HOKLAS 015 (First Edition)

Technical Criteria for Laboratory Accreditation (Medical Laboratories)

Hong Kong Accreditation Service
June 2003

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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 for laboratories, certification bodies and inspection bodies. It may offer other accreditation services in the future when the need arises.

The principal aims and objectives of HKAS are :-

- to upgrade the standard of conformity assessment services provided by laboratories, certification bodies and inspection bodies;
- to identify and officially recognize competent conformity assessment bodies in Hong Kong; and
- to promote the acceptance of conformity assessment data from accredited conformity assessment bodies, both locally and internationally.

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, including the accreditation schemes undertaken by HKAS. At present, there are three schemes: the Hong Kong Laboratory Accreditation Scheme (HOKLAS) for laboratories, the Hong Kong Certific3ation Body Accreditation Scheme (HKCAS) for certification bodies and the Hong Kong Inspection Body Accreditation Scheme (HKIAS) for inspection bodies. Participation in the three schemes is voluntary.

Organisations which are applying to be accredited or have been accredited under any of the three schemes are required to demonstrate that :-

- they are competent in the performance of specific activities for which they are applying for accreditation or have been accredited;

- they have implemented an effective quality system which is in compliance with the accreditation criteria as required under the relevant scheme; and

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

The procedures for seeking HOKLAS accreditation and for processing applications are detailed in Appendix A of this booklet.

1.1 Basis of HOKLAS Technical Criteria (Medical Laboratories) - ISO 15189:2003

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 15189:2003 – "Medical laboratories - Particular requirements for the quality and competence". This standard is based upon ISO/IEC 17025:1999 and ISO 9001:2000, and was published by ISO for use by medical laboratories wishing to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results. The standard is also for use by laboratory accreditation bodies.

In Sections 4 and 5 of this document, the requirements and notes of ISO 15189:2003 are reproduced as the main text and relevant HOKLAS policy is given in shaded boxes following the main text. The notes provide clarification of the requirements, examples and guidance. HOKLAS will consider that a laboratory has met the requirements if it follows the guidance. The reference documents referred to in the HOKLAS policy are given for information only. They are not part of the HOKLAS policy unless explicitly stated as such.

The use of an international standard for recognising competence has led to increased confidence in testing and calibration laboratories and facilitated the acceptance of test results by authorities around the world. In this respect, HOKLAS has established a number of mutual recognition agreements/arrangements (MRA) with other laboratory accreditation bodies. Signatories to the MRA recognise the equivalence of one another's accreditation and accept endorsed test and calibration certificates issued. As at April 2003, HKAS has concluded MRA with 44 accreditation bodies in 35 economies. MRAs with other laboratory accreditation bodies are being arranged. A list of HKAS MRA partners and their contact information are available from the HKAS website at http://www.info.gov.hk/itc/hkas. New agreements will be negotiated from time to time.

This document sets out the specific quality management system and technical requirements which all HOKLAS accredited medical laboratories must meet. Testing laboratories other than medical testing laboratories shall meet the technical criteria given in HOKLAS 003 Technical Criteria for Laboratory Accreditation. 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, sets out the requirements to be met by a laboratory but does not dictate how such requirements should be met. It is the responsibility of the laboratory management to determine the best methods 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 the HKAS Executive and the HKAS internet website. The HKAS Executive has also published some "HOKLAS Information Notes". They give useful information on specific areas of laboratory operation and are not mandatory. A list of these notes is also available from the HKAS Executive and the HKAS internet website. This website also provides links to other websites which provide useful information on accreditation and laboratory operation.

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

Each laboratory accredited under HOKLAS will have the specific examinations, tests or calibrations for which it is accredited clearly stated as its "scope of accreditation".

The 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
- Medical Testing
- Miscellaneous
- Textiles and Garments
- Toys and Children's Products

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

Appendix B provides examples of the ranges of products and materials and the types of test and calibration covered under the above test categories.

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 tests or calibrations.

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

1.3 Technical criteria

Accredited and applicant laboratories shall demonstrate to HOKLAS assessors that they can perform competently all of the specific examinations for which accreditation is required. Additionally, the HKAS Executive shall be assured that the integrity and laboratory management practices of the organisation are maintained at a sufficiently high standard for confidence to be maintained in the validity of issued results.

Applicant laboratories have to demonstrate compliance with the criteria in Sections 4 and 5 as well as criteria in the relevant Supplementary Criteria before accreditation can be granted and accredited laboratories shall comply with the same criteria at all times for maintaining accreditation.

