HOKLAS 003:2015

Abridged Version

(Requirements and notes of ISO/IEC 17025 are not included in this document. This document should be read in conjunction with ISO/IEC 17025:2005)

Technical Criteria for Laboratory Accreditation

(ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories, MOD)

Hong Kong Accreditation Service
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HKAS Introduction

The Hong Kong Accreditation Service (HKAS) was set up in 1998 by the Government of the Hong Kong Special Administrative Region to provide accreditation service to the public. It was formed through the expansion of the Hong Kong Laboratory Accreditation Scheme (HOKLAS). HKAS now offers accreditation for laboratories, reference material producers, proficiency testing providers, certification bodies, greenhouse gas (GHG) validation or verification bodies and inspection bodies. It may offer other accreditation services in the future when the need arises.

The principal aims and objectives of HKAS are :

- to upgrade the standard of operation of conformity assessment bodies;
- to offer official recognition to competent conformity assessment bodies which meet international standards;
- to promote the acceptance of endorsed reports and certificates issued by accredited conformity assessment bodies;
- to conclude mutual recognition arrangements with other accreditation bodies; and
- to eliminate the need for repetition of conformity assessment in the importing economies and thereby reducing costs and facilitating free trade across borders.

Endorsed report and certificate means a report or certificate bearing the accreditation symbol of HKAS or its mutual recognition arrangement partners

The operating cost of HKAS is funded by the Government and is partly recovered by charging fees for services provided by HKAS.

HKAS Executive is responsible for administering HKAS and its accreditation schemes. At present, there are three schemes: the Hong Kong Laboratory Accreditation Scheme (HOKLAS) for laboratories, reference material producers and proficiency testing providers, the Hong Kong Certification Body Accreditation Scheme (HKCAS) for certification bodies and GHG validation or verification bodies and the Hong Kong Inspection Body Accreditation Scheme (HKIAS) for inspection bodies. All accreditation schemes of HKAS are operated in accordance with the requirements of the international standard, ISO/IEC 17011 and the criteria established by relevant international and regional cooperations of accreditation bodies. Participation in the three schemes is voluntary.

Organisations applying for accreditation or those that have been accredited under any of the three schemes are required to demonstrate that:

- they are competent to perform the specific activities for which they are applying for accreditation or have been accredited;

- they have implemented an effective management system which complies with the accreditation criteria of the relevant scheme; and

- they comply with all the regulations in HKAS 002 - Regulations for HKAS Accreditation. These regulations are the governing rules for the administration of the three schemes and contain the obligations of any organisation which has applied for HKAS accreditation or has been accredited by HKAS.

The procedures for seeking HOKLAS accreditation and for processing applications are detailed in Annex AA of this booklet. HKAS will grant accreditation for an activity to an organisation only when it meets the conditions given in clause 4.15 of HKAS 002 – 'Regulations for HKAS Accreditation'.

i Basis of HOKLAS 003 Technical Criteria for Laboratory Accreditation - ISO/IEC 17025:2005

This technical criteria booklet is applicable to all types of laboratory other than medical testing laboratories, proficiency testing providers (PTPs) and reference material producers (RMPs). Technical criteria HOKLAS 015, HOKLAS 017 and HOKLAS 022 are published separately for medical testing laboratories, PTPs and RMPs respectively.

This booklet is a modified adoption of International Standard, ISO/IEC 17025:2005 – 'General Requirements for the Competence of Testing and Calibration Laboratories'. ISO/IEC 17025:2005 was jointly published by International Organisation for Standardisation (ISO) and International Electrotechnical Commission (IEC).

The title of this booklet varies from the ISO/IEC 17025:2005 and is entitled as 'Technical Criteria for Laboratory Accreditation'.

ISO, ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) have signed the following joint Communiqué:

'A laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and ***management system requirements*** that are necessary for it to consistently deliver technically valid test results and calibrations. The ***management system requirements*** in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001.'

In Sections 1 to 5 of this booklet, the requirements and notes of ISO/IEC 17025:2005 are reproduced verbatim as the main text and relevant HOKLAS policies are given in shaded boxes following the main text. Annexes AA to AC are also added following the original text of the ISO/IEC 17025:2005. HOKLAS policies serve as additional explanation of the requirements of ISO/IEC 17025:2005 and are mandatory. The reference documents referred to in the HOKLAS policy are given for information only. They are not part of the requirements unless explicitly stated as such.

The use of an international standard for recognising competence has led to increased confidence in testing and calibration laboratories and facilitated the acceptance of test results by authorities around the world. In this respect, HKAS has established a number of mutual recognition arrangements (MRAs) with other laboratory accreditation bodies. Signatories to the MRA recognise the equivalence of one another's accreditation and accept endorsed test reports and calibration certificates issued by such laboratories. As at December 2015, HKAS has concluded MRA with 91 accreditation bodies in 85 economies. A list of HKAS MRA partners, and their contact information, is available from the HKAS website at www.hkas.gov.hk

The term 'shall' is used throughout this booklet to indicate those provisions which are mandatory. The term 'should' is used to indicate guidance which, although not mandatory, is provided by HKAS as a recognised means of meeting the requirements.

This booklet sets out the basic management and technical requirements which all

laboratories accredited under HOKLAS other than medical testing laboratories, RMPs and PTPs shall meet. Medical testing laboratories, PTPs and RMPs shall meet the requirements given in HOKLAS 015 Technical Criteria for Laboratory Accreditation (Medical Laboratories), HOKLAS 017 Technical Criteria for Accrediting Proficiency Testing Providers and HOKLAS 022 Technical Criteria for Accreditation of Reference Material Producers respectively. More detailed requirements specific to certain administrative aspects and technical disciplines are issued as individual HKAS and HOKLAS Supplementary Criteria.

This and other criteria documents set out the requirements to be met by a laboratory but do not dictate how such requirements should be met. It is the responsibility of the laboratory management to determine the best method to meet such requirements, the relative significance of individual activities to the overall quality of the laboratory and the emphasis and resource that should be allocated to each of them. The laboratory management may be required to demonstrate to the assessment team that the method it has selected is adequate in meeting the requirements stated in criteria documents.

A list of HKAS and HOKLAS Supplementary Criteria is available from the HKAS Executive and the HKAS website. This website also provides links to other websites which provide useful information on accreditation and laboratory operation.

ii Scope of accreditation - What activities may be accredited under HOKLAS

Each laboratory accredited under HOKLAS will have the specific tests or calibrations for which it is accredited clearly given in its 'scope of accreditation'.

HKAS Executive will define from time to time the specific areas which are available for accreditation under HOKLAS. These areas are called 'test categories' and the categories currently available for accreditation are:

- Calibration Services
- Chemical Testing
- Chinese Medicine
- Construction Materials
- Electrical and Electronic Products
- Environmental Testing
- Food
- Forensic Testing
- Medical Testing
- Miscellaneous
- Pharmaceutical Products
- Physical and Mechanical Testing
- Proficiency Testing Providers
- Reference Materials Producers
- Testing required by the China Compulsory Certification System (CCC)
- Textiles and Garments
- Toys and Children's Products

Other test categories may be added when significant needs are identified.

A laboratory may apply to be accredited for one or more test or calibration in specific test categories and may seek to have its scope of accreditation expanded or reduced

as its needs change. Any expansion of an accreditation will normally require a full assessment of the laboratory's competence to perform the additional tests or calibrations.

All accredited laboratories are reassessed at regular intervals to ensure continuing conformity with HOKLAS requirements at all times for all accredited activities. In addition, their performance is monitored closely through surveillance visits, participation in proficiency testing programmes and other appropriate means.

iii Measurement Uncertainty

Calibration Laboratories

For laboratories accredited for calibrations under the 'Calibration Services' test category (as distinct from testing), the scope of accreditation will include a Calibration and Measurement Capability (CMC) which will be assigned to each of the calibrations for which a laboratory is accredited. CMC is defined as the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation, when performing more or less routine calibrations of nearly ideal measurement standards intended to define, realise, conserve or reproduce a unit of that quantity or one or more of its values, or when performing more or less routine calibration of nearly ideal measuring instruments designed for the measurement of that quantity. Laboratories may wish to refer to the publication, the ISO 'Guide to Expression of Uncertainty in Measurement' (GUM) for background information on derivation of measurement uncertainties and for referral to other useful guidance documents. The HOKLAS policy in this respect is detailed in HOKLAS Supplementary Criteria No. 13.

