

HOKLAS 015 (Fifth Edition)

Abridged Version

(Requirements and notes of ISO 15189 are not included in this document. This document should be read in conjunction with ISO 15189 : 2012)

Technical Criteria for Laboratory Accreditation (Medical Laboratories)

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1 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 to laboratories, certification bodies, inspection bodies, proficiency testing providers and reference material producers. It may offer other accreditation services in the future when the need arises.

The primary aims and objectives of HKAS are:

- (a) to upgrade the standard of conformity assessment services provided by conformity assessment bodies;
- (b) to identify and officially recognise competent conformity assessment bodies in Hong Kong;
- (c) to promote the acceptance of conformity assessment data from accredited conformity assessment bodies, both locally and internationally;
- (d) to establish mutual recognition agreements with overseas accreditation bodies; and
- (e) to eliminate the need for repetition of conformity assessment in the importing economies and thereby reducing costs and facilitating free trade across borders.

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, proficiency testing providers and reference material producers, the Hong Kong Certification Body Accreditation Scheme (HKCAS) for certification bodies and Greenhouse Gas (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 relevant international standard, i.e. ISO/IEC 17011 and other criteria set by relevant international and regional cooperations of accreditation bodies. Participation in the three schemes is voluntary.

Organisations applying for accreditation or 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 quality 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 Appendix A of this booklet. HKAS will grant accreditation for an activity to an organisation only when it meets the conditions given in 4.15 of HKAS 002 - Regulations for HKAS Accreditation.

1.1 Basis of HOKLAS Technical Criteria (Medical Laboratories) - ISO 15189:2012

This technical criteria booklet is applicable to all types of medical testing laboratories regardless of the number of personnel or the extent of the scope of examination. The requirements in this booklet are based on an international standard, ISO 15189:2012 – “Medical laboratories - Requirements for quality and competence”. This International Standard can be used by medical laboratories in developing their quality management systems and assessing their own competence. While it is intended for use throughout the currently recognised disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics could also find it useful and appropriate. This international standard is not intended to be used as the basis for certification of laboratories. It can be used for confirming or recognising the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

A medical laboratory’s fulfilment of the requirements of this international standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results. This standard continues the alignment established in ISO/IEC 17025:2005. The management system requirements in ISO 15189 (Section 4) are written in a language relevant to a medical laboratory’s operations and meet the principles of ISO 9001:2008, *Quality management systems — Requirements*, and are aligned with its pertinent requirements (Joint IAF-ILAC-ISO Communiqué issued in 2009).

In Sections 2 to 5 of this booklet, the normative references, terms and definitions, requirements and notes of ISO 15189:2012 are reproduced verbatim as the main text and relevant HOKLAS policies are given in shaded boxes following the main text. The notes provide clarification of the requirements, examples and guidance. A laboratory is considered to have met the requirements if it follows the guidance. HOKLAS policies serve as additional explanation of the requirements of ISO 15189:2012 and shall be regarded as mandatory.

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 (MRA) with other laboratory accreditation bodies. Signatories to the MRA recognise the equivalence of one another’s accreditation and accept the endorsed test reports and calibration certificates issued by their accredited organisations. HKAS has concluded MRA with accreditation bodies that are also signatories of the International Laboratory Accreditation Cooperation (ILAC) and Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement. The number of MRA partners is on the rise year by year. The up-to-date list of MRA signatories of APLAC and of ILAC is available on their respective websites.

This booklet sets out the specific management system and technical requirements which all HKAS accredited medical laboratories shall meet. Testing laboratories other than medical testing laboratories and proficiency testing providers shall meet the technical criteria given in HOKLAS 003 Technical Criteria for Laboratory Accreditation and HOKLAS 017 Technical Criteria for Accrediting Proficiency Testing Providers, 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 arrangement is adequate in meeting the requirements stated in criteria documents.

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

1.2 Scope of Accreditation - What activities may be accredited under HOKLAS?

Each laboratory accredited under HOKLAS will have the specific examinations, 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 Material Producers
- Textiles and Garments
- Testing Required by the China Compulsory Certification System (CCC)
- Toys and Children’s Products

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

Appendix B lists the disciplines under the test category of Medical Testing and the corresponding supplementary criteria.

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 in the additional examinations, 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, proficiency testing programmes and other appropriate means.

1.3 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.

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

2 Normative references

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

3 Terms and definitions

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4 Management requirements

4.1 Organisation and management responsibility

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.1.H HOKLAS Policy on Organisation and management responsibility

It is the responsibility of the laboratory to carry out its work in accordance with the relevant Laws and Regulations of Hong Kong.

Where a laboratory is part of a larger organisation, the organisational arrangements should be such that departments having conflicting interests, such as operation, commercial marketing or financial should not adversely influence the laboratory's compliance with the requirements of this document. The laboratory management shall have evidence in place to demonstrate its arrangement to ensure staff do not work under undue pressure that may affect the integrity and quality of their work.

A laboratory applies accreditation for its specimen collection centres shall demonstrate that those collection centres are under the same legal entity and management of the parent organisation. Laboratories operating at different sites from the main laboratory but under the same legal entity may be accredited as its branch facilities under the same accreditation.

The Laboratory Director, and divisional heads of each discipline in the case of large laboratories, shall have broad knowledge of medical and clinical laboratory sciences, and laboratory operation. They shall provide adequate supervision and have the ability to make critical evaluations of examination results. Detailed requirements on personnel are given in 5.1 of this document.

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

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 staff member shall be fully briefed or instructed. Adequate supervision shall be provided at each level of the staff structure to ensure close adherence to laboratory procedures and accepted techniques at all times.

There shall be clearly defined and recognisable lines of authority and responsibility within the organisation. All staff members shall be aware of both the extent and limitations of their own responsibilities. A concise organisation chart with names of key staff and number and rank of staff in respective test area should be documented (preferably in the quality manual, see also 4.2.2.2 c) showing the laboratory's overall organisation and lines of responsibilities.

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The technical management may be a designated technical manager or may comprise a number of designated technical managerial and supervising staff members, each of them responsible for a specified discipline or technical area. The responsibility of technical issues for all accredited activities shall be fully covered by the technical management.

The scope of responsibilities and authority of the Quality Manager shall be clearly defined and documented. The responsibilities of the Quality Manager or his/her designees shall include the following functions:

- (a) maintenance of the quality manual and associated operation documentation;
- (b) monitoring of laboratory practices to verify continuing compliance with documented policies and procedures;
- (c) ensuring instruments are calibrated and maintained according to schedules;
- (d) selection, training and evaluation of internal auditors; and
- (e) scheduling and coordination of internal audits and management reviews.

