HKAS Policy Document No. 2

HKAS Policy for Accreditation of Laboratories according to ISO 15189:2022 under HOKLAS (ISO 15189:2022 HOKLAS Policy)

Introduction

This document provides HKAS policy for accreditation of laboratories according to ISO 15189:2022 under the Hong Kong Laboratory Accreditation Scheme (HOKLAS). This document contains policy that serves as additional explanation of the requirements of ISO 15189:2022 and is mandatory. This document shall therefore be read in conjunction with ISO 15189:2022. More detailed requirements specific to certain administrative aspects and technical disciplines are issued as individual HKAS and HOKLAS Supplementary Criteria.

1 Scope

(No additional explanation)

2 Normative reference

(No additional explanation)

3 Terms and definition

(No additional explanation)

4 General requirements

4.1 Impartiality

(No additional explanation)

4.2 Confidentiality

(No additional explanation)

4.3 Requirements regarding patients

(No additional explanation)

5 Structural requirements

5.1 Legal entity

A laboratory applies accreditation for its specimen collection centres shall demonstrate that those collection centres are of the same legal entity as the laboratory. Laboratories operating at different sites from the main laboratory but of the same legal entity may be accredited as its branch facilities under the same accreditation. (ISO 15189:2022 Cl 5.1)

5.2 Laboratory director

(a) HOKLAS Policy on Laboratory Director (ISO 15189:2022 Cl 5.2.1)

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 its overall operation, administration and quality of service. The requirements for the Pathologist / Biomedical Scientist Director are related to the Scope of Accreditation of a laboratory. Laboratories with a pathologist as the 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 the 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.

A qualified pathologist (as advised by the Hong Kong College of Pathologists) 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 Category S shall meet one of the following set of requirements:

(A) (i) a higher professional or academic qualification such as a doctoral degree in medical sciences or related subjects and 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 five 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 and 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 eight years of relevant medical testing experience, three of which shall be at a supervisory level.

(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 supervisory level.

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. Requirement (C) shall be revoked on 16 February 2024. A Biomedical Scientist Director who meets requirement (C) and has been accepted as the laboratory director of an accredited laboratory before 16 February 2024 can still be recognised as a qualified Biomedical Scientist Director as long as he / she remains in the same accredited laboratory.

All Biomedical Scientist Directors need to participate in documented continuing professional development programmes endorsed by the MLT Board.

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.

5.3 Laboratory activities

(No additional explanation)

5.4 Structure and authority

(No additional explanation)

5.5 Objectives and policies

(No additional explanation)

5.6 Risk management

(No additional explanation)

6 Resource requirements

6.1 General

(No additional explanation)

6.2 Personnel

(a) HOKLAS Policy on Professional Personnel Responsible for Giving Clinical Interpretation of Examination Results (ISO 15189:2022 Cl 6.2.2)

Clinical interpretation of examination results is 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. 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 indicated 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 6.2.2 of ISO 15189:2022 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 Hong Kong Academy of Medicine 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 the 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.

(b) HOKLAS Policy on Consulting Pathologists (ISO 15189:2022 Cl 6.2.2)

A consulting pathologist is a qualified pathologist who periodically visits a laboratory and provides specialist services. The laboratory shall engage a consulting pathologist when there is no full-time pathologist in-house to provide the necessary clinical input, consultation and interpretation of results for accredited examinations under a particular discipline.

The consulting pathologist shall be a qualified pathologist 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 relevant requirements.

A formal and written arrangement between the laboratory and the

consulting pathologist(s) shall be established. The arrangement shall ensure the following:

(i) a close and effective working relationship between the Laboratory Director and consulting pathologist(s) is established;
(ii) advice and recommendations of the consulting pathologist(s) are being acted upon within an appropriate timeframe;
(iii) 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 meet with laboratory staff once a month and visit the laboratory physically once every three months; 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;
(iv) 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.
(v) the functions, roles and activities of the consulting pathologist as well as his/her authorities and responsibilities are clearly defined;
(vi) the means by which the consulting pathologist can be contacted in cases when his/her advice is required urgently is established;
(vii) 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;
(viii) liabilities of the examination results and their interpretations are clearly defined.

(c) HOKLAS Policy on Approved Signatories for HOKLAS Endorsed Reports (ISO 15189:2022 Cl 6.2.2)

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.

A person nominated for signatory approval 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:

(i) qualifications and experience;

Generally, the persons shall be

1. qualified pathologists, including medically qualified persons with overseas qualifications in pathology by examination as recognised by the HKCPath; or

2. registered pathologist trainees under supervision of a qualified pathologist; or

3. 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.