The smallest uncertainty assigned to a laboratory shall be quoted only for work carried out under the same conditions that CMCs are based and the uncertainty contribution from the equipment under calibration does not add significantly to the uncertainty of measurement. Typically, the equipment under calibration will contribute to uncertainty and as a result the actual measurement uncertainty will normally be greater than the CMC. Likewise, when the conditions under which a calibration is performed restrict the accuracy of measurement, appropriate changes shall be made to the uncertainty of measurement quoted in the corresponding calibration report or certificate.

Assessors, by examination of the calibration records of laboratory measuring equipment and the conditions under which calibrations are performed, determine whether the smallest uncertainty of measurement for each calibration proposed by the laboratory is acceptable. If there is doubt, the matter will be discussed in detail and, if necessary, check calibrations will be made to ensure that all concerned are in agreement on the CMC to be stated in the scope of accreditation.

Testing Laboratories

Testing laboratories are also required to estimate the uncertainty of measurement in accordance with clause 5.4.6.2 of this booklet. Requirements for specific test areas may be given in relevant HKAS and HOKLAS Supplementary Criteria.

iv Accreditation criteria

Applicant laboratories have to demonstrate conformity with the criteria in Sections 4 and 5 as well as the criteria in the relevant Supplementary Criteria and the regulations listed in HKAS 002 before accreditation can be granted, and accredited laboratories shall comply with the same criteria at all times for maintaining accreditation. Accredited and applicant laboratories may also be required to demonstrate to HKAS Executive that they can perform competently all the activities proposed for accreditation. Additionally, they shall maintain complete integrity and impartiality in all circumstances.

Annex AB is a list of selected documents published by ISO and international and regional laboratory accreditation cooperations. Unless otherwise stated in other parts of this booklet, they are provided for information only and are not part of the accreditation criteria.

Introduction

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

1 Scope

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

2 Normative references

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

3 Terms and definitions

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4 Management requirements

4.1 Organisation

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.1.H HOKLAS Policy on Organisation

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.

The 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, an officer exercising technical control may be relatively inexperienced with respect to one facet of the laboratory's work, but another officer working in close collaboration with him may complement him in that aspect. The accreditation in such a case will be reviewed if there is a major change in either person's duties.

HOKLAS assessments will pay particular attention to the mode of supervision of staff. The laboratory management shall decide who can work under direction and who requires supervision. Each laboratory officer 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.

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 should be documented (preferably in the quality manual) showing the laboratory's overall organisation and lines of responsibility.

The technical management may be a designated technical manager or may consist of a combination of designated technical managerial personnel each of them responsible for specified testing and calibration areas. The responsibility of technical issues for all accredited testing and calibration activities shall be fully covered by the technical management.

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.

4.2 Management system

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.2.H HOKLAS Policy on Management system

The management system of a laboratory need not be complex and its format will depend on a number of factors including the size of the laboratory, number of staff members and the range, volume and complexity of the work it performs.

The quality manual describing the laboratory's management system shall be developed as a working document for use by laboratory managers and other staff members, and should not be developed as a checklist for presentation to laboratory assessors. It shall be available for examination as a part of the accreditation process.

In cases where a laboratory is part of a larger organisation, laboratory activities may already be incorporated in a quality manual covering the organisation's total range of operations. If so, it may be necessary to extract that information and expand on it to establish a manual specifically relating to the laboratory's functions.

4.3 Document control

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.4 Review of requests, tenders and contracts

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.4.H HOKLAS Policy on Review of requests, tenders and contracts

When reviewing requests, tenders and contracts, laboratories shall ensure that the tests or calibrations requested suit the needs and intended purposes of the customers. As far as practicable, laboratories should give advice to the customers and help them to determine their testing or calibration needs.

4.5 Subcontracting of tests and calibrations

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.5.H HOKLAS Policy on Subcontracting of tests and calibrations

Laboratories shall document their policy and procedures for sub-contracting in the quality manual or related documents. 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. Relevant regulations governing the subcontracting of work and reporting of results from subcontractors are given in HOKLAS Supplementary Criteria No. 33 and relevant HKAS Supplementary Criteria. The HOKLAS policy on reporting results from subcontractors for which a laboratory is not responsible as allowed in clause 4.5.3 is detailed in 5.10.H(g).

Documentation issued to subcontractors as a result of a successful evaluation by the laboratory shall state that this is only for the purpose of contract and is not certification or accreditation.

When a laboratory subcontracts its test or calibration, it shall require the subcontractor to perform the subcontracted test or calibration by itself, and not to further subcontract it to another laboratory.

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.

4.6 Purchasing services and supplies

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.6.H HOKLAS Policy on Purchasing services and supplies

There are two commonly encountered situations where a laboratory will have to purchase services and supplies :

(a) Purchase of consumables or perishable items, e.g. media, chemical 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 should where appropriate include results of the acceptance tests on each new batch prior to use. When a particular brand shows an undesirably high rejection rate, consideration should be given to excluding it from the list of acceptable sources of supplies.

(b) 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.

It is further recommended that when choosing suppliers of service or products, priority should be given to those certified to the ISO 9001 by an accredited certification body.

It should be noted that requirements given in other sections of this document may also apply for specific services and supplies purchased by laboratories, e.g. section 5.5 for equipment, section 5.6.3 for reference standards and reference materials, etc.

4.7 Service to the customer

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.7.H HOKLAS Policy on Service to the customer

HOKLAS policy on service to the customer is detailed in HOKLAS Supplementary Criteria No. 33.

4.8 Complaints

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.8.H HOKLAS Policy on Complaints

In addition to the requirements in the preceding paragraph, laboratories shall note that when a complaint relating to any of their HOKLAS accredited tests or calibrations is not satisfactorily resolved within 60 days from the date of receipt, they are required to notify HKAS Executive in writing of the matter. Laboratories shall also comply with the regulations on the handling of complaints given in HKAS 002.

4.9 Control of nonconforming testing and/or calibration work

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.9.H HOKLAS Policy on Control of nonconforming testing and/or calibration work

Common examples of non-conforming work include laboratory environmental conditions exceeded the specified limits, duration of conditioning of test specimens not complying with the specification of the test standard, holding times of test samples exceeded the maximum permissible, tests performed using instruments with overdue calibration, acceptance criteria of quality control not met, unsatisfactory performance in proficiency testing programmes, etc. It is important that laboratories should not just correct the problem but shall initiate actions according to the requirements given in clause 4.9.1, which include a determination of whether the non-conforming work is an isolated incident or is due to some underlying causes with a possibility of recurrence. In the latter case, requirement given in clause 4.9.2 shall be conformed to. It should be emphasized that all laboratory personnel need to be familiar with the procedures for handling non-conforming work, particularly those involved directly with testing and calibration work. They should follow the documented procedures whenever non-conforming work is identified. Training on the procedures is essential to ensure relevant staff understands the procedures. Internal audit should include checking the effectiveness of implementation of this aspect.

4.10 Improvement

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.11 Corrective action

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.11.H HOKLAS Policy on Corrective action

It must be emphasized that corrections and corrective actions are different. ISO 9000:2015 defines correction as 'action to eliminate a detected nonconformity' whereas corrective action is defined as 'action to eliminate the cause of a detected nonconformity or other undesirable situation'. Hence, it is necessary to determine the cause(s) of a nonconformity before any corrective action can be taken. Without identifying the cause(s), actions cannot be taken to eliminate them. It is thus important to distinguish actions that are taken to eliminate the cause(s) of the nonconformity (corrective actions) from those which are just for eliminating the nonconformity (corrections). Carrying out correction without taking proper corrective action is ineffective as the cause of the nonconformity still exists and hence the nonconformity will recur. Making correction only without taking corrective action is rarely acceptable unless extensive investigation has demonstrated convincingly that there is no underlying cause and the nonconformity will not recur.