4.2 Quality management system

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.2.H HOKLAS Policy on Quality management system

The quality management system of a laboratory needs 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 quality system shall be developed as a working document for use by the laboratory 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 an 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 15189 : 2012)

4.3.H HOKLAS Policy on Document control

All controlled documents shall be reviewed, and revised if necessary, at least annually. Posted information and instructions related to test operations shall be considered as controlled documents. Other posted information and posters unrelated to test operations are recommended to be authorised for posting and reviewed periodically for continual suitability. Where a laboratory's document control system allows hand written amendments, a revised document shall normally be issued upon its annual review.

Laboratories shall note that all worksheets and record forms shall also be controlled under the document control system to maintain uniformity in the types of information to be recorded. Attention shall also be paid to controlled documents distributed for use at the branch and mobile facilities to ensure only the latest edition is being used at these sites.

4.4 Service agreements

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.4.H HOKLAS Policy on Service agreements

When reviewing service agreements, laboratories shall ensure that the examinations requested relate to the needs of customers for the intended purposes. As far as practicable, laboratories should give advice to customers and help them determine their needs. In cases samples would be further referred to another laboratory for confirmation or for supplementary tests, circumstances and/or conditions upon which such referral takes place shall be made known to the customers before they enter into service agreements. In this regard, the requirements in 4.7 of this document shall be met.

In the case where a laboratory is a part of a hospital and provides in-house services to the hospital, internal communication between user clinicians and the laboratory can be considered as the agreement and the requirements of this clause apply. The communication may be in the form of memorandum, manual, letter, emails, etc.

4.5 Examination by referral laboratories

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.5.H HOKLAS Policy on Examination by referral laboratories

Laboratories shall document, in the quality manual or other related documents, their policy and procedures for selecting and referring examinations to other laboratories and consultants. These examinations refer to repeat testing of a registered sample with the same method; for result confirmation with a second method; for testing on a registered sample by a test not routinely available in the laboratory or for secondary testing or opinions and/or interpretation of results. Where by structure (for instance, the relationship between a satellite laboratory and its parent laboratory) or by regulation that a sample has to be referred to a regulatory authority for confirmation or for secondary tests, such a laboratory is not considered as a referral laboratory (see definition and note under 3.23 referral laboratory). Nevertheless, the laboratory should state clearly in such a report that further examination has been performed by another specified laboratory as required.

For examinations carried out on a sample registered under the accredited laboratory, the referral laboratory should be accredited by HKAS, be a laboratory accredited under a scheme with which HKAS has a mutual recognition arrangement (MRA) for the examinations concerned; or where such accredited laboratories are not available, the referral laboratory should be reputable with demonstrated evidence of competency for the referred test. The referring laboratory shall be responsible to ensure the referral laboratories meet this requirement. The updated register to be maintained of all referral laboratories, and consultants from whom opinions are sought, shall include information on specific tests or type of tests that a particular referral laboratory or consultant is competent to perform.

Relevant regulations governing the subcontracting of work and reporting of results from subcontractors given in HOKLAS Supplementary Criteria No. 33 (Accreditation Regulations Specific for HOKLAS – Laboratory) are applicable to examinations by referral laboratories. HKAS will grant accreditation to a laboratory only for those activities that the laboratory itself is competent to carry out. When the referring laboratory is preparing the consolidated report with part of the results originated from it together with referral results, the laboratory shall clearly state which part of the results is performed by a referral laboratory.

Where a sample is intended to be examined by another laboratory, as requested by the clinicians of a hospital, or as indicated in a laboratory's service manual that the pathology laboratory serves as a distribution centre on behalf of the requester, there shall not be any statement on its accreditation status regarding such examination results.

4.6 External services and supplies

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.6.H HOKLAS Policy on External services and supplies

There are two commonly encountered situations where a laboratory needs to seek external 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 examination results. The records 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 source of supplies.

- (b) Purchase of equipment :

Separate records shall be kept for each manufacturer supplying major items of equipment. The records should include results of the acceptance tests and the subsequent maintenance history of their products. Manufacturers whose products consistently do not meet their stated performance specifications and/or show undesirably high proportion of instrument down time and/or are not supported by good after-sales service should be noted and their names removed from the list of acceptable suppliers.

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

4.7 Advisory services

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.7.H HOKLAS Policy on Advisory services

Laboratories shall ensure that the examinations requested relate to the needs of customers for the intended purposes. Advice regarding secondary or confirmatory testing shall be provided to the users as needed. There shall be documented communication between the laboratory and the users with regard to the quality of services provided and the advice provided by the laboratory. The users shall be advised on limitations of the tests, and circumstances and/or conditions where confirmatory or supplementary tests would aid in the interpretation of results. Please also refer to the requirements in 4.4 on service agreements.

4.8 Resolution of complaints

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.8.H HOKLAS Policy on Resolution of complaints

Laboratories shall note that when a complaint involving a HOKLAS accredited examination, or a HOKLAS endorsed examination report, is not satisfactorily resolved within 60 days from the date of receipt of the complaint, they are required to notify HKAS Executive the nature of the complaint immediately. HKAS undertakes to keep information provided confidential. Reference should be made to HKAS 002.

4.9 Identification and control of nonconformities

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.9.H HOKLAS Policy on Identification and control of nonconformities

It is important that laboratories address nonconformities identified properly. Laboratories should not only correct the immediate problem but shall initiate actions according to the requirements given in 4.9, which include a determination of whether the nonconforming work is an isolated incident or is due to some underlying causes with a possibility of recurrence. It should be emphasised that all laboratory personnel need to be familiar with the procedures for handling nonconforming work, particularly those involved directly with testing. Providing training to relevant staff on the procedures is essential. Internal audit should cover the effectiveness of implementation in this aspect.

4.10 Corrective action

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.10.H HOKLAS Policy on Corrective action

Corrective actions may be identified through internal audits, external assessments by accreditation bodies, customer and staff feedback and complaints, analysis of quality control data, performance in proficiency testing programmes, incidence of nonconforming work, etc. Corrective actions shall be evaluated, prioritised and implemented according to an agreed timescale. Their effectiveness shall be monitored. Some corrective actions may involve a number of staff members as well as more than one division of the laboratory. The Quality Manager or other designated staff members shall coordinate the work arising from such corrective actions.

It must be emphasised that corrections and corrective actions are different. ISO 9000:2005 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". 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 action for its elimination. The nonconformity should only be considered adequately addressed if the actions taken have 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.

4.11 Preventive action

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.11.H HOKLAS Policy on Preventive action

Preventive actions shall be taken against needed improvements and potential nonconformities. This highlights the need for identifying 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, instead of merely checking for conformities, internal audits should be more forward looking and oriented towards identifying areas of risks. Whenever an observation is identified in an audit, its level of risk should be assessed and suitable preventive actions recommended for preventing the occurrence of the nonconformities. In most cases, preventive actions should be commensurate with the level of risk as well as the consequence of the potential problem.

