation (http://www.european-accreditation.org), provides useful guidelines for the assessment of the appropriateness of small ILC within the process of laboratory accreditation.

3.8 The laboratory shall establish a one-year PT participation plan. The coverage of the plan shall be representative and adequate to demonstrate the laboratory's competence in performing tests within its scope of accreditation. Where suitable PT activities do not exist or are not practical, suitable alternative means aiming to demonstrate the laboratory's competence shall be included in the plan. The plan shall be regularly reviewed and updated where necessary (for example, in response to changes of the scope of accreditation, staffing, methodology, instrumentation, outcome of the laboratory's risk assessment and other factors that may affect the validity of the laboratory's test or calibration results). Any change to the plan shall be documented and justified. When the laboratory updates its PT plan, it shall ensure its continual suitability in relation to its scope of accreditation.

3.9 Records of PT participation for the past four years shall be available to show that the laboratory participated in PT activities representative of the accredited tests/calibration activities under each test area of its scope of accreditation. PT activities participated to represent a group of tests in a test area are expected to vary in subsequent cycles. It should be noted that the necessary level of participation in PT for certain technical disciplines may be specifically defined in the relevant HOKLAS Supplementary Criteria. Where defined, the laboratory shall ensure that the planned participation fulfils the respective PT requirements as stated in the relevant supplementary criteria. Where more stringent PT requirements are stipulated in the relevant supplementary criteria, the more stringent requirements shall be followed.

3.10 An assessment team shall determine the adequacy of the PT participation plan and the appropriateness of any PT activities and may, at its discretion, require the laboratory to participate in other forms of PT 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 PT activity because it fails to identify a suitable PT programme or ILC, it shall demonstrate to the satisfaction of the assessment team that it has taken all reasonable steps to identify such PT programme or ILC and any justification to use alternative suitable means shall be documented. In this clause, PT activity includes any international, regional and national interlaboratory comparisons as well as measurement audits and check samples acceptable to HKAS.

3.11 Where the performance of an accredited laboratory in a PT activity is unsatisfactory, the laboratory shall investigate the cause and take effective corrective actions where necessary. Relevant records of corrective actions shall be kept. It shall demonstrate promptly to HKAS Executive the effectiveness of its corrective actions and that it can achieve satisfactory PT performance for the activity in question. If the laboratory cannot rectify the unsatisfactory PT performance for an accredited activity within a reasonable timeframe (e.g. three months), the laboratory shall notify HKAS Executive in writing of the actions taken to address the problem and the measures taken to deal with request for the problematic activity.

3.12 An applicant laboratory shall nominate person(s) to HKAS Executive for signing endorsed reports and certificates for every test, calibration or other activity in the scope of application. 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.

3.13 A person nominated for approved signatory shall:

3.13.1 be an employee of or under contract to the laboratory and has been authorised by the accredited laboratory to sign reports or certificates issued by the laboratory for specific activities;

3.13.2 be familiar with the management system and operation of the laboratory;

3.13.3 have sufficient contact with the laboratory to enable him/her to

have an in-depth understanding on the operation of the laboratory and have confidence in the validity of the test or calibration results which are obtained in accordance with the laboratory's documented procedures;

3.13.4 be competent to make critical evaluation of the reported results with adequate knowledge of the technical procedures and understanding of their underlying principles, interpretations and limitations;

3.13.5 occupy a position in his/her organisation's staff structure that makes him/her responsible for the accuracy of such results;

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

3.13.7 have the necessary qualifications and experience.

Note: Signatory approval may be limited to specific tests or calibrations or may be granted for all tests and calibrations for which the laboratory is accredited.

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

3.15 An accredited laboratory shall inform HKAS Executive forthwith of any change in the availability and duties of any of its HOKLAS approved signatories. HKAS Executive 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.

3.16 An applicant laboratory shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, if the applicant laboratory intentionally provides false information or if the applicant laboratory 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

4.1 The authorised representative of a laboratory shall identify and inform its affected customers within 14 calendar days from the effective date of suspension or termination of the accreditation of an accredited activity (whether voluntarily or by HKAS Executive). For example, any unreliable results associated with such activity had been issued before the suspension/termination and were discovered during related investigation. For voluntary suspension, the effective date shall be advised by the laboratory or the same as the issue date of the notification letter confirming the suspension if the laboratory 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 laboratory shall provide to HKAS Executive an action plan to solve the concerns related to the suspended activity(ies) 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 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(s) of an activity accredited under HOKLAS. Such a document is referred to hereafter as a HOKLAS endorsed report or certificate.