To ensure that maximum benefit can be derived from handling nonconformities, laboratory management should insist that the real root cause of the problem be identified and addressed. In many cases, what is said to be the root cause is only a consequence of the root cause. For example, the ostensible root cause for an incompetent operator might be identified as inadequate training while the real root cause was that the training had been provided by an incompetent trainer.

Therefore, when a nonconformity is detected, the laboratory shall make the necessary correction, analyse the situation to find the real root cause and take remedial action to eliminate it. The nonconformity should only be considered adequately addressed if the remedial action has been proven effective in preventing recurrence of the nonconformity. Recurrence of nonconformity is an indication of ineffective corrective actions, which is a nonconformity against the requirements of this clause.

4.12 Preventive action

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.12.H HOKLAS Policy on Preventive action

The requirement that actions shall be taken against needed improvements and 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. For example, in addition to checking for conformity, internal audits should also identify areas of risk and improvement. Whenever a potential non-conformity or needed improvement is observed in an audit, its level of risk should be assessed and preventive action recommended for avoiding occurrence of the nonconformities or enhancing the system. The extent of preventive actions should be commensurate with the likelihood and consequence of the potential nonconformity. Preventive actions may also be taken in response to staff or customer feedback and complaints.

4.13 Control of records

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.13.H HOKLAS Policy on Control of records

(a) Each laboratory shall maintain a record system designed to suit its particular requirements. The system shall be in conformity with this document but need not be an elaborate one.

(b) Technical records shall include all original observations and raw data and provide a traceable link between the test sample or calibration item as received and the report or certificate which is eventually issued. This applies equally to electronic and paper record systems. If a laboratory uses a Laboratory Information Management System (LIMS), the system shall meet all the relevant requirements, including audit trail, data security, safety and integrity, etc. It shall be fully validated and records of validation shall be maintained. Laboratories shall keep back-up copies of electronic records within their retention period. They shall also have a system to ensure that electronic records remain accessible within that period even though the hardware and software of their computer system are being updated from time to time.

(c) The record system shall allow for ready retrieval of original observations and data pertinent to any issued reports or certificates.

(d) For each sample tested or item calibrated, the records system shall retain and provide ready access to the following detailed information :

(i) its full description;

(ii) its unique identification (e.g. its unique identification code assigned by the laboratory) ;

(iii) the test or calibration method or procedure used to process it;

(iv) identification of equipment and reference materials used to process it;

(v) original observations during the test or calibration and calculations based on the observed data;

(vi) identification of persons performing the work;

(vii) an exact copy of the issued report or certificate of the test or calibration conducted.

(e) Original observations shall be recorded directly into bound notebooks, or onto properly designed proforma worksheets at the time when the observations are made. Observations shall be written in indelible ink. Any amendment shall be crossed out with the signature of the person making the amendment and the date of the amendment. The reasons for making the amendment shall also be recorded. Where data processing systems are used, records of raw data shall be retained unless data are (electrically) fed directly into the processing system. When the laboratory instrument provides a printout of the raw data / results, a copy of the printout shall be kept.

continued …….

(f) Sheets of plain paper shall not be used, not only because they may be easily lost or discarded, but also because they engender a less disciplined approach to the recording of information.

(g) Errors in calculations and incorrect transfer of data are major causes of incorrect results. Calculations and data transfers shall be checked and signed or initialled, preferably by a second person. It is desirable to design workbooks and worksheets so that there is a dedicated place for the signature of the checking person. On the other hand, laboratory adopting LIMS may upload instrument data into the system for subsequent processing and reporting without using worksheets, and the person(s) undertaking the data upload and result checking may not be identified by hand-written signature(s). In spite of this, the identity of responsible person(s) shall be captured by the system in a reasonably secure manner. Similar to 4.13.H(e), any amendment made to the data/result already approved shall be recorded with reasons in the audit trail of the system.

(h) The minimum period for retention of original test data, other laboratory records and HOKLAS endorsed reports or certificates set by the HKAS Executive is three 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 three years shall be counted from the date on which the use of the equipment or the operation procedures stopped. Similarly, the retention period of at least three years for personnel records shall be counted from the date of departure of the staff member concerned.

4.14 Internal audits

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.14.H HOKLAS Policy on Internal audits

HOKLAS policy on internal audits is detailed in HKAS Supplementary Criteria No. 5.

4.15 Management reviews

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

4.15.H HOKLAS Policy on Management reviews

HOKLAS policy on management reviews is detailed in HKAS Supplementary Criteria No. 5.

5 Technical requirements

5.1 General

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.2 Personnel

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.2.H HOKLAS Policy on Personnel

The appraisal of personnel is a major part of each laboratory assessment as the standard of performance depends largely on their skills.

Four categories of personnel will be assessed. They are:
(a) Technical personnel
(b) Supervisory personnel
(c) Management personnel
(d) Personnel responsible for providing opinions and interpretations

HOKLAS Policy on Technical Personnel

Technical personnel shall have suitable qualifications or training and have sufficient experience and ability to perform the work. They may be asked to demonstrate specific techniques during an assessment.

A laboratory shall have proper procedures for training new technical personnel and for developing the expertise of existing technical personnel in new or rarely used techniques. The criteria used to assess the competence of trainees shall form an integral part of the procedures. Records of training and assessments of competence shall be kept. These shall include or refer to records of results of tests or calibrations performed during training and competence assessment. The continuing competence of technical personnel shall be assessed at suitable intervals and records of such assessment shall be kept.

The validity of results produced by technical personnel, particularly in the early stages after completion of training in new techniques shall be monitored closely.

The HKAS Executive may define minimum technical qualifications and testing experience requirements for laboratory personnel involved in specific technical disciplines.

Colour vision defects may prevent people from performing certain work satisfactorily (such as in textile, chemical or microbiological testing). It is the responsibility of the laboratory management to ensure in such cases that colour vision problems will not affect validity of results.

continued …….

HOKLAS Policy on Supervisory and Management Personnel

The qualifications and experience of supervisory and management personnel will be carefully examined during the assessment of a laboratory. Factors which will be considered include:

(a) the size of the laboratory and the number of tests or calibrations for which accreditation is required;

(b) the technical complexity of the work involved;

(c) the frequency at which specific tests or calibrations is conducted in the laboratory, particularly for work which is highly experience dependent;

(d) the contact that the management personnel maintain with the development of methodology and adoption of new methodology within the laboratory.

Supervisory personnel shall have suitable qualifications or training and have sufficient authority, skills and experience to train, and supervise technical personnel properly. They shall demonstrate appropriate understanding of the technical areas in which they exercise supervision.

In assessing qualifications, the balance between relevant academic qualifications and practical experience will be examined in light of the range of work performed by the laboratory, its complexity and the precision required.

Management personnel are not required to have in-depth understanding of every technical area but shall have adequate experience of laboratory operation. They shall have suitable qualifications or training, and have sufficient experience and ability to direct the operations of the laboratory, and to accept responsibility for the implementation of the management system.

For a laboratory seeking accreditation for a wide range of complex tests or calibrations, management personnel will be expected to hold qualifications satisfying the corporate membership requirement of an appropriate professional body. For a laboratory engaged in a limited range of relatively simple tests or calibrations, the management personnel, while holding lower qualifications, shall be able to demonstrate their competence by having adequate relevant experience.

HOKLAS Policy on Personnel responsible for giving opinions and interpretations

Personnel responsible for giving opinions and interpretations shall have in-depth knowledge of the relevant technical discipline. They shall comply with the additional aspects of competence given in NOTE 2 of 5.2.1 of this document for the areas they cover. The laboratory shall have effective procedures to ensure that responsible expert personnel have sufficient understanding of the relevant subjects and a realistic appreciation of the limits of their own knowledge in the context of the opinions and interpretations to be reported. For specific technical disciplines, HOKLAS may specify the minimum qualification and experience requirements for such personnel in relevant HOKLAS Supplementary Criteria. Where giving opinions or interpretations is included in the proposed scope of accreditation, the assessment will include the evaluation of the responsible expert personnel and the examination of relevant records and reports. The effectiveness of the training and appraisal system in ensuring that the responsible expert personnel are competent will be critically evaluated.

