HKAS Policy Document No. 1

HKAS Policy for Accreditation of Laboratories according to ISO/IEC 17025:2017 under HOKLAS (ISO/IEC 17025:2017 HOKLAS Policy)

Introduction

This document provides HKAS policy for accreditation of laboratories according to ISO/IEC 17025:2017 under the Hong Kong Laboratory Accreditation Scheme (HOKLAS). This document contains policy that serves as additional explanation of the requirements of ISO/IEC 17025:2017 and is mandatory. This document shall therefore be read in conjunction with ISO/IEC 17025:2017. More detailed requirements specific to certain administrative aspects and technical disciplines are issued as individual HKAS and HOKLAS Supplementary Criteria.

1 Scope

(No additional explanation)

2 Normative reference

(No additional explanation)

3 Terms and definition

(No additional explanation)

4 General requirements

(No additional explanation)

5 Structural requirements

(a) It is the responsibility of the laboratory to carry out its work in accordance with the applicable Laws and Regulations of Hong Kong, or of the country where the laboratory is located. It should be emphasized that assessment of the laboratory's compliance with the relevant regulatory requirements is outside the scope of HKAS accreditation schemes. (ISO/IEC 17025:2017 Cl 5.4)

(b) There shall be clearly defined and recognisable lines of authority and responsibility within the organisation. All staff shall be aware of both the extent and limitations of their own responsibilities. A concise organisation chart shall be documented showing the laboratory's overall organisation and lines of responsibility. (ISO/IEC 17025:2017 Cl 5.5)

6 Resource requirements

6.1 (No additional explanation)

6.2 Personnel

(a) The officer-in-charge of a laboratory or section leaders in the case of large laboratories shall have sound knowledge of the principles of the technical discipline, provide adequate supervision and have the ability to make critical evaluations of test and calibration results. (ISO/IEC 17025:2017 Cl 6.2.1)

(b) HKAS Executive will pay particular attention to the mode of supervision of staff during assessments. The laboratory management shall decide who can work under direction and who requires supervision. Each laboratory staff member shall be fully briefed or instructed. Adequate supervision shall be provided at each level of the staff structure to ensure close adherence to laboratory procedures and accepted techniques at all times. (ISO/IEC 17025:2017 Cl 6.2.3)

Note: HKAS Executive considers each laboratory on its merits and relates staff and management requirements to the range, complexity and frequency of performance of tests or calibrations for which accreditation is sought. In some circumstances, adequate technical control may be achieved with a combination of staff. For example, a staff member exercising technical control may be relatively inexperienced with respect to one facet of the laboratory's work, but another staff member working in close collaboration with him/her may complement him/her in that aspect. The accreditation in such a case will be reviewed if there is a major change in either person's duties.

6.3 Facilities and environmental conditions

(No additional explanation)

6.4 Equipment

(No additional explanation)

6.5 Metrological traceability

Please refer to HOKLAS Supplementary Criteria No.2.

6.6 Externally provided products and services

(a) For purchase of consumables or perishable items (e.g. spare parts, reagents and glassware), records shall be kept of the different brands of those items which bear a critical influence on the test and calibration results. The record shall, where appropriate, include results of the acceptance tests on each new batch or shipment prior to use. When a particular brand shows an undesirably high rejection rate, consideration should be given to exclude it from the list of acceptable sources of supplies. (ISO/IEC 17025:2017 Cl 6.6.2 b))

(b) For purchase of equipment, separate records shall be kept for each manufacturer supplying major equipment. The records shall include results of the acceptance tests and the subsequent maintenance history of their products. Manufacturers whose products consistently do not meet their stated performance specification and/or show undesirably high proportion of instrument down time and/or are not supported by good after-sale service should be noted and their names removed from the list of acceptable suppliers as appropriate. (ISO/IEC 17025:2017 Cl 6.6.2 b))

7 Process requirements

7.1 Review of requests, tenders and contracts

(No additional explanation)

7.2 Selection, verification and validation of methods

(a) A formal system shall be in operation for issuing, reviewing and updating of methods and specifications. (ISO/IEC 17025:2017 Cl 7.2.1.2)

(b) The system shall alert the laboratory to any new editions of published standards. Methods shall be reviewed regularly with respect to the publications of new editions of standards, development in testing or calibration technology and other relevant information. (ISO/IEC

17025:2017 Cl 7.2.1.3)

(c) Laboratories using 'in-house' methods shall have policy and procedure for their design, development and subsequent validation. Such 'in-house' methods may include, for example, non-standard methods, laboratory designed/development methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods. The procedure shall include a step to confirm that the 'in-house' methods fulfill the requirements of their intended use(s). (ISO/IEC 17025:2017 Cl 7.2.1.6)

Note 1: If a new edition of a test standard has been published and a laboratory wishes to be accredited for the new edition, it may seek extension of accreditation to cover the new edition. HKAS Executive will consider the extent and nature of the changes included in the new edition and decides if an on-site assessment is required or not. Normally, an on-site assessment is not required if the changes are only editorial.