(ii) familiarity with technical procedures and awareness of the basic concepts behind the procedures and any limitations;

(iii) knowledge of the procedures for recording, reporting and checking results;

(iv) awareness of the needs for periodic recalibration of equipment;

(v) awareness of the regulations and criteria of HKAS/HOKLAS, and particularly those related to reports.

For specified disciplines e.g. cytogenetics, medically qualified persons who obtained Fellowship in an appropriate specialty 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.

(d) Staff are expected to be assessed at least annually for their competence in performing assigned 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) programmes. CPD could be in the form of attending training courses, conferences and seminars, journal based learning, refereed publications, giving lectures, seminars, conference presentations, etc. (ISO 15189:2022 Cl 6.2.4)

6.3 Facilities and environmental conditions

(a) The laboratory and its personnel shall follow local and international biosafety requirements. (ISO 15189:2022 Cl 6.3.1)

(b) 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. (ISO 15189:2022 Cl 6.3.2)

(c) 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. (ISO 15189:2022 Cl 6.3.4)

6.4 Equipment

(No additional explanation)

6.5 Equipment calibration and metrological traceability

(a) 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.

(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. (ISO 15189:2022 Cl 6.5.3)

(b) 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.

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. (ISO 15189:2022 Cl 6.5.3)

(c) 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. (ISO 15189:2022 Cl 6.5.3)

(d) 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 competent laboratory. (ISO 15189:2022 Cl 6.5.3)

6.6 Reagents and consumables

(No additional explanation)

6.7 Service agreements

(a) 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. (ISO 15189:2022 Cl 6.7.1)

(b) 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. (ISO 15189:2022 Cl 6.7.1)

6.8 Externally provided products and services

(a) 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. (ISO 15189:2022 Cl 6.8.2)

(b) 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. (ISO 15189:2022 Cl 6.8.2)

7 Process requirements

7.1 General

(No additional explanation)

7.2 Pre-examination processes

(a) 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. (ISO 15189:2022 Cl 7.2.4.4)

(b) 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. (ISO 15189:2022 Cl 7.2.4.4)

7.3 Examination processes

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. (ISO 15189:2022 Cl 7.3.7.3)

7.4 Post-examination processes

(No additional explanation)

7.5 Nonconforming work

Please refer to Clause 8.7 of this document.

7.6 Control of data and information management

(No additional explanation)

7.7 Complaints

(No additional explanation)

7.8 Continuity and emergency preparedness planning

(No additional explanation)

8 Management system requirements

8.1 General Requirements

(No additional explanation)

8.2 Management system documentation

(No additional explanation)

8.3 Control of management system documents

All controlled documents shall be reviewed, and revised if necessary, at least once every 12 months. 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. (ISO 15189:2022 Cl 8.3.2)

8.4 Control of records

The minimum period for retention of original test data, laboratory records and HOKLAS endorsed reports has been set by HKAS Executive to be four 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 four 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 four years for personnel records shall be counted from the date of departure of the staff member concerned. (ISO 15189:2022 Cl 8.4.3)

8.5 Actions to address risks and opportunities for improvement

(No additional explanation)

8.6 Improvement

(No additional explanation)

8.7 Nonconformities and corrective actions

(No additional explanation)

8.8 Evaluations

(a) The cycle for internal audit should be completed in 12 months. (ISO 15189:2022 Cl 8.8.3.1)

(b) Personnel conducting internal audit shall be trained in the techniques of auditing and shall have the knowledge of the activities to be audited. The personnel shall, wherever resources permit, be independent of the activity to be audited. The records of training, supervision and authorisation of the personnel conducting internal audit shall be retained. (ISO 15189:2022 Cl 8.8.3.2)

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

assessment visit. (ISO 15189:2022 Cl 8.8.3.2)

(d) The records of audit shall include name(s) of auditor, date(s) and type(s) of audit, area(s) audited, details of aspects examined (even where no nonconformities were observed), nonconformities observed or recommendations for improvement, linked to references to relevant documents, underlying cause(s) of the nonconformities, corrective action agreed, time frame agreed for completion, and the person responsible for carrying out the action, date of confirmation of completion of corrective action and signature of the responsible person confirming that the corrective action has been completed and recommending whether or not discussion for preventive action is necessary. (ISO 15189:2022 Cl 8.8.3.2)

8.9 Management reviews

(a) The interval between management reviews should be no greater than 12 months; however, shorter intervals should be adopted when a management system is being established. (ISO 15189:2022 Cl 8.9.1)

(b) There shall be clear indications in the records for outputs of management review of the actions to be taken, by whom and by what date. (ISO 15189:2022 Cl 8.9.3)