Appendix C is a list of selected documents published by 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 following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31 (all parts), Standardisation and related activities – General vocabulary

ISO Guide 31, Quantities and units

ISO/IEC Guide 43-1, Proficiency testing by interlaboratory comparisons – Part 1: Development and operation of proficiency testing schemes

ISO 9000, Quality management systems – Fundamentals and vocabulary

ISO 9001:2000, Quality management systems – Requirements

ISO/IEC 17025:1999, General requirements for the competence of testing and calibration laboratories

International vocabulary of basic and general terms in metrology (VIM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 2, VIM and the following apply.

3.1 accuracy of measurement

closeness of the agreement between the result of a measurement and a true value of the measurand

[VIM: 1993, definition 3.5]

3.2 biological reference interval

reference interval

central 95 % interval of the distribution of reference values

NOTE 1 This supersedes such incorrectly used terms as "normal range".

NOTE 2 It is an arbitrary but common convention to define the reference interval as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases. See [10].

3.3 examination

set of operations having object of determining the value or characteristics of a property

NOTE In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements.

3.4 laboratory capability

physical, environmental and information resources, personnel, skills and expertise available for the examinations in question

NOTE A review of laboratory capability could include results of earlier participation in interlaboratory comparisons or external quality assessment schemes or the running of trial examination programmes, or all these, in order to demonstrate uncertainties of measurement, limits of detection, etc.

3.5 laboratory director

competent person(s) with responsibility for, and authority over, a laboratory

NOTE 1 For the purposes of this International Standard, the person or persons referred to are designated collectively as *laboratory director*.

NOTE 2 National, regional and local regulations may apply with regard to qualifications and training.

3.6 laboratory management

person(s) who manage the activities of a laboratory headed by a laboratory director

3.7 measurement
set of operations having the object of determining a value of a quantity

[VIM:1993, definition 2.1]

3.8 medical laboratory
clinical laboratory
laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation

NOTE These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or micro-organisms. Facilities which only collect or prepare specimens, or act as a mailing or distribution centre, are not considered to be medical or clinical laboratories, although they may be part of a larger laboratory network or system.

3.9 post-examination procedures
postanalytical phase
processes following the examination including systematic review, formatting and interpretation, authorisation for release, reporting and transmission of the results, and storage of samples of the examinations

3.10 pre-examination procedures
preanalytical phase
steps starting, in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins

3.11 primary sample
specimen
set of one or more parts initially taken from a system

NOTE In some countries, the term "specimen" is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.

3.12 quantity
attribute of a phenomenon, body or for a substance that may be distinguished qualitatively and determined quantitatively

[VIM:1993, definition 1.1]

3.13 referral laboratory
external laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure and report

3.14 sample
one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production

EXAMPLE A volume of serum taken from a large volume of serum.

3.15 traceability
property of the result of a measurement or the value or a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

[VIM:1993, definition 6.10]

3.16 trueness of measurement
closeness of agreement between the average value obtained from a large series of results of measurements and a true value

NOTE Adapted from ISO 3534-1:1993, definition 3.12

3.17 uncertainty of measurement
parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand

[VIM:1993, definition 3.9]

4 Management requirements

4.1 Organisation and management

4.1.1 The medical laboratory or the organisation of which the laboratory is a part shall be legally identifiable.

4.1.2 Medical laboratory services, including appropriate interpretation and advisory services, shall be designed to meet the needs of patients and all clinical personnel responsible for patient care.

4.1.3 The medical laboratory (hereafter referred to as "the laboratory") shall meet the relevant requirements of this International Standard when carrying out work in its permanent facilities, or at sites other than the permanent facilities for which it is responsible.

4.1.4 The responsibilities of personnel in the laboratory with an involvement or influence on the examination of primary samples shall be defined in order to identify conflicts of interest. Financial or political considerations (e.g. inducements) should not influence testing.

4.1.5 Laboratory management shall have responsibility for the design, implementation, maintenance and improvement of the quality management system. This shall include the following:

a) management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties;

b) arrangements to ensure that management and personnel are free from any undue internal and external commercial, financial or other pressures and influences that may adversely affect the quality of their work;

c) policies and procedures for ensuring the protection of confidential information (see Annex C);

d) policies and procedures for avoiding involvement in any activities that would diminish confidence in its competence, impartiality, judgement, or operational integrity;

e) the organisational and management structure of the laboratory and its relationship to any other organisation with which it may be associated;

f) specified responsibilities, authority, and interrelationships of all personnel;

g) adequate training of all staff and supervision appropriate to their experience and level of responsibility by competent persons conversant with the purpose, procedures and assessment of results of the relevant examination procedures;

h) technical management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory procedures;

i) appointment of a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the quality arrangement system, who shall report directly to the level of laboratory management at which decisions are made on laboratory policy and resources;

j) appointment of deputies for all key functions, while recognising that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.