The HOKLAS policy on including opinions and interpretations in reports and certificates is given in 5.10.H of this document.

continued …….

HOKLAS Policy on approved signatories for HOKLAS Endorsed Reports and Certificates

HOKLAS endorsed reports and certificates shall be signed by an approved signatory. An approved signatory is an individual who is an employee of or under contract to an accredited laboratory and has been authorised by the accredited laboratory to sign reports or certificates issued by the laboratory for specific activities and to whom HKAS Executive has given approval for signing endorsed reports or certificates for such activities.

A person nominated for approved signatory shall be familiar with the quality system and operation of the laboratory. There shall be objective evidence demonstrating that he/she has made sufficient contact with the laboratory to enable him to have an in-depth understanding on the operation of the laboratory and have confidence in the validity of the test results which are obtained in accordance with the laboratory's documented procedures. He/she shall 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. He/she shall occupy a position in his/her organisation's staff structure that makes him/her responsible for the accuracy of such results and be fully aware of the requirements detailed in this document, HKAS 002, HKAS Supplementary Criteria No. 01, HOKLAS Supplementary Criteria No. 33 and other relevant HOKLAS Supplementary Criteria.

Approval may be limited to specific tests or calibrations or may be granted for all tests and calibrations for which the laboratory is accredited. As signatory approval is granted in the context of the work being performed in a particular laboratory, they shall not be considered as a personal qualification.

Signatory approval may be granted to management personnel, provided that they have maintained sufficient contact with relevant techniques to retain the capability for critical evaluation of test or calibration results.

The following attributes are taken into account when assessing the suitability of a staff member for approval as a signatory:

(a) qualifications and experience;
(b) position in the staff structure;
(c) knowledge of the technical procedures and understanding of their underlying principles, interpretation and limitations;
(d) knowledge of the procedures for recording, reporting and checking results;
(e) awareness of the needs for periodic recalibration of equipment;
(f) understanding of the HKAS regulations and accreditation criteria, particularly those referring to reports and certificates.

HOKLAS Policy on Contracted Staff and Additional Technical or Key Support Personnel

When a laboratory uses contracted staff or additional technical or key support personnel on a short term basis, the laboratory shall ensure that the requirements for staff competence are met. Evaluation of the competence of these staff shall be carried out and evaluation records shall be kept. Where necessary, training shall be provided, particularly with regard to those parts of the laboratory management system which are relevant to their assigned duties. Direct and close supervision may be required initially to ensure that they are competent to carry out their duties.

5.3 Accommodation and environmental conditions

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.3.H HOKLAS Policy on Accommodation and environmental conditions

Suitability of the accommodation and environmental conditions for a specific range of calibrations and tests will be assessed based on their effect on the validity of the test or calibration results, including how they affect:

(a) the integrity of the samples tested or units calibrated;
(b) the performance of laboratory equipment;
(c) the competent performance of laboratory staff;
(d) compliance with the conditions specified in calibration or test methods.

Consideration of environmental effects on units to be calibrated and samples to be tested includes precautions necessary to prevent contamination and degradation. The areas for the sample preparation, preconditioning, testing or calibration and storage shall be of adequate size, free from dust, fumes and other factors (such as excessive temperature, humidity and direct sunlight) which may affect the integrity of the units or samples. If samples require refrigeration before and after testing, refrigerators or freezers of adequate capacity shall be provided.

Sufficient storage space shall be available to retain samples or units for recommended periods in conditions designed to maintain their integrity.

The potential effects of environment on equipment performance include corrosion, temperature, humidity, vibration, electrical power stability, dust and electromagnetic influences. The location of all items of equipment likely to be affected by these factors shall be chosen to eliminate or minimise any adverse effects.

Accommodation and environmental conditions will also be assessed based on their effects on staff competence in performing specific tests. There shall be sufficient space available for staff to perform their duties comfortably, with adequate provision of lighting and with precautions taken to minimise noise.

Adequate space shall also be provided for laboratory clerical functions (recording, reporting and documentation activities) and for separate amenity facilities. All necessary services for gas, water, power (suitably stabilised if necessary), waste disposal and for extraction of fumes shall be available and be conveniently located.

Some calibration and test methods also specify features and conditions of the environment in which calibration, sample preparation, and testing should take place. Where environmental features and conditions such as temperature and humidity ranges, airflow rates, illumination levels, etc., are specified, these conditions shall be met in the relevant testing, calibration and sample preparation sections of the laboratory. Monitoring equipment such as thermometers, hygrometers, psychrometers, thermohygrographs and anemometers, shall be available and be operated over the relevant testing, calibration and sample preparation period specified by the methods. The monitoring equipment itself may need to be calibrated in accordance with the equipment calibration schedules set by HKAS Executive.

For laboratories undertaking microbiological tests, the laboratory layout should generally provide for sample receipt, washing-up and sterilisation, media preparation and general testing areas, and should be designed to minimise potential contamination of samples and to ensure protection of laboratory staff. Laboratories involved in handling pathogenic organisms need to take special environmental precautions.

5.4 Test and calibration methods and method validation

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.4.H HOKLAS Policy on Test and calibration methods and method validation

(a) A formal system shall be in operation for issuing, reviewing and updating of methods and specifications. 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. 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 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.

(b) 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.

(c) 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 ISO/TS 13530 'Water Quality - Guidance on analytical quality control for chemical and physicochemical water analysis', 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.

(d) HOKLAS classifies test methods 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 the 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.

(e) 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.

continued …….

(f) Non-standard methods shall be fully documented and validated.

(g) 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 fulfil the requirements of their intended use(s).

(h) It is a HOKLAS 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.

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.

5.5 Equipment

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.5.H HOKLAS Policy on Equipment

(a) A laboratory shall assign designated officers the responsibility for the management of equipment, including their calibration and maintenance.

(b) A system shall be in operation to alert laboratory staff the due dates of calibration, verification and maintenance for all items of equipment.

(c) Where an instrument is sent to an external laboratory for calibration, consideration shall be given to the effect of its absence on routine operation.

(d) HKAS Executive may require laboratories to submit copies of up-to-date calibration certificates issued by external laboratories.

5.6 Measurement traceability

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.6.H HOKLAS Policy on Measurement traceability

(a) Not all items of equipment used for tests or calibrations need to be calibrated. Only those items of equipment having a significant effect on the accuracy or validity of the results are required to be calibrated. For any particular item of equipment, the laboratory should evaluate its applications and how it affects the final results. Such evaluations require the knowledge on how the measurements obtained using that item of equipment affect the final measurement uncertainty or validity of the final results. The calibrations and the required calibration uncertainties shall meet the requirements of those applications.

(b) Clause 5.6.2.1 is not applicable to testing laboratories when the calibration contributes little to the total uncertainty of the test result. The following are some examples of such cases:

(i) When determining compliance and it has been shown that there is a large margin (compared with the instrument uncertainty) between the specified limits and the measured results.

(ii) The allowable tolerances for the parameters to be measured are very large compared with the uncertainty of the measurement instrument, even when the possible drifts and errors of the instrument have been taken into account.

(iii) The uncertainty contributed by that measurement is very small (say, an order of magnitude smaller) compared with other uncertainty contribution factors, e.g. the uncertainty arising from the testing process.

In such cases, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed. This may be achieved by internal calibrations or verifications, or by calibrations performed by a competent laboratory which need not satisfy the criteria as defined in 5.6.H(e).