Note 2: Accreditation will normally be granted only to tests or calibrations performed regularly by the laboratory being assessed, particularly, if they are considered to be experience-dependent. However, under some special circumstances, accreditation for infrequently performed tests or calibrations may also be considered. In such cases, the laboratory will be required to set up a regular schedule of performance checks to verify and demonstrate their continuing capability to meet the relevant competence requirements.

Note 3: It is recognised that validation requirements differ significantly from one technical discipline to another. Generally, the depth and extent of validation should commensurate with the intended uses of the methods. The objective of validation is to confirm that the methods are fit for the intended use. Reference should be made to published guidelines on this aspect, such as EURACHEM Guide 'The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics', ISO Guide 33 'Reference materials - Good practice in using reference materials', and other publications of professional bodies on this topic.

Note 4: Test methods are classified in accordance with the following principles:

- A test method which conforms exactly to a particular standard will be described as such;
- Where the test method differs from the particular standard, and HKAS Executive, as advised by the technical assessors, is satisfied that the deviation(s) are unlikely to affect the test results, the test will be described

as being the particular standard with modifications. Such modifications shall be clearly stated on the test reports;
- Any other test method will be described as being an in-house method, without mention any particular standard or reference.

Whereas standard methods have been validated by the standard writing bodies for their intended scope, the capability of a laboratory to conduct the tests has to be demonstrated. The demonstration may include, for example, verification of performance of the equipment against test standard requirements, availability of the required reference materials and/or standards, suitability of the laboratory environment, skills and competence of testing staff, as well as the overall ability of the laboratory to achieve the required precision, detection limits, and other performance characteristics of the methods.

7.3 Sampling

(No additional explanation)

7.4 Handling of test or calibration items

(No additional explanation)

7.5 Technical records

(No additional explanation)

7.6 Evaluation of measurement uncertainty

It is a requirement that the uncertainties of all measurements covered under the ‘Calibration Services’ test category shall be estimated in accordance with the ISO ‘Guide to the Expression of Uncertainty in Measurement’ (GUM). Testing laboratories conducting internal calibrations should follow the uncertainty estimation practice accepted in the relevant discipline. (ISO/IEC 17025:2017 Cl 7.6.2)

Note: For testing, the complexity involved in estimation of uncertainty may vary considerably from one testing field to another and even within a particular field. It is often achieved by a process which is metrologically less rigorous than the method which can be followed for calibration. For chemical measurements, reference to the EURACHEM/CITAC document ‘Quantifying Uncertainty in Analytical Measurement’ may be useful. For any particular testing discipline, the uncertainty estimation method generally

accepted within that discipline will also be accepted by HKAS Executive.

7.7 Ensuring the validity of results

When developing new tests or calibrations, the laboratory shall establish and document the quality control requirements for monitoring the validity of results. Where necessary, the existing quality control procedures should be extended to cover the new work or new procedures. The adequacy of the quality control procedures will be examined critically during assessments. (ISO/IEC 17025:2017 Cl 7.7.1)

Note: The policy on participation in proficiency testing activities is stated in HOKLAS Supplementary Criteria No. 33. HOKLAS Supplementary Criteria for a given discipline may also specify participation requirements specific to that discipline.

7.8 Reporting of results

It should be recognised that the end-users of test reports may not be the laboratory direct customers and as such all information that is necessary for the understanding of the results shall be included in the test reports. Omission of the necessary information is not allowed unless the test reports are for use by internal users, i.e. by users of the same organisation as the laboratory, or the customer is the end-user of the test reports. This shall be taken into account when the agreement with the customers on reporting of test results in a simplified way is being negotiated. If test results are reported in a simplified way, the test reports shall bear a note clarifying that the test report is a simplified report and full details of the report are available from the laboratory, unless it is prohibited by law. (ISO/IEC 17025:2017 Cl 7.8.1.3)

Determination of conformity with specification

Note 1: When a statement of conformity to a requirement or specification has to be reported, laboratories should determine conformity in accordance with ILAC G8, which is available at ILAC website at ilac.org. Reference may also be made to JCGM 106 which is available from the BIPM website at www.bipm.org.