In addition, preventive actions may also be taken in response to staff or customer feedback and complaints.

4.12 Continual improvement

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.13 Control of records

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.13.H HOKLAS Policy on Control of records

In applying the criteria for this section, the following HOKLAS policies shall be noted :

- (a) Each laboratory shall maintain a record system designed to suit its particular requirements. The system shall be in compliance 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 examined specimen as received and the report which is eventually issued. This applies equally to computer and manual 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 system shall allow for ready retrieval of original observations and data pertinent to any issued report.
- (d) The record system shall include ready access to the following detailed information :
 - (i) full description of each sample examined;
 - (ii) identification of the examined sample;
 - (iii) identification of examination method used;
 - (iv) identification of equipment and reference materials used;
 - (v) original observations and calculations;
 - (vi) identification of persons performing the work;
 - (vii) a full copy of the issued report or certificate.

Original observations shall be recorded immediately into bound notebooks, or onto properly designed proforma worksheets. Where data processing systems are used, records of raw data shall be retained unless data are (electronically) fed directly into the processing system. Evidence of counterchecking data transcribed from recorded raw data shall be available.

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

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- (f) Errors in calculations and incorrect transfers of data are major causes of incorrect reports. Calculations and data transfers shall be checked and signed or initialled 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.

- (g) The minimum period for retention of original test data, laboratory records and HOKLAS endorsed reports has been set by HKAS Executive to be three years unless a longer period is specified by the regulatory authorities, or in the relevant HKAS or HOKLAS Supplementary Criteria, or other requirements such as the customer's instructions. The retention period of at least three years for equipment records and laboratory operation procedures shall be counted from the date on which the use of the equipment or the operation procedures has been discontinued. 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 Evaluation and audits

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.14.H HOKLAS Policy on Evaluation and audits

To solicit user feedback as required in 4.14.3 could be achieved in a number of ways, including but not limited to having annual customer feedback survey, holding regular customer liaison meetings or encouraging completion of readily available customer suggestion forms.

Laboratories are encouraged to take note of the examples of quality indicators given under 4.14.7 and in Note 1 and 2 for implementation and where measurable indicators are established, they shall be monitored.

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

4.15 Management review

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

4.15.H HOKLAS Policy on Management review

HOKLAS policy on management review is detailed in HKAS Supplementary Criteria No. 5. The required elements listed in HKAS Supplementary Criteria No. 5 are complementary to those required in ISO 15189:2012.

5 Technical requirements

5.1 Personnel

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.1.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 the skills of the laboratory's personnel.

The continuing training programmes shall be defined and annual refreshing training courses should be provided to staff. Staff are expected to be assessed at least annually for their competence in performing assigned managerial or technical tasks. Safety training shall be included as part of the training programme and documented. Competence shall be demonstrated by evidence of continuing practice and experience in the specialty, with documented participation in appropriate continuing professional development (CPD). CPD could be in the form of attending accredited courses, conferences and seminars, journal based learning, refereed publications, giving lectures, seminars, conference presentations, etc.

Four categories of personnel will be assessed. They are:-

- (a) Professional personnel responsible for providing clinical interpretations
- (b) Management personnel, including the Laboratory Director
- (c) Supervisory personnel
- (d) Technical personnel

Laboratory management shall ensure that any special requirements of legislation and regulations on personnel shall be met. Competency assessment of staff is normally conducted by respective supervisors. Evidence of satisfactory performance in EQAP and records of continuing medical education (CME) or continuing professional development (CPD) shall be considered as objective evidence of a laboratory director's continuing competence and effort made to keep abreast with technology advancement.

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

HOKLAS Policy on Professional Personnel Responsible for Giving Clinical Interpretation of Examination Results

Clinical interpretation of examination results are defined as opinions that are based on the examination results and made for the purpose of medical diagnosis or treatment of persons suffering from, or believe to be suffering from, any disease, injury or disability of mind or body. Such opinions also include those for the purpose of prevention of disease and the assessment of the health of a person.

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Laboratories fulfilling the specific requirements for professional staff may be accredited for providing clinical interpretation of examination results in reports.

The availability of pathologists to provide direct input to examinations will be delineated in the Scope of Accreditation of a laboratory. Personnel responsible for giving clinical interpretation of examination results shall have in-depth knowledge of the relevant disciplines. They shall comply with the competence requirements given in 5.1.2 of this document for the specialty areas they cover. The laboratory shall have effective procedures to ensure that responsible pathologists have sufficient understanding of the relevant specialty areas and an appreciation of the limits of their own knowledge in the context of the interpretations to be reported.

For specific disciplines, HOKLAS may specify the minimum qualification and experience requirements for such personnel in relevant HOKLAS Supplementary Criteria.

Generally, only qualified pathologists as defined by the Medical Council can provide clinical consultation and interpretation of examination results in the specialty areas where he/she is qualified. Trainee pathologists registered with the Hong Kong College of Pathologists who are undergoing formal training can also provide clinical consultation and interpretation, provided that they are under the direction and supervision of a qualified pathologist in that discipline. A system shall be in place to verify and cross-examine the clinical interpretation of examination results, if necessary.

An applicant laboratory may be required to provide a written confirmation letter from HKCPath that the nominated pathologist is qualified to provide the service for the scope of accreditation proposed by the laboratory.

The person who provides clinical consultation and interpretation may or may not be the Laboratory Director who takes the overall responsibility of the operation of the laboratory. However, person(s) providing clinical interpretation of examination results on his/her specialty area(s) shall have the authority to make decisions on the operations of the laboratories with respect to matters relating to his/her specialties.

Where giving such clinical interpretations are included in the proposed Scope of Accreditation, the assessment will include the evaluation of the responsible persons and the examination of relevant records and reports. The effectiveness of the training and appraisal system in ensuring that the responsible persons are competent will be critically evaluated. Approvals for signing HOKLAS endorsed reports containing clinical interpretations will be granted to those persons who are found to fulfil the relevant requirements.

The laboratory will be given a list of approved signatories of HOKLAS endorsed reports. Where the signatory is also approved for signing reports containing clinical interpretations, it will be stated. The responsibility for providing clinical interpretation of laboratory's examination results rests with those on the list and such responsibility cannot be delegated to other signatories not approved for giving clinical interpretation. The person giving the interpretation shall authorise the release of the report containing his/her clinical interpretation personally.