(c) Specific recommendations for calibration and recalibration of selected items of equipment required by laboratories operating in the test categories for which HOKLAS accreditation is currently available has been set. These recommendations are given in HOKLAS Supplementary Criteria No. 2 and will be reviewed regularly as additional test categories become available for accreditation under HOKLAS. Laboratories shall note that any recommendations on calibration, including recalibration intervals are given for reference only. For any individual instrument, it is the responsibility of the laboratory to determine the appropriate calibration regime based on its application, construction and drift history. Laboratories should not adopt the recommendations indiscriminately in lieu of detailed investigation. More detailed guidance on determining calibration requirements is given in the same Supplementary Criteria.

(d) 'Calibration Services' is one of the test categories covered by HOKLAS and accreditation is available to laboratories providing calibration services for specific items of equipment.

continued …….

(e) The HKAS Executive accepts calibrations performed by one of the options specified in Clause 2.1 of HOKLAS Supplementary Criteria No. 2 as evidence of traceability to SI units.

(f) Calibration of some items of equipment may be performed by accredited laboratories themselves, provided that the laboratories have the necessary reference standards and materials and technical personnel having the competence to perform the calibration. In addition, the uncertainty of calibration achieved shall meet the requirements of the applications. HOKLAS assessments will cover assessments of the competence of the laboratory performing the calibration.

(g) Many items of equipment, and particularly for chemical analyses, are calibrated by comparative techniques using reference materials. The employment of reference materials to ensure demonstrated traceability to the SI units or the appropriate measurement standards is essential to the accuracy of results.

The metrological quality of such calibrations depends on:
- the uncertainty of the reference materials used;
- the appropriateness of the reference materials with respect to the practical conditions of use, taking into account the analytical method to be employed and the characteristics of the test samples.

Laboratories should follow the guidelines specified in ISO Guide 33 on the use of certified reference materials for equipment calibration and assessment of a measurement process.

Laboratories should note the following definitions:

Reference material (RM): Material, sufficiently homogeneous and stable with respect to specified properties, which has been established to be fit for its intended use in a **measurement** or in examination of **nominal properties**.

NOTE 1: Examination of a nominal property provides a nominal property value and associated uncertainty. This uncertainty is not a **measurement uncertainty**

NOTE 2: Reference materials with or without assigned **quantity values** can be used for **measurement precision** control whereas only reference materials with assigned quantity values can be used for **calibration** or **measurement trueness** control.

NOTE 3: 'Reference materials' comprises materials embodying **quantities** as well as nominal properties.

NOTE 4: A reference material is sometimes incorporated into a specially fabricated device.

NOTE 5: Some reference materials have assigned quantity values that are metrologically traceable to a **measurement unit** outside a **system of units**. Such materials include vaccines to which International Units (IU) have been assigned by the World Health Organisation.

NOTE 6: In a given **measurement**, a given reference material can only be used for either calibration or quality assurance.

NOTE 7: The specifications of a reference material should include its material traceability, indicating its origin and processing.

Continued …….

Certified reference material (CRM): Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures.

NOTE 1: 'Documentation' is given in the form of a 'certificate'.

NOTE 2: Procedures for the production and certification of certified reference materials are given, e.g. in ISO Guide 34 and ISO Guide 35.

NOTE 3: In this definition, 'uncertainty' covers both 'measurement uncertainty' and 'uncertainty associated with the value of a **nominal property'**, such as for identity and sequence. 'Traceability' covers both '**metrological traceability** of a quantity value' and 'traceability of a nominal property value'.

NOTE 4: Specified quantity values of certified reference materials require metrological traceability with associated measurement uncertainty.

HOKLAS policy on the use and acceptability of CRMs and RMs for the calibration of equipment is detailed in HOKLAS Supplementary Criteria No. 1.

(h) A laboratory shall assign designated officers the responsibility for the management of reference materials. (See also 5.5.H (a).)

(i) Where a laboratory uses an external calibration laboratory to perform equipment calibrations, it shall inform the external calibration laboratory of the calibration requirements, including the ranges, the cardinal points, the required calibration uncertainties and the conditions under which the calibrations are to be performed.

5.7 Sampling

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.7.H HOKLAS Policy on Sampling

(a) The involvement of laboratories in sampling varies. Some laboratories have no responsibility for sampling, others have partial involvement, while many have total responsibility for both sampling and testing.

In the last two cases, it is recommended that laboratories seek to have their sampling activities included in their scope of accreditation.

(b) To obtain accreditation for sampling, a laboratory shall have fully documented sampling procedures. These may take the form of existing national or international standards. In-house procedures will be assessed on their suitability for the intended purposes. All sampling equipment and devices specified in the procedure shall be available, well maintained and in full compliance with dimensional requirements specified in the relevant procedure.

(c) Supervisory staff responsible for the design and documentation of sampling procedures shall be able to demonstrate the validity of the procedures. The training and supervision of samplers shall be shown to be satisfactory. The sampling procedures will usually be witnessed as part of on-site assessments for laboratories seeking such accreditation.

(d) Where laboratories have no, or only partial responsibility for sampling, their applications for accreditation for subsequent testing will also be considered. However, certain precautions shall be taken by these laboratories. The report or certificate shall include the supplier of the sample and any other historical details available on the sample such as source, condition, date of sampling, etc. If an unreliable sample is presented for test, but it is not possible to reject the sample, a clear statement of its perceived deficiencies shall be included in the report or certificate.

(e) If a standard test method specifies that a sample should be taken in accordance with a standard procedure, and a laboratory does not know whether the original sampler complied with this procedure, this shall be acknowledged on the test report or certificate covering the subsequent testing. This may be reported as, for example, 'sample tested as received', together with any other known information on the history of the sample.

(f) When laboratories arrange for non-laboratory staff to take samples, such as customers, suppliers, factory personnel, etc., such personnel shall be adequately instructed and preferably supplied with written sampling instructions. In some cases it will also be necessary for the laboratories to provide samplers with suitably cleaned and labelled containers (with preservatives added if necessary) together with appropriate training on the relevant sampling technique and required documentation.

All samples shall be uniquely and clearly identified. Identification labels shall be secure and legible. Labelling on caps or lids is considered poor practice as it can lead to possible mixing of sample identities during testing of like batches and hence is not acceptable.

continued …….

(g) Containers shall be leak-proof and impervious to possible contamination during transport. Where specified, samples shall be maintained within set temperature limits or other environmental tolerances during transfer to the laboratory and prior to testing. In some cases, it may be necessary for sample containers to be pre-tested prior to use to ensure freedom from contamination.

(h) Laboratories shall have procedures to ensure that test portions taken from laboratory samples for testing are representative.

(i) International standards for sampling are available and laboratories may refer to these for guidance. Some examples of these standards are ISO 8213, ISO 5667, etc.

5.8 Handling of test and calibration items

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.8.H HOKLAS Policy on Handling of test and calibration items

(a) On receipt, a calibration or test item shall be registered into the laboratory records system. The form of registration may vary. In most laboratories a sample or item register will be used, but in some cases, details of the samples or items may be written directly on worksheets or into workbooks. Certain information on the received sample or item is essential and such criteria are covered in section 4.13.2 on 'Technical Records'.

(b) Where it is necessary to store samples or items after tests or calibrations, the laboratory shall ensure that appropriate storage facilities are available for avoiding deterioration, loss or damage. The suitability of such storage facilities will be examined in assessments.

(c) The disposal procedure of tested samples and items shall be such that confidential information and proprietary rights of the customers are well protected in the process. Where appropriate, prior agreement with the customers on sample disposal method shall be made during the contract review stage.

5.9 Assuring the quality of test and calibration results

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.9.H HOKLAS Policy on Assuring the quality of test and calibration results

Each HOKLAS accredited or applicant laboratory shall adopt an appropriate set of quality control procedures suitable for the range of work undertaken and for the number of testing staff available. The results of such procedures shall be fully recorded and be available for review during HOKLAS assessments. Where a test standard specifies a quality control procedure, it shall be followed.

The HOKLAS 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.

When developing new tests or calibrations, the laboratory shall establish and document the quality control requirements as part of the quality assurance plan for those tests or calibrations. 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.