Opinions and interpretations

Note 2: A statement of conformity which is determined based on the limits and procedures prescribed in the specification or the document standard against which the test or calibration is conducted is not considered as an

opinion or an interpretation. However, a statement which extends or interprets the specific statement of conformity to cover non-specific and general requirements (e.g. whether a product will be acceptable in the market because it satisfies a certain standard, whether a product in conformity with a certain safety standard is suitable for a specific application, or whether conformity with a certain standard is equivalent to conformity with another standard) is considered as an opinion or an interpretation.

Note 3: Opinions and interpretations may sometimes be classified into two categories: (i) objective ones: These are based on objective evidence and arrived at under well-defined rules. These opinions and interpretations can be verified by independent experts; (ii) subjective ones: Those based on individual experience, circumstances and feelings and cannot be verified by a second person. It is recommended that only objective opinions and interpretations should be included in reports and certificates and subjective opinions and interpretations should not be included.

Note 4: The competence of a laboratory to provide valid objective opinions and interpretations relating to a given test or calibration is considered separately from its competence to perform the given test or calibration, and will be separately assessed. Laboratories wishing to include opinions and interpretations in HOKLAS endorsed reports or certificates should state explicitly in their proposed scope of accreditation the types of opinion and interpretation to be covered. Laboratories not accredited for making opinions and interpretations shall not claim that they are accredited for such. Inclusion of opinions and interpretations in HOKLAS endorsed reports and certificates when the laboratory is not accredited for making opinions and interpretations is governed by the same regulation applicable to reporting other non-accredited activities and is detailed in HOKLAS Supplementary Criteria No. 33.

7.9 Complaints

(No additional explanation)

7.10 Nonconforming work

(No additional explanation)

7.11 Control of data and information management

Note: Where results are transmitted by electronic or electromagnetic means, particular attention should be paid to the security and integrity of the data

being transmitted. Transmission may be handled by the method agreed with the customer in writing, however, it is the responsibility of the laboratory to point out any risk of such methods.

8 Management system requirements

8.1 Options

Note: Certification to ISO 9001 is not a requirement for Option B.

8.2 Management system documentation (Option A)

(No additional explanation)

8.3 Control of management system documents (Option A)

(No additional explanation)

8.4 Control of records (Option A)

The minimum period for retention of records set by HKAS Executive is four years unless a longer period is specified by regulatory authorities, in relevant HKAS or HOKLAS Supplementary Criteria, or in other requirements such as the customer's instructions. For equipment records and laboratory operation procedures, the retention period of at least four years shall be counted from the date on which the use of the equipment or the operation procedures stopped. For personnel records, the retention period of at least four years shall be counted from the date of departure of the staff member concerned. (ISO/IEC 17025:2017 Cl 8.4.2)

8.5 Actions to address risks and opportunities

The requirement that actions shall be taken against opportunities (e.g. needed improvements) and risks (e.g. potential nonconformities) highlights the need to look out for potential problems and opportunities for improvement. In other words, the laboratory shall take a proactive approach rather than a passive and reactive approach. When considering risk and opportunities for needed improvement, the risk level should be assessed and suitable action should be recommended for addressing the risk or enhancing the system. The extent of the action taken should be commensurate with the likelihood and consequence of the risk. Actions for addressing risks and opportunities may be taken in response to e.g. operational process analysis (Annex B of ISO/IEC 17025:2017), internal audit or external assessment findings, output from

management review, complaints, staff and customer feedback, analysis of data and proficiency testing results. (ISO/IEC 17025:2017 Cl 8.5.2)

8.6 Improvement (Option A)

(No additional explanation)

8.7 Corrective actions (Option A)

(No additional explanation)

8.8 Internal audits (Option A)

(a) The cycle for internal auditing should be completed in one year.

(b) Personnel conducting internal audit shall be trained in the techniques of auditing and shall have the knowledge of the activities to be audited. The personnel shall, wherever resources permit, be independent of the activity to be audited. The records of training, supervision and authorisation of the personnel conducting internal audit shall be retained.

(c) When an organisation seeks extension of scope of accreditation, the laboratory management should ensure that audits are carried out and corrective actions are satisfactorily completed prior to the HKAS on-site assessment visit.

(d) The records of audit shall include name(s) of auditor, date(s) and type(s) of audit, area(s) audited, details of aspects examined (even where no nonconformities were observed), nonconformities observed or recommendations for improvement, linked to references to relevant documents, underlying cause(s) of the nonconformities, corrective action agreed, time frame agreed for completion, and the person responsible for carrying out the action, date of confirmation of completion of corrective action and signature of the responsible person confirming that the corrective action has been completed and recommending whether or not discussion for preventive action is necessary.

8.9 Management reviews (Option A)

(a) A management review should be conducted once every year.

(b) There shall be clear indications in the records for outputs of management review of the actions to be taken, by whom and by what date.