HKAS shall be informed of departure or changes in the availability of the persons approved for giving clinical interpretations as soon as possible. HKAS will take the necessary actions such as amendment of the Scope of Accreditation of the laboratory regarding the availability of clinical consultation and interpretation service, or suspension of the laboratory's accreditation, depending on the circumstances.

continued

HOKLAS Policy on Management and Supervisory Personnel

The need for management and supervisory personnel, including the Laboratory Director, and requirements for their qualifications and experience will be carefully examined during the assessment of each laboratory. Factors which will be considered include :

- (a) the size of the laboratory, the scope of examinations for which accreditation is required;
- (b) the technical complexity and nature of the work involved;
- (c) the frequency at which specific examinations or activities are 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.

Management personnel, including the Laboratory Director, shall have suitable qualifications and training, and have sufficient professional experience and ability to direct the operations of the laboratory, to supervise and train technical personnel and to accept responsibility for the implementation of the quality system. For a laboratory seeking accreditation for a wide range of complex tests and examinations, management personnel will be expected to be fellows or members of appropriate professional bodies.

Laboratory Director

The Pathologist / Biomedical Scientist Director who assumes the role of laboratory director as defined in ISO 15189 **and takes the overall responsibility** for the operation of the laboratory shall be a full-time staff member of the laboratory and shall be responsible for the overall operation, administration and quality service of the laboratory. The requirements for the Pathologist / Biomedical Scientist Director are related to the Scope of Accreditation of a laboratory. Laboratories with a pathologist as laboratory director will have **Category P (Directed by Pathologist)** stated on the accreditation certificate and "P" appended to the laboratory registration number. Laboratories with a biomedical scientist as laboratory director will have **Category S (Directed by Biomedical Scientist)** stated on the accreditation certificate and "S" appended to the laboratory registration number. For both categories of laboratories, if clinical input is required, the service shall be provided by a pathologist of the appropriate discipline, either as a full-time member of staff or as a consulting pathologist.

A qualified pathologist who directs a **Category P** laboratory shall be called the '**Pathologist Director**'. He/she is expected to be available to provide clinical input and consultation on examinations of his/her discipline when necessary.

Pathologist Directors are expected to comply with the Continuing Medical Education (CME) programme of the Hong Kong College of Pathologists.

A biomedical scientist who directs a **Category S** laboratory shall be called the '**Biomedical Scientist Director**'. Biomedical Scientist Directors of laboratories in the Category S shall meet one of the following set of requirements:

continued

- A. (i) a higher professional or academic qualification such as a doctoral degree in medical sciences or related subjects after obtaining a qualification by examination in medical sciences or related subjects accepted by the Medical Laboratory Technologists (MLT) Board for registration as Part I technologists, and
- (ii) at least 5 years of relevant medical testing experience, three of which shall be at a supervisory level.
- B. (i) a Master's degree (or equivalent qualifications) in medical sciences or related subjects after obtaining a qualification by examination in medical sciences or related subjects accepted by the Medical Laboratory Technologists (MLT) Board for registration as Part I technologists, and
- (ii) at least 8 years of relevant medical testing experience, three of which shall be at a senior supervisory level i.e. supervising a whole laboratory or a specific area of a discipline.
- C. (i) a Bachelor's degree in medical sciences or related subjects (related subjects include those which have been accepted by the Medical Laboratory Technologists (MLT) Board for registration as Part I technologists), and
- (ii) at least 15 years of relevant medical testing experience, seven of which shall be at a senior supervisory level i.e. supervising a whole laboratory or a specific area of a discipline.

Both C (i) and (ii) have to be acquired before 16 February 2004. A Biomedical Scientist Director who meets requirement (C) shall remain in the same accredited laboratory if he/she wishes to maintain the HOKLAS recognition as a qualified Biomedical Scientist Director.

All Biomedical Scientist Directors need to participate in documented continuing professional development programmes.

Under the legislation of the Hong Kong Special Administrative Region, all persons registered under the Medical Laboratory Technologists (Registration and Disciplinary Procedure) Regulations shall carry out their duties in accordance with the Code of Practice of the Medical Laboratory Technologists Board of Hong Kong. Notwithstanding this, it is recommended that laboratories without full-time pathologists engage a consulting pathologist. The assessment team of HKAS will decide for each case, the need for a full-time pathologist or the extent of coverage needed to be provided by a consulting pathologist.

The requirements for Laboratory Director will be subjected to continual review, taking into account the availability of educational opportunities, supply of personnel with appropriate qualifications and new professional qualifications developed and recognised in the future.

Academic degrees and working experience gained outside Hong Kong may be accepted if it can be proved that they are equivalent to the requirements given above.

continued

Supervisory personnel are senior technical personnel who shall have suitable qualifications and training, and have sufficient authority, skills and experience to train, and supervise technical personnel properly. They shall be Part I registered under the Hong Kong Medical Laboratory Technologists Board (or personnel with equivalent qualifications and exempted by the Supplementary Medical Professions Ordinance Cap. 359) and have at least one year post-Part I working experience in the areas for which they are responsible and shall have at least 3 years of relevant experience in the test areas. They shall demonstrate appropriate understanding of the technical areas for which they are responsible.

In assessing qualifications, both the relevant academic qualifications and professional experience will be examined in light of the range and type of work performed by the laboratory, as well as the complexity of the work and the precision required.

HOKLAS Policy on Technical Personnel

Technical personnel shall have suitable qualifications or training and have sufficient experience and ability to perform the work. Technical staff shall be registered with the Hong Kong Medical Laboratory Technologists Board (or personnel with equivalent qualifications and exempted by the Supplementary Medical Professions Ordinance Cap. 359). They may be asked to demonstrate specific techniques during an assessment of the laboratory.

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 examinations performed during training and competence assessment.

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

HKAS Executive may define minimum levels of technical qualifications and testing experience required for approval of laboratory personnel involved in specific technical disciplines.

HOKLAS Policy on Contracted Staff

When a laboratory uses contracted staff, irrespective of the duration of the contract and whether the contracted staff member is employed on a full-time or part-time basis, the laboratory shall ensure that the requirements for staff competence are met. Evaluation of the competence of contracted staff shall be carried out and records kept. Where necessary, training shall be provided, particularly with regard to those parts of the laboratory quality management system which are relevant to their assigned duties. Direct supervision may be required initially to ensure the contracted staff are competent to carry out their duties.

HOKLAS Policy on Approved Signatories for HOKLAS Endorsed Reports

HOKLAS endorsed reports shall be signed by an approved signatory. An approved signatory is a staff member nominated by the laboratory and subsequently assessed and approved by HKAS Executive to sign such reports.

continued

A person nominated for approved signatory shall be competent to make critical evaluation of the validity of examination results and spend sufficient time in the laboratory to enable him/her to make this evaluation, occupy a position in his/her organisation's staff structure that makes him/her responsible for the adequacy of such results and be fully aware of the requirements detailed in this document, HKAS 002, HOKLAS Supplementary Criteria No. 33 and relevant Supplementary Criteria.