Some of the quality control procedures commonly adopted by laboratories are :

a) Programmed submission of certified reference materials and other materials of known characteristics during the course of routine sets of analyses. This practice, done routinely, also allows for the use of analytical control charts and for the monitoring of the ongoing level of precision being achieved in the laboratory, and if sufficient reference materials are available, for evaluation of the accuracy being achieved at various concentration levels.

b) Regular testing of replicate samples by the same operator. This allows for an ongoing estimate of the repeatability being achieved by an individual operator. It may be done either fully known to the operator or by programmed resubmission of previously tested samples suitably re-identified.

c) Regular testing of the same sample or calibration of the same item by two or more operators. This allows for the estimation of between-operator precision being achieved in the laboratory and for identifying any significant biases evident in an individual operator's results.

d) Programmed testing of the same sample by different analytical techniques or two different items of the same apparatus type. For calibration, the same items may be measured by different instruments or using different techniques. This allows for estimation of any technique-dependent bias or equipment bias in the laboratory's results.

e) Recording and monitoring of results obtained from the same sample by the laboratory's customers or suppliers. This allows, given sufficient data, for control charts to be established to monitor the between-laboratory precision achieved between the two laboratories concerned. The data obtained may also be compared with any available published data on reproducibility for the tests concerned, if both laboratories are using the same test method.

continued …….

f) Participation in proficiency testing programmes or other forms of inter-laboratory comparisons. This allows the laboratory to compare its performance and comparability of its data to those of broader groups involved in the same tests. It provides a useful alerting mechanism to any faults in technique, operators or equipment which may not otherwise be evident. Such programmes also provide a mechanism for estimation of reproducibility for specific tests.

5.10 Reporting the results

(The main text of this clause is the text of the same clause of ISO/IEC 17025 : 2005)

5.10.H HOKLAS Policy on Reporting the results

Laboratories shall note the following in addition to the criteria specified in section 5.10:

(a) Numerical expression of results and rounding of numbers

Laboratories may refer to the Australian Standard 2706 which gives guidance on numerical expression of results and rounding of numbers.

(b) Transmission of results by electronic or electromagnetic means

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.

(c) Determination of compliance with specification

When a statement of compliance with requirements or specifications has to be included in a calibration report or certificate, laboratories should determine compliance in accordance with the APLAC TC004 which is available from the APLAC website at www.aplac.org. Reference may also be made to ISO 14253-1.

(d) Opinions and interpretations

A compliance statement 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 compliance statement 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 compliance with a certain safety standard is suitable for a specific application, or whether compliance with a certain standard is equivalent to compliance with another standard) is an opinion or an interpretation.

Opinions and interpretations may sometimes be classified into two categories: a) 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. b) 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 subjective opinions and interpretations should not be included.

Where the inclusion of opinions and interpretations in reports and certificates are required, it is recommended that the laboratory should state the basis upon which the opinions and interpretations have been made and all the necessary information for their understanding in the same document.

continued …….

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 other non-accredited items and is detailed in HOKLAS Supplementary Criteria No. 33.

The HOKLAS policy on including opinions and interpretations in HOKLAS endorsed reports is explained in HOKLAS Supplementary Criteria No. 33.

The HOKLAS policy on the personnel responsible for giving opinions and interpretations is given in 5.2.H of this document.

(e) HOKLAS endorsed certificates and reports

The following are applicable specifically to HOKLAS endorsed certificates or reports :

(i) All HOKLAS endorsed certificates or reports shall also comply with the regulations detailed in HKAS 002 and HKAS Supplementary Criteria No. 1 and HOKLAS Supplementary Criteria No. 33.

(ii) It is the responsibility of the HOKLAS approved signatory to ensure that all information, including calculations and transfers of data, has been checked before signing the report or certificate.

(f) Reporting of measurement uncertainty

For calibrations, the uncertainty of measurement shall in general be included in calibration reports and certificates. An example where the uncertainty can be considered to be unnecessary for the interpretation of the calibration result is given in the Explanatory Note to Clause 1 of HOKLAS Supplementary Criteria No. 13.

For testing, a statement of the estimated uncertainty of measurement shall be included in reports when it is necessary for the interpretation of the test results. Cases where such a statement shall be included are listed in clause 5.10.3.1 c). As a laboratory may be required to include such a statement upon a customer's request, its ability in formulating the statement will be covered in HOKLAS assessments.

(g) Reports and certificates containing results from subcontractors

The HOKLAS regulations governing the reporting of results from subcontractors are detailed in HOKLAS Supplementary Criteria No. 33. When a laboratory does not take responsibility for the subcontracted work as provided for in clause 4.5.3, this fact shall be clearly stated in the report or certificate.

(h) Necessary information on certificates and reports

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. In addition, the test reports shall bear a note saying that only the original copy or the laboratory's certified true copy is valid.

Annex A
(informative)

Nominal cross-references to ISO 9001:2000

Table A.1 - Nominal cross-references to ISO 9001:2000

ISO 9001:2000	**ISO/IEC 17025**
Clause 1	Clause 1
Clause 2	Clause 2
Clause 3	Clause 3
4.1	4.1, 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.5, 4.2, 4.2.1, 4.2.2, 4.2.3, 4.2.4
4.2 1	4.2.2, 4.2.3, 4.3.1
4.2.2	4.2.2, 4.2.3, 4.2.4
4.2.3	4.3
4.2.4	4.3.1, 4.12
5.1	4.2.2, 4.2.3
5.1 a)	4.1.2, 4.1.6
5.1 b)	4.2.2
5.1 c)	4.2.2
5.1 d)	4.15
5.1 e)	4.1.5
5.2	4.4.1
5.3	4.2.2
5.3 a)	4.2.2
5.3 b)	4.2.3
5.3 c)	4.2.2
5.3 d)	4.2.2
5.3 e)	4.2.2
5.4.1	4.2.2 c)
5.4.2	4.2.1
5.4.2 a)	4.2.1
5.4.2 b)	4.2.1
5.5.1	4.1.5 a), f), h)
5.5.2	4.1.5 i)
5.5.2 a)	4.1.5 i)

ISO 9001:2000	ISO/IEC 17025
5.5.2 b)	4.11.1
5.5.2 c)	4.2.4
5.5.3	4.1.6
5.6.1	4.15
5.6.2	4.15
5.6.3	4.15
6.1 a)	4.10
6.1 b)	4.4.1, 4.7, 5.4.2, 5.4.3, 5.4.4, 5.10.1
6.2.1	5.2.1
6.2.2 a)	5.2.2, 5.5.3
6.2.2 b)	5.2.1, 5.2.2
6.2.2 c)	5.2.2
6.2.2 d)	4.1.5 k)
6.2.2 e)	5.2.5
6.3.1 a)	4.1.3, 4.12.1.2, 4.12.1.3, 5.3
6.3.1 b)	4.12.1.4, 5.4.7.2, 5.5, 5.6
6.3.1 c)	4.6, 5.5.6, 5.6.3.4, 5.8, 5.10
6.4	5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5
7.1	5.1
7.1 a)	4.2.2
7.1 b)	4.1.5 a), 4.2.1, 4.2.3
7.1 c)	5.4, 5.9
7.1 d)	4.1, 5.4, 5.9
7.2.1	4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10
7.2.2	4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10
7.2.3	4.4.2, 4.4.4, 4.5, 4.7, 4.8
7.3	5, 5.4, 5.9
7.4.1	4.6.1, 4.6.2, 4.6.4
7.4.2	4.6.3
7.4.3	4.6.2
7.5.1	5.1, 5.2, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9
7.5.2	5.2.5, 5.4.2, 5.4.5
7.5.3	5.8.2
7.5.4	4.1.5 c), 5.8
7.5.5	4.6.1, 4.12, 5.8, 5.10
7.6	5.4, 5.5

ISO 9001:2000	ISO/IEC 17025
8.1	4.10, 5.4, 5.9
8.2.1	4.10
8.2.2	4.11.5, 4.14
8.2.3	4.11.5, 4.14, 5.9
8.2.4	4.5, 4.6, 4.9, 5.5.2, 5.5.9, 5.8, 5.8.3, 5.8.4, 5.9
8.3	4.9
8.4	4.10, 5.9
8.5.1	4.10, 4.12
8.5.2	4.11, 4.12
8.5.3	4.9, 4.11, 4.12

ISO/IEC 17025 covers several technical competence requirements that are not covered by ISO 9001:2000.

