

HOKLAS Supplementary Criteria No. 39

Accreditation Regulations Specific for HOKLAS - Reference Material Producers

1 INTRODUCTION

- 1.1 This document provides specific regulations for accreditation of reference material producers under the Hong Kong Laboratory Accreditation Scheme (HOKLAS). An accredited reference material producer shall conform to all the regulations stated in this document at all times. For an applicant reference material producer, 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 REFERENCE MATERIAL PRODUCER ACCREDITATION PROCEDURES

- 2.1 An assessment team may require a reference material producer to demonstrate a production step, a test, a calibration or other activities 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 reference material producer:-
 - (a) within twelve months after the date of the notification letter in which HKAS Executive has granted the accreditation to the reference material producer;

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- (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 reference material producer (refer to HKAS SC-04 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 reference material producer, of any change in the structure and circumstances of the reference material producer since the last assessment or reassessment and in the opinion of HKAS Executive, such change may affect the reference material producer'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 reference material producer if neither reassessment, assessment for extension of accreditation nor surveillance visit to it has been conducted for the past twelve months, or at such time intervals as specified for the Monitoring Plan adopted by the reference material producer. HKAS Executive may, at its discretion, vary the surveillance visit schedule.

2.4 Upon granting of accreditation to a reference material producer, HKAS Executive shall issue to it a certificate of HOKLAS accreditation for reference material producers.

3 OBLIGATIONS OF ACCREDITED OR APPLICANT REFERENCE MATERIAL PRODUCERS

3.1 HOKLAS Accreditation Criteria

An accredited reference material producer shall at all times comply with the following accreditation criteria:-

HKAS 002 - Regulations for HKAS Accreditation,

Relevant HKAS Supplementary Criteria,

Relevant HOKLAS Supplementary Criteria, and

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HOKLAS 022:2017 - Technical Criteria for Accreditation of Reference Material Producers

For testing and calibration activities:

ISO/IEC 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories, HKAS PD001 'HKAS Policy for Accreditation of Laboratories according to ISO/IEC 17025:2017 under HOKLAS' and other relevant requirement documents relating to laboratory accreditation.

HKAS and HOKLAS publications relevant to the accreditation of reference material producers are listed in an HOKLAS application package 'HOKLAS AP013 - Accreditation of Reference Material Producers', which is available at the website of HKAS. All documents mentioned in the package except HOKLAS 022:2017 can be downloaded from the same website.

- 3.2 An accredited reference material producer 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 produced, 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 reference material producer accredited under HOKLAS shall afford its customers or their representatives reasonable cooperation to monitor the reference material producer's performance (in so far as to their respective contracts are concerned). However, the reference material producer shall ensure that the confidentiality of its other customers will be protected and their information will not be divulged to any third party.

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

- 3.4 The use of competent subcontractors to undertake certain aspects of the processing, handling, homogeneity and stability assessment, characterisation, storage or distribution of the reference material is allowed. An applicant or accredited reference material producer itself needs not be competent to perform the subcontracted tasks and will not be assessed for

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such tasks unless it specifically requests HKAS to do so, but will be assessed for how it determines the competence of the subcontractor in performing the assigned task. However, some tasks shall not be subcontracted. These tasks are specified in HOKLAS 022:2017. These key tasks/aspects include production planning, selection of subcontractors, assignment of property values and their uncertainties, authorisation of property values and their uncertainties, and authorisation of reference material documents. For testing and calibration activities, the subcontractors shall be accredited by HKAS or an accreditation body recognised by HKAS under a mutual recognition arrangement, and the scope of accreditation should cover the specific tests and/or calibrations performed in support of producing the reference materials concerned. Where the subcontractor is not accredited for such activities, HKAS reserves the right to assess the competence of the subcontractor through on-site visits or other means as appropriate, and the subcontractor may be required to carry out demonstration of the activities as requested by the assessment team. The reference material producer shall document the production process for each type of reference material included in the scope of accreditation or the proposed scope of accreditation to indicate which tasks are performed by itself and which tasks are performed by subcontractors and the identities of the subcontractors. If there is any change in the arrangement, its authorised representative or in his absence, another responsible person shall inform HKAS Executive in writing immediately of the details of the change.