Approvals may be limited to specific tests or examinations or may be granted for all tests and examinations for which the laboratory is accredited. Approvals may also be granted to sign reports containing clinical interpretation of examination results. As approvals are granted in the context of the work being performed in a particular laboratory, they shall not be considered as personal qualifications. Signatories approved for authorising release of reports with or without clinical interpretation of examination results shall note that the responsibility of approving the release of a result shall not be delegated to others.

Signatory approval may be granted to management personnel, provided that they have maintained sufficient contact with relevant techniques to allow them to critically evaluate the validity of test and examination 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;
Generally, the persons shall be
 - (i) qualified pathologists, including medically qualified persons with overseas qualifications in pathology by examination as recognised by the HKCPath;
or
 - (ii) registered pathologist trainees under supervision of a qualified pathologist;
or
 - (iii) Laboratory personnel with supervisory duties who are Part I registered under the Hong Kong Medical Laboratory Technologists Board (or personnel with equivalent qualifications and exempted by the Supplementary Medical Professions Ordinance Cap. 359) and have at least one year post-Part I working experience in the areas for which they are responsible and shall have at least 3 years of relevant experience in the test areas.
- (b) familiarity with technical procedures and awareness of the basic concepts behind the procedures and any limitations;
- (c) knowledge of the procedures for recording, reporting and checking results;
- (d) awareness of the needs for periodic recalibration of equipment;
- (e) awareness of the regulations and criteria of HKAS/HOKLAS, and particularly those related to reports.

continued

For specified disciplines e.g. cytogenetics, medically qualified persons who obtained Fellowship in an appropriate speciality such as obstetrics and gynaecology, paediatrics may be considered on a case by case basis. For details, please refer to the supplementary criteria of relevant disciplines. In case queries concerning the qualifications of a proposed signatory arise, it is the responsibility of the laboratory concerned to refer the matter to the appropriate bodies such as the Hong Kong College of Pathologists or the Medical Laboratory Technologists Board for advice and to provide further evidence to HKAS Executive for consideration.

Consulting pathologists

A consulting pathologist is a qualified pathologist who periodically visits a laboratory and provides specialist services. The service of a consulting pathologist is required when the Laboratory Director, or other staff members of the laboratory, (i) cannot provide the necessary clinical interpretation of examination results; or (ii) cannot provide clinical input and consultation for a particular specialty.

The consulting pathologist shall be qualified in the specialty area where he/she is providing clinical input and consultation. His/her responsibilities shall include inputs relating to his/her specialty such as the choice of tests, the examination procedures and the interpretation of examination results. The consulting pathologist shall have the authority to make decisions with respect to issues related to areas under his/her responsibilities. He/she shall have a clear understanding of the quality system and operation of the laboratory.

If the service of the consulting pathologist includes signing HOKLAS endorsed reports, he/she has to be a HOKLAS approved signatory and be fully aware of the requirements detailed in this document, HKAS 002 and HOKLAS Supplementary Criteria No. 33.

A formal and written arrangement between the laboratory and the consulting pathologist(s) shall be established. The arrangement shall ensure the following:

- (a) a close and effective working relationship between the Laboratory Director and consulting pathologist(s) is established;
- (b) advice and recommendations of the consulting pathologist(s) are being acted upon within an appropriate timeframe;
- (c) the frequency and duration of consultative visits are defined and appropriate to the volume and scope of work undertaken by the consulting pathologist(s). At a minimum, the consulting pathologist shall visit the laboratory once a month; and if the agreement is made between a group of pathologists of the same specialty area and the laboratory, one of the pathologists shall be nominated as the consulting pathologist of that specialty and pay regular visits to the laboratory; and the other pathologists are called service pathologists;
- (d) a written report shall be provided by the consulting pathologist on a quarterly basis. At a minimum, the report shall include the date and duration of each visit, topics and issues discussed, details of the interactions with laboratory staff, recommendations and advice given to the laboratory, etc.
- (e) the functions, roles and activities of the consulting pathologist as well as his/her authorities and responsibilities are clearly defined;

continued

- (f) the means by which the consulting pathologist can be contacted in cases when his/her advice is required urgently is established;
- (g) an effective system to allow the provision of clinical advice as well as signing of examination reports by the consulting pathologist within a timescale appropriate to the clinical situation is in place;
- (h) liabilities of the examination results and their interpretations are clearly defined.

5.2 Accommodation and environmental conditions

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.2.H HOKLAS Policy on Accommodation and environmental conditions

Accommodation and environmental condition requirements vary greatly depending on the nature of the samples to be examined or tested and the order of accuracy required of the examinations or tests. The laboratory and its personnel shall follow local and international biosafety requirements. Suitability of the accommodation and environmental conditions for a specific range of examinations and tests will be judged against how they affect :

- (a) the integrity of the samples tested or examined;
- (b) the performance of laboratory equipment;
- (c) the competent performance of laboratory staff;
- (d) compliance with the conditions set in test or examination methods;
- (e) safety of laboratory staff.

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

Sufficient storage space shall be available to retain samples for the required periods in conditions designed to maintain their integrity.

Factors of the environment that may affect the performance of equipment 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 may also be judged on how it affects 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 examination methods also specify features of the environment in which sample preparation, and examination should take place. Where environmental features such as temperature and humidity ranges, airflow rates, illumination levels, etc., are specified, these conditions must be met in the relevant testing, examination and sample preparation sections of the laboratory.

continued

Monitoring equipment such as thermometers, hygrometers, psychrometers, thermohygrographs and anemometers, shall be available and be operated over the relevant testing, examination and sample preparation period specified by the methods. The monitoring equipment itself may need to be calibrated in accordance with the equipment calibration schedules recommended 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.

For certain disciplines such as anatomical pathology and medical genetics, there are other specific requirements on accommodation and environmental conditions. Those requirements are stated in the relevant HOKLAS supplementary criteria.

When the examination involves radionuclides, considerations should be given for bench space, shield working space, storage, transportation, disposal and safety of staff performing the examination and others working around. Handling of these radioactive materials shall comply with the local regulations, and staff involved shall be adequately trained and their health situation be closely monitored and documented.