Annex B
(informative)

Guidelines for establishing applications for specific fields

B.1 The requirements specified in this International Standard are stated in general terms and, while they are applicable to all test and calibration laboratories, explanations might be needed. Such explanations on applications are herein referred to as applications. Applications should not include additional general requirements not included in this International Standard.

B.2 Applications can be thought of as an elaboration of the generally stated criteria (requirements) of this International Standard for specified fields of test and calibration, test technologies, products, materials or specific tests or calibrations. Accordingly, applications should be established by persons having appropriate technical knowledge and experience, and should address items that are essential or most important for the proper conduct of a test or calibration.

B.3 Depending on the application at hand, it may be necessary to establish applications for the technical requirements of this International Standard. Establishing applications may be accomplished by simply providing detail or adding extra information to the already generally stated requirements in each of the clauses (e.g. specific limitations to the temperature and humidity in the laboratory).

In some cases the applications will be quite limited, applying only to a given test or calibration method or to a group of calibration or test methods. In other cases the applications may be quite broad, applying to the testing or calibration of various products or items or to entire fields of testing or calibration.

B.4 If the applications apply to a group of test or calibration methods in an entire technical field, common wording should be used for all of the methods.

Alternatively, it may be necessary to develop a separate document of applications to supplement this International Standard for specific types or groups of tests or calibrations, products, materials or technical fields of tests or calibrations. Such a document should provide only the necessary supplementary information, while maintaining this International Standard as the governing document through reference. Applications which are too specific should be avoided in order to limit the proliferation of detailed documents.

B.5 The guidance in this annex should be used by accreditation bodies and other types of evaluation bodies when they develop applications for their own purposes (e.g. accreditation in specific areas).

Annex AA

Procedures for HOKLAS Accreditation

Full details of the processes involved in achieving HOKLAS accreditation are given in Chapter 4 of HKAS 002 - Regulations for HKAS Accreditation. A brief summary of the main features is given below:

STEP 1 - INITIAL CONTACT

(i) A laboratory interested in seeking accreditation contacts HKAS Executive in writing.

(ii) Appropriate documents are provided to the laboratory including:

HKAS 002	Regulations for HKAS Accreditation
HOKLAS 003	Technical Criteria for Laboratory Accreditation
HOKLAS 005	Application Form for Laboratory Accreditation
HOKLAS 006/013	Schedule of Accreditation Fees for Hong Kong Laboratories/Laboratories located outside Hong Kong.
HOKLAS 007	Application Questionnaire

Relevant HKAS and HOKLAS Supplementary Criteria and Information Notes

(iii) The laboratory lodges the application by providing the following to HKAS Executive

(a) A completed Application Form for Laboratory Accreditation (HOKLAS 005)

(b) A completed Application Questionnaire (HOKLAS 007)

(c) The documents specified in the Application Questionnaire

(d) Appropriate application fees as stated in HOKLAS 006/013

STEP 2 - PRELIMINARY VISIT TO LABORATORY

(i) Following examination of the documentation submitted by the laboratory, HKAS Executive arranges a preliminary visit to:

(a) answer any questions relating to HKAS regulations and technical criteria.

(b) identify any obvious and necessary improvements to existing practices.

(c) evaluate the readiness of the laboratory for an accreditation, particularly whether the laboratory's management system meets HKAS criteria.

(d) address any issues on the compilation of the laboratory's quality manual.

STEP 3 - PREPARATION FOR ASSESSMENT

(i) The laboratory submits the final copies of its quality manual and test procedures.

(ii) HKAS Executive seeks any further information required from the laboratory.

(iii) HKAS Executive selects suitable technical assessors to undertake the on-site assessment of the laboratory.

(iv) Arrangements are made with the laboratory for a mutually convenient date or dates for an on-site assessment of the laboratory.

NOTE : Applicant laboratories may object on reasonable grounds to the assessors nominated for the assessment of their laboratories.

STEP 4 - ASSESSMENT OF LABORATORY

(i) An on-site assessment is undertaken at the laboratory.

NOTES : All key laboratory personnel shall be available for interview during the on-site assessment.
The laboratory may be asked to undertake typical tests as part of the assessment process.

(ii) On completion of the on-site assessment, the laboratory management is provided with an assessment report by the assessment team which includes

- the assessment team's recommendation regarding granting of accreditation for all or part of the list of tests sought by the applicant laboratory;
- list of any action which may be necessary before accreditation for all or any of the tests can be further considered;
- details of follow-up actions.

STEP 5 - ASSESSMENT OUTCOME

For reassessments and assessments for extension of scope of accreditation within a test category for which the laboratory is already accredited, the assessment report will normally be reviewed by HKAS Executive. Any amendment to the assessment report will be issued to the laboratory within 10 working days of the assessment.

For initial assessments for a test category or a major test area, the assessment report will be reviewed by HKAS Executive as well as Accreditation Advisory Board (AAB). The reviewed assessment results will be issued to the laboratory in an outcome letter.

In most cases, there are specific matters requiring attention before accreditation can be considered further, and these are listed in the assessment report or in the outcome letter.

STEP 6 - REMEDIAL ACTIONS (if required)

(i) On receipt of formal advice from an applicant laboratory that all required actions have been taken, the HKAS Executive will take follow-up action. If the matters are of a minor nature, remedial actions may be confirmed through submission of supporting documents or through a brief visit by a member of HKAS Executive and where necessary with an assessor, but in some cases, a further on-site assessment may be needed.

(ii) Assuming the remedial actions are found acceptable, a decision on granting of accreditation will normally follow. A formal notification letter and a certification of accreditation will be issued.

(iii) The laboratory may lodge an appeal to HKAS Executive against the decision made by HKAS Executive. (See Chapter 7 Complaints and Appeals in HKAS 002).

STEP 7 - AFTER ACCREDITATION

(i) After accreditation has been granted, laboratories are reassessed the following year and thereafter in accordance with a reassessment plan. Surveillance visits will also be conducted. The purpose is to ensure that the standards required for continued accreditation are being maintained.

(ii) Laboratories may seek to have their scope of accreditation extended or reduced or they may seek changes to their HOKLAS approved personnel. Such changes may require on-site assessment.

(iii) Laboratories are required from time to time to participate in proficiency testing programmes organised or specified by HKAS (where appropriate).

(iv) Laboratories are required under HKAS regulations to notify HKAS Executive immediately in writing of any changes in the laboratory's circumstances which may affect their continued compliance with HKAS regulations or HOKLAS requirements.

The following list, which is not exhaustive, gives examples of such changes:

(a) change in ownership or name of the accredited organisation including the change in legal, commercial or organisational status, e.g. mergers, company dissolution, bankruptcies, compulsory or voluntary liquidation or any other matters concerning the Official Receiver;

(b) change in its organisational structure and managerial staff;

(c) change of the approved personnel;

(d) change in the organisational policies, where relevant;

(e) change in its registered address or any premises of the organisation where accredited activities are to be carried out;

(f) change in working procedures and resources including personnel, equipment, facilities, working environment, where significant;

(g) change in the nature of the work performed by an accredited organisation; and,

(h) any other matters that may affect the organisation's capability, or its scope of accreditation or its conformity with the accreditation criteria.