- 3.5 An accredited reference material producer shall take part in proficiency testing programmes for its testing and calibration activities which are relevant to its scope of accreditation. The performance of an applicant or an accredited reference material producer in any proficiency testing activity relevant to its scope of accreditation shall be acceptable to HKAS Executive. Where relevant, the reference material producer shall also require its subcontractors for tests and calibrations to participate in suitable proficiency testing programmes. Where proficiency testing programmes are not available, other means to demonstrate competence, e.g. use of measurement audits and check samples, shall be considered.
- 3.6 Requirements relating to the participation in proficiency testing activities as stated in HOKLAS SC-33 and relevant HOKLAS Supplementary Criteria apply to the tests and calibrations undertaken by the reference material producers and its subcontractors.
- 3.7 Where the performance of an applicant reference material producer or an accredited reference material producer in a proficiency testing activity is unsatisfactory, the reference material producer shall take immediate

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remedial actions, investigate the cause of the unsatisfactory performance and take effective corrective actions.

- 3.8 An applicant reference material producer shall nominate persons to HKAS Executive for approval as signatories for signing HOKLAS endorsed certificates and documentation for the reference materials of which it seeks accreditation for production. Accreditation 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 reference material producer shall have at least one approved signatory for each reference material it is accredited for producing. Additional persons may be nominated by an accredited reference material producer to HKAS Executive for approval as approved signatories at any time.
- 3.9 An accredited reference material producer 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 approved signatory who no longer meets the requirements for approved signatories as laid down in the accreditation criteria. HKAS Executive may suspend the accreditation for producing a reference material if it does not have any approved signatory for such reference material 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 reference material.
- 3.10 An applicant reference material producer shall maintain complete integrity at any point in the application and assessment process. If there is evidence of fraudulent behaviour, or if the applicant intentionally provides false information or 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 reference material producer, which has its accreditation suspended or terminated (voluntarily or by HKAS Executive) shall employ best efforts to, within 14 days from the effective date of such suspension or termination, notify the customers who have purchased the affected reference materials which have been found to be unreliable because of the deficiencies discovered during the investigation of the suspension and termination, and inform them that the reference

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materials are unreliable. Where the reference materials are subject to resale through an authorised distributor, with whom the producer has a contractual relationship, the reference material producer shall pass on this information to its authorised distributor and require the distributor to pass on the information to the users of the reference materials.

- 4.2 For voluntary suspension of accreditation, the effective date shall be advised by the reference material producer, or the same as the issue date of the notification letter confirming the suspension if the reference material producer does not provide one. For suspension imposed by HKAS Executive, the effective date shall be the issue date of the relevant notification letter. The reference material producer shall provide to HKAS Executive an action plan to resolve 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 The reference material producer shall issue a certificate for certified reference materials and provide appropriate documentation for non-certified reference materials in the form of a statement, analysis report, or information sheet howsoever named. An accredited reference material producer may display the appropriate HOKLAS accreditation symbol in the certificate for certified reference material, or in the documentation issued by it for the reference materials it is accredited for producing. When the HOKLAS accreditation symbol is used in a certificate or documentation of a reference material produced by the accredited reference material producer, the certificate or documentation shall also contain other details as described in clause 5.2 below. Such a document is referred to hereafter as a HOKLAS endorsed certificate or documentation.
- 5.2 An accredited reference material producer shall include in a HOKLAS endorsed certificate or documentation the following:-
- (a) the HOKLAS accreditation symbol (which includes the reference material producer's registration number and identification code of the accreditation programme) at the top right hand corner of the front page, and

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

“HKAS has accredited this reference material producer (Reg. No. HOKLAS XXX) under HOKLAS for producing specific reference materials as listed in the scope of accreditation.”

The word “this reference material producer” in the first sentence of the above endorsement statement may be replaced by the full identity of the reference material producer as it appears on the scope of accreditation.