5.3 Laboratory equipment, reagents, and consumables

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.3.H HOKLAS Policy on Laboratory equipment, reagents, and consumables

In applying the criteria for this section, the following HOKLAS policies shall be noted :

- (a) Designated officers of the laboratory shall be assigned the responsibility for the management of equipment, including its calibration and maintenance.
- (b) Each item of equipment shall be uniquely identified. In most cases, assigning a unique identification number to each piece of equipment is necessary to eliminate confusion.
- (c) A system shall be in operation to alert laboratory staff the due dates of calibration, verification and maintenance for all items of equipment.
- (d) Where an instrument is sent to an external laboratory for calibration, consideration shall be given to the effect on routine operation due to the absence of that instrument.
- (e) HKAS Executive may require laboratories to submit copies of up-to-date calibration certificates issued by external calibration laboratories.
- (f) An autoanalyser or a **commercial** test kit shall be evaluated to confirm its suitability for the intended use before it is put into service. An evaluation report with details of the studies and conclusions shall be prepared. For any change of autoanalysers or commercial test kits used for any HOKLAS accredited tests, the evaluation report shall be provided to HKAS Executive for review before the analyser or test kit is put into service.

In applying the criteria for measurement traceability, the following HOKLAS policies shall be noted :

- (a) Not all items of equipment used need to be calibrated. Only those items of equipment having a significant effect on the accuracy or validity of the results need 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.

continued

- (b) Specific recommendations for calibration and re-calibration of selected items of equipment required by laboratories operating in the test categories for which HOKLAS accreditation is currently available have been set. These recommendations are given in HOKLAS Supplementary Criteria No. 2. Laboratories shall note that any recommendation on calibration, including re-calibration intervals, is given for guidance only. For any individual instrument, it is the responsibility of the laboratory to determine the appropriate calibration regime based on its application, construction, drift history, etc. It is not advisable to adopt the recommendations indiscriminately in lieu of detailed investigation. More detailed guidance on determining calibration requirements is given in the same Supplementary Criteria.
- (c) Where traceability to the International System of Units (SI) is required, the calibration shall be performed by a “competent calibration body”. The HKAS Executive accepts as evidence of traceability to SI units:
- (i) The Government of the HKSAR Standards and Calibration Laboratory;
 - (ii) National metrology institutes referred to in HOKLAS Supplementary Criteria No. 2.
 - (iii) Laboratories accredited under HOKLAS for the specific calibration services provided that the calibration results are documented in HOKLAS-endorsed calibration reports/certificates.
 - (iv) Calibration laboratories accredited by MRA Partners of HKAS for the relevant calibration, provided that the calibration results are documented in endorsed calibration reports/certificates of the respective accreditation body.
 - (v) Other specified calibration laboratories designated by HKAS Executive from time to time.
- (d) When the laboratory has demonstrated that traceability to the International System of Units (SI) is not technically possible or reasonable, it is the responsibility of the laboratory to choose a way to satisfy Clause 5.3.1.4 and to provide appropriate documented evidence.
- (e) 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 the calibration procedures do not demand specialised techniques which are outside the capabilities and experience of the laboratory staff. However, the uncertainty of calibration shall meet the requirements of the applications.
- (f) Many items of equipment are calibrated using reference materials to ensure traceability to the SI units or the appropriate measurement standards is an essential condition for the accuracy of results.

ISO 17511 describes the metrological traceability chain and calibration hierarchy of the reference materials and reference measurement procedures used in laboratory medicine. Laboratory medicine routinely provides results for 400 to 700 types of quantity. For most of these, the metrological traceability of the assigned value for a product calibrator stops after only one or two metrologically higher steps. Depending on the possibility of metrological traceability to SI and on the availability of various metrological levels of measurement procedures and calibrators, the following five levels of metrological traceability chain can be identified.

continued

- (i) A primary reference measurement procedure and one or more (certified) primary reference materials (used as calibrators) are available. These levels exist for 25 to 30 types of quantity having well defined components, e.g. some electrolytes, metabolites, steroid hormones, and some thyroid hormones. These types of quantity cover a large proportion of the routine results provided by medical laboratories.
- (ii) An international conventional reference measurement procedure and one or more international conventional calibration materials with values assigned by that procedure are available. These conditions apply for quantities with components such as HbA1c.
- (iii) An international conventional reference measurement procedure is available but no international conventional calibration materials. These conditions apply for about 30 types of quantity with components such as haemostatic factors.
- (iv) One or more international conventional calibration materials (used as calibrators) with a protocol for value assignment are available, but no international conventional reference measurement procedure. These conditions apply for over 300 types of quantity, e.g., for quantities referred to World Health Organisation's International Standards, such as protein hormones, some antibodies, and tumour markers.
- (v) Neither reference measurement procedure nor reference materials for calibration are available. The manufacturer can establish in-house measurement procedure(s) and calibrator(s) to support value assignment to his product calibrator. These conditions apply for about 300 types of quantity with components such as tumour markers and antibodies.

The Joint Committee for Traceability in Laboratory Medicine (JCTLM) has published three lists of higher order reference materials and reference measurement procedures.

Certified reference materials and reference measurement procedures for well-defined chemical entities with determined values traceable to SI units, or internationally recognised reference procedure-defined measurands are placed in List I. Example entries to List I are electrolytes, enzymes, drugs, metabolites and substrates, non-peptide hormones, and some proteins.

Reference materials that are value-assigned using an internationally agreed upon protocol such as WHO reference materials for Blood Typing, Coagulation Factors, Microbial Serology, Nucleic Acids and some Proteins, are placed in List II. The values of the measurands in the reference materials on List II are not SI-traceable and/or no internationally-recognised reference measurement procedures exist that are applicable to patient samples. List II also contains a group of purified substances which, due to the absence of reference measurement procedures, should not be directly used for calibration of routine methods unless commutability is established and/or matrix effect independent internationally recognised standardised value transfer protocols to commutable samples are applied.

List III are certified reference materials for nominal properties such as prothrombin fragment. The lists, which will be updated regularly, can be accessed at www.bipm.org or www.ifcc.org.

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Laboratories are expected to use, as far as possible, manufacturer's product calibrators or other calibrators with demonstrable traceability to the reference materials or reference measurement procedures given on the JCTLM lists.

Reference cultures in microbiology

To establish traceability in microbiology laboratories, laboratories must hold and maintain a collection of cultures of organisms required to perform verification checks on methods and to conduct performance checks on batches of media prepared. Cultures used by laboratories must be traceable to a recognised culture collection such as American Type Culture Collection (ATCC), National Collection of Type Culture (NCTC), etc. Additional wild strains (e.g. isolates from samples) may only be used to supplement reference strains, but not to replace them.

- (g) The requirement for measurement traceability is not applicable to laboratories when the calibration contributes little to the total uncertainty of the examination result. 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 laboratory which need not satisfy the criteria as defined in 5.3.H(c)(i) to (v) but which should be competent.
- (h) Designated officers of the laboratory shall be assigned the responsibility for the calibration of equipment and management of reference materials and reference cultures.
- (i) Where an external calibration laboratory is used, the laboratory shall also be informed of the calibration requirements, including the ranges, the cardinal points, the required calibration uncertainties and the conditions under which calibrations are to be performed.