CONFIDENTIALITY

HKAS Executive will keep confidential all information provided by an organisation in relation to preliminary enquiries or to an application for accreditation and all information obtained in connection with an assessment of an organisation, such that only personnel who require the information for the assessment will have access to such information. Such personnel will include HKAS Executive and staff, assessors involved in the assessment and members of AAB (except where a conflict of interest arises). Without written consent of the organisation, HKAS Executive will not disclose confidential information of an applicant or accredited organisation outside HKAS Executive except as allowed in HKAS 002 Regulations for HKAS Accreditation. However, an organisation shall note that it may be necessary to pass the HKAS's files, including any information in relation to it to persons responsible for evaluating the performance of HKAS under a mutual recognition arrangement which HKAS has concluded or intended to conclude with other accreditation bodies. HKAS will notify those persons the confidential nature of the information. Where the law requires any information to be disclosed to a third party, HKAS will, where possible and permitted by the law, inform the organisation concerned. Furthermore, HKAS will comply with the provisions under the Personal Data (Privacy) Ordinance (Cap. 486) and the rules under the Code on Access to Information of the Government.

Annex AB

(Informative)

Bibliography

Given below is a list of selected documents published by ISO, and international and regional laboratory accreditation cooperations, which are useful for laboratory operation. Some of the documents are available from their websites. Unless otherwise stated in other parts of this document, they are provided for information only and are not part of the accreditation criteria.

A. ISO

ISO 5725-1	Accuracy (trueness and precision) of measurement methods and results – Part 1: General principles and definitions
ISO 5725-2	Accuracy (trueness and precision) of measurement methods and results – Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method
ISO 5725-3	Accuracy (trueness and precision) of measurement methods and results – Part 3: Intermediate measures of the precision of a standard measurement method
ISO 5725-4	Accuracy (trueness and precision) of measurement methods and results – Part 4: Basic methods for the determination of the trueness of a standard measurement method
ISO 5725-5	Accuracy (trueness and precision) of measurement methods and results - Part 5: Alternative methods for the determination of the precision of a standard measurement method
ISO 5725-6	Accuracy (trueness and precision) of measurement methods and results – Part 6: Use in practice of accuracy values
ISO 9000	Quality management systems – Fundamentals and vocabulary
ISO 9001	Quality management systems – Requirements
ISO 10012	Measurement management systems – Requirements for measurement processes and measuring equipment
ISO/IEC 17011	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17043	Conformity assessment – General requirements for proficiency testing
ISO 19011	Guidelines for auditing management system
ISO Guide 30	Terms and definitions used in connection with reference materials
ISO Guide 31	Reference materials – Contents of certificates and labels
ISO Guide 33	Reference materials – Good practice in using reference materials
ISO Guide 34	General requirements for the competence of reference material producers
ISO Guide 35	Reference materials – General and statistical principles for certification
ISO/IEC Guide 98-3	Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement
ISO/IEC 98-3/Suppl 1	Propagation of distributions using a Monte Carlo method
ISO/IEC Guide 98-3/Suppl 2	Extension to any number of output quantities

B. International Laboratory Accreditation Cooperation (ILAC) (Website: www.ilac.org)

Guidance Series (G series)

ILAC G7:06/2009	Accreditation Requirements and Operating Criteria for Horseracing Laboratories
ILAC G8:03/2009	Guidelines on the Reporting of Compliance with Specification
ILAC G17:2002	Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
ILAC G18:04/2010	Guideline for the Formulation of Scopes of Accreditation for Laboratories
ILAC G19:08/2014	Modules in a Forensic Science Process
ILAC G21:09/2012	Cross Frontier Accreditation – Principles for Cooperation
ILAC G24:2007	Guidelines for the Determination of Calibration Intervals of Measuring instruments

Procedural Series (P series)

ILAC P5:10/2013	ILAC Mutual Recognition Arrangement (Arrangement)
ILAC P8:12/2012	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies
ILAC P9:06/2014	ILAC Policy for Participation in Proficiency Testing Activities
ILAC P10:01/2013	ILAC Policy on Traceability of Measurement Results
ILAC P13:10/2010	Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers
ILAC P14:01/2013	ILAC Policy for Uncertainty in Calibration

C. European Accreditation (EA)
(Website: www.european-accreditation.org)

EA-4/02 M:2013	Expressions of the Uncertainty of Measurements in Calibration
EA-4/09 G:2003	Accreditation for Sensory Testing Laboratories
EA-4/14 INF:2003	The Selection and Use of Reference Materials
EA-4/15 G:2002	Accreditation for Non-Destructive Testing
EA-4/16 G:2003	EA Guidelines on the Expression of Uncertainty in quantitative testing
EA-4/18 INF:2010	Guideline on the level and frequency of proficiency testing participation

D. Asia-Pacific Laboratory Accreditation Cooperation (APLAC)
(Website: www.aplac.org)

APLAC PT001	Calibration Interlaboratory Comparisons
APLAC PT002	Testing Interlaboratory Comparisons
APLAC PT003	Proficiency Testing Directory
APLAC PT005	Artefacts for Measurement Audits
APLAC PT006	Proficiency Testing Frequency Benchmarks
APLAC TC002	Internal Audits for Laboratories and Inspection Bodies
APLAC TC003	Management Review for Laboratories and Inspection Bodies
APLAC TC004	Method of Stating Test and Calibration Results and Compliance with Specification
APLAC TC005	Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing
APLAC TC007	Guidelines for Food Testing Laboratories
APLAC TC010	General Information on Uncertainty of Measurement
APLAC TC011	Why are these test results so different? The importance of testing methods in chemical and microbiological testing
APLAC TC012	Guidelines for acceptability of chemical reference materials and commercial chemicals for calibration of equipment used in chemical testing

Annex AC

(Informative)

Variations to ISO/IEC 17025:2005 for HOKLAS 003:2015

This Annex lists out all variations of this booklet to ISO/IEC 17025:2005 as follows:

Clause	**Modifications**
Forward	Replaced by 'HKAS Introduction' and i, ii, iii and iv under 'HKAS Introduction'.
4 Management requirements	Add 4.1.H 'HOKLAS Policy on Organisation'
	Add 4.2.H 'HOKLAS Policy on Management system'
	Add 4.4.H 'HOKLAS Policy on Review of requests, tenders and contracts'
	Add 4.5.H 'HOKLAS Policy on Subcontracting of tests and calibrations'
	Add 4.6.H 'HOKLAS Policy on Purchasing services and suppliers'
	Add 4.7.H 'HOKLAS Policy on Service to the customer
	Add 4.8.H 'HOKLAS Policy on Complaints'
	Add 4.9.H 'HOKLAS Policy on Control of nonconforming testing and/or calibration work'
	Add 4.11.H 'HOKLAS Policy on Corrective action'
	Add 4.12.H 'HOKLAS Policy on Preventive action'
	Add 4.13.H 'HOKLAS Policy on Control of records'
	Add 4.14.H 'HOKLAS Policy on Internal audits'
	Add 4.15.H 'HOKLAS Policy on Management reviews'
5 Technical requirements	Add 5.2.H 'HOKLAS Policy on Personnel'
	Add 5.3.H 'HOKLAS Policy on Accommodation and environmental conditions'
	Add 5.4.H 'HOKLAS Policy on Test and calibration methods and method validation'
	Add 5.5.H 'HOKLAS Policy on Equipment'
	Add 5.6.H 'HOKLAS Policy on Measurement traceability'
	Add 5.7.H 'HOKLAS Policy on Sampling
	Add 5.8.H 'HOKLAS Policy on Handling of test and calibration items'
	Add 5.9.H 'HOKLAS Policy on Assuring the quality of test and calibration results'
	Add 5.10.H 'HOKLAS Policy on Reporting the results'
Bibliography	Delete Bibliography of ISO/IEC 17025:2005
--	Add Annex AA 'Procedures for HOKLAS Accreditation'
--	Add Annex AB 'Bibliography'
--	Add Annex AC 'Variations to ISO/IEC 17025:2005 for HOKLAS 003:2015'

Explanation:

HOKLAS policies added serve as additional explanation of the requirements of ISO/IEC 17025:2005 and shall be regarded as mandatory under Hong Kong Laboratory Accreditation Scheme (HOKLAS).

Bibliography of this booklet (Annex AB) not only covers the bibliography of ISO/IEC 17025:2005, but also contains documents published international and regional laboratory accreditation cooperations, which are useful for laboratory operation.

Annex AC is an informative annex listing out all variations of this booklet to ISO/IEC 17025:2005.