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 and identification code of the accreditation programme) at the top right hand corner of the front page;

(b) on the same page, one of the following statements:-

(i) for non-medical laboratories

'HKAS has accredited this laboratory (Reg. No. HOKLAS 999) under HOKLAS for specific laboratory activities as listed in the HOKLAS directory of accredited laboratories.'

(ii) for calibration laboratories

'HKAS has accredited this laboratory (Reg. No. HOKLAS 999) under HOKLAS for specific calibration activities as listed in the HOKLAS

directory of accredited laboratories. The results shown in this report (or certificate, where appropriate) are traceable to the International System of Units (SI) or recognised measurement standards.'

(iii) for medical laboratories

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

'HKAS has accredited this medical laboratory (Reg. No. HOKLAS 888P) under HOKLAS for performing specific examinations and, in some cases, for providing clinical interpretation as listed in its scope of accreditation.'

accredited for performing examinations only:

'HKAS has accredited this medical laboratory (Reg. No. HOKLAS 888S) under HOKLAS for performing specific examinations as listed in its scope of accreditation.'

The word 'this laboratory' in the first sentence of the above statement may be replaced by the full identity of the laboratory as listed in the scope of accreditation. When the statement is used alone to claim a laboratory's accreditation status without displaying the accreditation symbol (See clause 5.3), the same words shall be replaced by the full identity, registration number and identification code of the accreditation programme (in form of e.g., ABC Testing Limited, Registration Number HOKLAS 999 and the appropriate identification code such as 'TEST', 'CAL' or 'MED'.).

(c) A HOKLAS endorsed report or certificate shall also bear either:-

(i) a statement indicating that such report or certificate shall not be reproduced except in full, or

(ii) 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 (b) 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.

5.3 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, claiming of accreditation status may be made with the statements in 5.2 (b) without displaying the accreditation symbol. Such claim without displaying the accreditation symbol is subject to prior written agreement by HKAS Executive. The laboratory should note that an endorsed report or certificate shall bear the accreditation symbol. It should also note that if it selects to claim the accreditation status with one of the statements 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 or certificates.

5.4 The term 'HOKLAS', the HOKLAS accreditation symbol and/or a statement claiming accreditation status under HOKLAS shall not be used in any report or certificate of laboratory activities except as described above in clause 5.2 and 5.3.

5.5 The form, size, colour and usage of the HOKLAS accreditation symbol shall be in accordance with the HKAS Supplementary Criteria No. 1.

5.6 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 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 or certificates 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.

5.7 A HOKLAS endorsed report or certificate may contain signatures of others provided that one of the laboratory's HOKLAS approved signatories has signed the report or certificate. Where signatures other than the approved signatory also appear on the report or certificate, the capacity of the one who signed (such as his capacity as the quality manager) shall appear on the report or certificate.

5.8 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 5.9.

5.9 The results of any activity, including sampling 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, unless the activities have been explicitly excluded in the scope of accreditation of the laboratory.

5.10 An accredited laboratory shall keep at least one exact copy of the test report or certificate for any accredited activities issued by it for record. It shall also keep such copies of report or certificate, all original observations and records in relation to any accredited activity performed by it for a period specified by HKAS Executive in HKAS Policy Document No. 1 or relevant HOKLAS Supplementary Criteria, as applicable.

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

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 to the specification requirements and the

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 accreditation service from HKAS shall be made in appropriate forms. These forms can be downloaded at the HKAS website.

## 7 TEST REPORT AND CALIBRATION CERTIFICATE

7.1 An example of a HOKLAS endorsed test report is provided on page 13. It is provided for reference only. An accredited laboratory shall submit the letterhead and formats of its HOKLAS endorsed report and certificate, or formats of reports claiming its accreditation status but without the use of the accreditation symbol as per clause 5.3 to HKAS Executive for approval before use.

7.2 An accredited laboratory shall not issue any test report or calibration certificate containing any logo, symbol or statement that may be interpreted by any person that the activities or results reported are covered by certification.

***Sample Endorsed Test Report***

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

# ABC Testing Limited

23, Testing Avenue, Kowloon, Hong Kong.
Tel.: 3995 5555 Fax: 3955 5556 Website: www.abctesting.com

HOKLAS 999
TEST

## TEST REPORT

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| Test Report No.: | 0001 |
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| Date of Issue: | 16 February 2015 |

CHAN Tai Man

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