5.4 Pre-examination processes

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.4.H HOKLAS Policy on Pre-examination processes

Both the examination request document and the specimen submitted shall bear at least two identifiers. One of the identifiers shall be the name of the patient, or the number of his/her identity document, such as identity card or passport number.

A laboratory shall define a list of time critical tests which sample collection time must be available. The laboratory shall also have a documented procedure on the actions to be taken when sample collection time is not available for these time critical tests.

5.5 Examination processes

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.5.H HOKLAS Policy on Examination processes

For certain examinations, due to their nature, accreditation will only be granted when clinical interpretation of examination results is also provided. Examples of these types of examination are given in relevant HOKLAS Supplementary Criteria.

Biological reference intervals shall be validated by a laboratory before being adopted for routine use. Their original source shall be documented.

5.6 Ensuring quality of examination results

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.6.H HOKLAS Policy on Ensuring quality of examination results

Each HOKLAS accredited laboratory shall adopt an appropriate set of quality control procedures suitable to the range of work done and to 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 standard specifies a quality control procedure, it shall be followed.

The laboratory shall participate in at least one proficiency testing programme annually for each discipline. The programme(s) shall cover all accredited test areas in each discipline. Specific requirements, if any, for each discipline are given in the respective HOKLAS Supplementary Criteria. Generally, laboratories shall perform the examinations and report the results to the organisers for all rounds of the programmes for all examinations that are within the Scopes of Accreditation of the laboratories.

When developing new examination procedures, the laboratory shall consider carefully their quality control requirements. This should be documented as part of the quality assurance plan for those examination procedures. 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. The quality control plan, together with the acceptable criteria and actions to be taken in out of control situations, shall be documented. Quality control plans shall include, where relevant, the use of control samples (positive and/or negative, relevant levels), duplicates, blanks, spikes, etc. Control samples shall be of a similar matrix as the patient samples. Correlation of results in a sample shall be reviewed, where relevant.

5.7 Post-examination processes

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.7 HOKLAS Policy on Post-examination processes

Processed samples should be properly stored for a period specified by the quality system before disposal to allow easy retrieval in case of need, such as for confirmation of patient's information displayed on the primary sample. When samples are disposal of, care shall be taken to protect patient's confidential information.

5.8 Reporting of results

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.8.H HOKLAS Policy on Reporting of results

Laboratories should report results of normal controls when they are necessary for the proper interpretations of the examination results.

There shall be established protocol to review clinically significant examination results. Moreover, there shall be a hierarchical method of review of examination results, that is, a sequential review of the same specimen, when indicated, by individuals with increasing levels of experience and/or responsibilities. Evidence of such activities shall be recorded.

For services accredited for performing examinations only, the laboratory shall fully understand its limitation. It shall, where necessary, state on the report that clinical interpretation by a qualified pathologist is recommended.

Where possible and relevant, age- and sex-specific biological reference intervals should be provided in the report. When they are relevant but not provided on the test reports, appropriate comments should be provided on the reports. Generally, such reference intervals shall be validated or established by the laboratory. If a reference interval study is not possible or practical, then the laboratory shall carefully evaluate the use of published data or data provided by the equipment manufacturer for its own reference intervals, and retain record of this evaluation. The number of significant figures used for reporting a test result shall match the measurement uncertainty of the result.

Laboratories shall note the following in addition to the criteria specified in 5.8:

- (a) Numerical expression of results and rounding of numbers

Laboratories are advised to obtain a copy of 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 by the customer in writing, however, it is the responsibility of the laboratory to point out any risk of such methods.

- (c) The following are applicable specifically to HOKLAS endorsed reports :

- (i) All HOKLAS endorsed reports shall also comply with the regulations detailed in HKAS 002, 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.

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(d) Reports containing results from referral laboratories

The HOKLAS regulations governing the reporting of results from subcontractors apply also to referral laboratories and are detailed in HOKLAS Supplementary Criteria No. 33.

5.9 Release of results

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.9 HOKLAS Policy on Release of results

For results that are automatically selected and reported by comparing them with a set of laboratory-defined acceptance criteria, the set of criteria shall be determined and subject to periodic review and checked by a signatory approved for authorising reports in that area.

5.10 Laboratory information management

(The main text of this clause is the text of the same clause of ISO 15189 : 2012)

5.10 HOKLAS Policy on Laboratory information management

The laboratory shall pay particular attention to protection of patient confidentiality if patient reports could be transmitted via internet. Storage of patient database with confidential information on standalone computers with accessibility to internet is not recommended. There shall be a system to verify correct data transmission and proper functioning after computer downtime or maintenance.

Annex A

Appendices

Appendix A

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

- A. A laboratory interested in seeking accreditation contacts HKAS Executive in writing.
- B. Appropriate documentation is provided to the laboratory including :
 - HKAS 002 Regulations for HKAS Accreditation
 - HOKLAS 005 Application Form for Laboratory Accreditation
 - HOKLAS 006 Schedule of Accreditation Fees for Hong Kong Laboratories
 - HOKLAS 015 Technical Criteria for Laboratory Accreditation (Medical Laboratories)
 - HOKLAS 016 Application Questionnaire (Medical Laboratories)
 - HOKLAS 021 General checklist for HOKLAS Supplementary Criteria for Medical Laboratories

Relevant HKAS and HOKLAS Supplementary Criteria
- C. 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 016)
 - (c) General checklist for HOKLAS Supplementary Criteria for Medical Laboratories (HOKLAS 021)

- (d) Checklist attached as annex to each relevant HOKLAS Supplementary Criteria (SC-23 to SC-30, SC-35);
- (e) The documents specified in the Application Questionnaire
- (f) Appropriate application fees as stated in HOKLAS 006

STEP 2 - PRELIMINARY ADVICE TO LABORATORY

- A. Following examination of the documentation submitted by the laboratory, HKAS Executive arranges a pre-assessment visit to :
 - (a) Answer any questions relating to technical criteria and regulations.
 - (b) Advise on any obvious improvements to existing practice necessary.
 - (c) Advise on probable calibration requirements for the tests for which accreditation is being sought.
 - (d) Comment on the acceptability of the laboratory's quality manual.

STEP 3 - PREPARATION FOR ASSESSMENT

- A. The laboratory submits the final copies of its quality manual and test procedures.
- B. HKAS Executive seeks any further information required from the laboratory.
- C. HKAS Executive selects suitable expert assessors to undertake on-site assessment of the laboratory.
- D. 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

- A. 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.