- 5.3 The claiming of accreditation status in a certificate or documentation for internal use may also be made with the statement in 5.2 (b) alone. Such claim without displaying the accreditation symbol is subject to prior written agreement by HKAS Executive. Such a document without the HOKLAS accreditation symbol is not considered as a HOKLAS endorsed certificate or documentation, but requirements that govern the issue of HOKLAS endorsed certificate or documentation as detailed in this document and HKAS 002 shall apply. The HOKLAS accreditation symbol shall not be used alone to claim the accreditation status.
- 5.4 The terms ‘HKAS’/‘HOKLAS’, the HOKLAS accreditation symbol and/or a statement claiming accreditation status under HOKLAS shall not be used in a certificate or documentation of any reference materials except as described above in clause 5.1 to 5.3.
- 5.5 The form, size, colour and usage of the HOKLAS accreditation symbol shall be in accordance with the HKAS SC-01.
- 5.6 A HOKLAS endorsed certificate or documentation shall be signed by a HOKLAS approved signatory of the issuing reference material producer. For printed certificates or documentation, such signature shall be made in hand-written form. For certificates or documentation 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 identity document such as identity card or passport) shall be clearly shown alongside the signature.

Other arrangements of signing HOKLAS endorsed certificates or documentation 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.

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- 5.7 A HOKLAS endorsed certificate or documentation may contain signatures of others provided that the certificate or documentation has been signed by a HOKLAS approved signatory of the reference material producer. Where signatures other than the approved signatory also appear on the report, the capacity of the one who signed (such as his capacity as reviewer) shall appear on the report.
- 5.8 A HOKLAS endorsed certificate or documentation shall only contain information on the reference material for which the reference material producer is holding valid HOKLAS accreditation. The scope of accreditation of a reference material producer for reference materials with numerical property values, except for those with identity and ordinal property values, include the range of the assigned values and, for certified reference material, the associated uncertainty of measurement (U_{CRM}). Those reference materials with assigned property values and their associated uncertainty falling within those listed in the scope of accreditation of a reference material producer are considered covered by HOKLAS accreditation. Any property values of a reference material that are outside the scope of accreditation, or an uncertainty of a property value that is less than or better than that stated in the scope of accreditation can only be included in a HOKLAS endorsed certificate or documentation if HKAS Executive has explicitly approved such inclusion in writing. The HOKLAS endorsed certificate or documentation which contains such values shall clearly state therein that they are not covered by the reference material producer's HOKLAS accreditation.
- 5.9 An accredited reference material producer shall keep at least one exact copy of the HOKLAS endorsed certificate and documentation 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 specified by HKAS Executive in HOKLAS022:2017 or relevant HOKLAS Supplementary Criteria, as applicable.
- 5.10 Each HOKLAS endorsed certificate/documentation, or any certificate/documentation with the accreditation status claimed, shall comply with all relevant accreditation criteria as specified by HKAS Executive from time to time.
- 5.11 A HOKLAS endorsed certificate and documentation shall also bear either:-
- (a) a statement indicating that certificate or documentation shall not be reproduced except in full, or

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- (b) a statement indicating the conditions under which such certificate or documentation may be reproduced either in full or in part.

Any extract or abstract of a HOKLAS endorsed certificate or documentation shall not contain the HOKLAS accreditation symbol nor other details as specified in clause 5.3 above unless the authorised representative of the accredited reference material producer which issues the certificate or documentation 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 reference material producer is not accredited for providing can only be included in a HOKLAS endorsed certificate or documentation if HKAS Executive has given its approval for such inclusion in writing. An endorsed certificate or documentation containing such opinions or interpretations shall in all cases clearly state that the reference material producer is not accredited for providing such opinions or interpretations.
- 5.13 An accredited reference material producer shall not claim HOKLAS accreditation for its testing and calibration activities even though such activities have been assessed in accordance with relevant requirements in ISO/IEC 17025:2017. It shall also forbid its subcontractors to claim HKAS accreditation for the subcontracted activities even though such activities have been assessed by HKAS Executive as part of the reference material production process.
- 5.14 Accreditation symbol may be used on labels of reference materials produced within the scope of accreditation provided that the label meets the requirements of HKAS SC-01 and HOKLAS 022:2017, and shall contain the following as a minimum:
- (a) HOKLAS accreditation symbol for reference material producers;
 - (b) Name of the accredited reference material producer;
 - (c) Designation of the product and batch number; and
 - (d) Cross reference to the certificate of the certified reference material or documentation for non-certified reference material.

The use of accreditation symbol on reference material label is voluntary.

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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.