- B. On completion of the on-site assessment, the laboratory management is provided with an assessment report by the assessment team which
 - (a) includes the assessment team's recommendation regarding granting of accreditation for all or part of the list of tests sought by the applicant laboratory;
 - (b) lists any action which may be necessary before accreditation for all or any of the tests can be further considered;
 - (c) details follow-up action.

STEP 5 - ADVICE OF ASSESSMENT OUTCOME

Generally, for reassessments and assessments for extension of accreditation within a test category for which the laboratory is already accredited, the assessment report will 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 assessment or extension of scope to a new test category, the assessment report will be reviewed by HKAS Executive as well as AAB. The reviewed assessment results will be issued to the laboratory in an outcome letter.

In most cases, there are specific matters requiring attention by the laboratory 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)

- A. On receipt of formal advice from an applicant laboratory that all required actions have been taken, HKAS Executive will take the necessary follow-up action. If the matters are of a minor nature, corrective 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.
- B. Assuming the remedial actions are found acceptable, a recommendation for accreditation will normally follow. A formal notification letter and a certificate of accreditation will be issued.

- C. 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

- A. After accreditation has been granted, laboratories are reassessed the following year and thereafter at intervals not exceeding two years. Surveillance visits will also be conducted. The purpose is to ensure that the standards required for continued accreditation are being maintained.
- B. Laboratories may seek to have their scope of accreditation extended or reduced or they may seek changes to their HOKLAS approved signatories. Such changes may require on-site assessment.
- C. Laboratories are required from time to time to participate in proficiency testing programmes organised or specified by HKAS (where appropriate).
- D. Laboratories are required under HOKLAS regulations to notify HKAS Executive immediately in writing of any changes in the laboratory's circumstances which may affect their continued compliance with 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 dissolutions, 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 signatories;
- (d) change in the organisational policies, where relevant;
- (e) change in its registered address or any place where the 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 compliance 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, 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/agreement 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.

Appendix B

DISCIPLINES UNDER THE TEST CATEGORY OF MEDICAL TESTING

HOKLAS accreditation is currently available in six disciplines under the test category of Medical Testing. Additional discipline may be added as the system develops. Technical criteria given in HOKLAS 015 - Technical Criteria for Laboratory Accreditation (Medical Laboratories) are applicable to all disciplines under the Medical Testing test category. Technical criteria for other test categories are given in HOKLAS 003 and HOKLAS 017, respectively.

Accreditation is currently available for the following six disciplines:

- 1. Anatomical Pathology**
 - 1.1 Hospital Autopsy**
 - 1.2 Cytopathology**
 - 1.3 Histopathology**
- 2. Chemical Pathology**
- 3. Clinical Microbiology and Infection**
- 4. Haematology**
- 5. Immunology**
- 6. Medical Genetics**
 - 6.1 Cytogenetics**
 - 6.2 Molecular Genetics**

Specific criteria related to these disciplines are detailed in the corresponding supplementary criteria as listed below:

Supplementary Criteria No. 23 on Hospital Autopsy
Supplementary Criteria No. 24 on Cytopathology
Supplementary Criteria No. 25 on Histopathology
Supplementary Criteria No. 26 on Chemical Pathology
Supplementary Criteria No. 27 on Clinical Microbiology and Infection
Supplementary Criteria No. 28 on Haematology
Supplementary Criteria No. 29 on Immunology
Supplementary Criteria No. 30 on Molecular Genetics
Supplementary Criteria No. 32 on Validation of Biological Reference Intervals from Other Sources
Supplementary Criteria No. 35 on Cytogenetics
Supplementary Criteria No. 38 on Evaluating Automated Analysers

Examples of typical expressions of the “Scope of Accreditation” are shown in the HOKLAS Directory of Accredited Laboratories published in the HKAS website <http://www.hkas.gov.hk/>.

Appendix C

(Informative)

SELECTED PUBLICATIONS OF LABORATORY ACCREDITATION COOPERATIONS

Documents useful to laboratory operation are published by international and regional laboratory accreditation cooperations. The following is a selected list of such documents. For further information, please visit their internet 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. International Laboratory Accreditation Cooperation (ILAC) (Website : www.ilac.org)

Guidance Series (G series)

ILAC G3 : 08/2012	Guidelines for Training Courses for Assessors Used by Accreditation Bodies
ILAC G8 : 03/2009	Guidelines on the Reporting of Compliance with Specification
ILAC G9 : 2005	Guidelines for the Selection and Use of Reference Materials
ILAC G11 : 07/2006	Guidelines on Assessor Qualification and Competence of Assessors and Technical Experts
ILAC G12 : 2000	Guidelines for the Requirements for the Competence of Reference Materials Producers
ILAC G13 : 08/2007	Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
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 : 2002	Guidelines for Forensic Science Laboratories
ILAC G20 : 2002	Guidelines on Grading of Non-conformities
ILAC G21 : 09/2012	Cross Frontier Accreditation – Principles for Cooperation
ILAC G22 : 2004	Use of Proficiency Testing as a Tool for Accreditation in Testing

ILAC G24 : 2007	Guidelines for the determination of calibration intervals of measuring instruments
ILAC-G25:01/2012	Accreditation of Proficiency Testing Providers to ISO/IEC 17043:2010 - A crosswalk to ILAC G13:2007
ILAC-G26:07/2012	Guidance for the Implementation of a Medical Laboratory Accreditation System

Procedural Series (P series)

ILAC-P8 : 07/2006	ILAC Mutual Recognition Arrangement (Arrangement):Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories
ILAC-P9 : 11/2010	ILAC Policy for Participation in Proficiency Testing Activities
ILAC-P10 : 01/2013	ILAC Policy on Traceability of Measurement Results

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

APLAC PT001	APLAC Calibration Interlaboratory Comparisons
APLAC PT002	APLAC Testing Interlaboratory Comparisons
APLAC PT003	APLAC Proficiency Testing Directory
APLAC PT006	Proficiency Testing Frequency Benchmarks
APLAC TC002	APLAC Internal Audits for Laboratories and Inspection Bodies
APLAC TC003	APLAC Management Review for Laboratories and Inspection Bodies
APLAC TC004	APLAC 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 TC010	General Information on Uncertainty of Measurement

Useful information can also be found at the following websites:

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

Inter American Accreditation Cooperation (IAAC): www.iaac.org.mx

Annex B

(informative)

Correlation with ISO 9001:2008 and ISO/IEC 17025:2005

(The main text of this annex is essentially the same text of the Annex of ISO 15189 : 2012)

Annex C

(informative)

Comparison of ISO 15189:2007 to ISO 15189:2012

(The main text of this annex is essentially the same text of the Annex of ISO 15189 : 2012)

Bibliography

(The references listed under this section are essentially the same as those listed in ISO 15189 : 2012)