4.1.H HOKLAS Policy on Organisation and management

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 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 clause 5.1 of this document.

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

The technical management may be a designated technical manager or may comprise a number of designated technical managerial 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

4.2.1 Policies, processes, programmes, procedures and instructions shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.

4.2.2 The quality management system shall include, but not be limited to, internal quality control and participation in organised interlaboratory comparisons such as external quality assessment schemes.

4.2.3 Policies and objectives of the quality management system shall be defined in a quality policy statement under the authority of the laboratory director and documented in a quality manual. This policy shall be readily available to appropriate personnel, shall be concise and shall include the following:

a) the scope of service the laboratory intends to provide;

b) the laboratory management's statement of the laboratory's standard of service;

c) the objectives of the quality management system;

d) a requirement that all personnel concerned with examination activities familiarize themselves with the quality documentation and implement the policies and procedures at all times;

e) the laboratory's commitment to good professional practice, the quality of its examinations, and compliance with the quality management system;

f) the laboratory management's commitment to compliance with this International Standard.

4.2.4 A quality manual shall describe the quality management system and the structure of the documentation used in the quality management system. The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation in the quality management system. The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual.

All personnel shall be instructed on the use and application of the quality manual and all referenced documents, and of the requirements for their implementation. The quality manual shall be kept up to date under the authority and responsibility of [see 4.1.5 i)] an individual appointed to be responsible for quality by the laboratory management.

The table of contents of a quality manual for a medical laboratory might be as follows.

a) Introduction.

b) Description of the medical laboratory, its legal identity, resources, and main duties.

c) Quality policy.

d) Staff education and training.

e) Quality assurance.

f) Document control.

g) Records, maintenance and archiving.

h) Accommodation and environment.

i) Instruments, reagents and/or relevant consumables management.

j) Validation of examination procedures.

k) Safety.

l) Environmental aspects. [For example, transportation, consumables and waste disposal, in addition to, and different from, h) and i).]

m) Research and development. (If appropriate.)

n) List of examination procedures.

o) Request protocols, primary sample, collection and handling of laboratory samples.

p) Validation of results.

q) Quality control (including interlaboratory comparisons).

r) Laboratory information system. (See Annex B.)

s) Reporting of results.

t) Remedial actions and handling of complaints.

u) Communications and other interactions with patients, health professionals, referral laboratories and suppliers.

v) Internal audits.

w) Ethics. (See Annex C.)

4.2.5 Laboratory management shall establish and implement a programme which regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have a documented and recorded programme of preventive maintenance and calibration (see 5.3.2), which, at a minimum, follows manufacturer's recommendations.

4.2.H HOKLAS Policy on Quality management system

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

The quality manual describing the laboratory's quality system shall be developed as a working document for use by the laboratory staff members -- not as a checklist for presentation to laboratory assessors. It shall be available for examination as a part of the accreditation process and the HKAS Executive will review and give comments on quality manuals during assessments.

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

4.3.1 The laboratory shall define, document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. A copy of each of these controlled documents shall be archived for later reference and the laboratory director shall define the retention period. These controlled documents may be maintained on any appropriate medium – including, or not, paper. National, regional and local regulations concerning document retention could apply.

NOTE In this context, "document" is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards or examination procedures.

4.3.2 Procedures shall be adopted to ensure that

a) all documents issued to laboratory personnel as part of the quality management system are reviewed and approved by authorised personnel prior to issue,

b) a list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained,

c) only currently authorised versions of appropriate documents are available for active use at relevant locations,

d) documents are periodically reviewed, revised when necessary, and approved by authorised personnel,

e) invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use,

f) retained or archived superseded documents are appropriately identified to prevent their inadvertent use,

g) if the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of documents, the procedures and authorities for such amendments are defined, while amendments are clearly marked, initialled and dated, and a revised document is formally re-issued as soon as practicable, and

h) procedures are established to describe how changes to documents maintained in computerised systems are to be made and controlled.

4.3.3 All documents relevant to the quality management system shall be uniquely identified, to include

a) title,

b) edition or current revision date, or revision number, or all these,

c) number of pages (where applicable),

d) authority for issue, and

e) source identification.

4.3.H HOKLAS Policy on Document control

All documents shall be reviewed, and revised if necessary, at least annually.

4.4 Review of contracts

4.4.1 Where a laboratory enters into a contract to provide medical laboratory services, it shall establish and maintain procedures for review of contracts. The policies and procedures for these reviews leading to a change in the arrangements for examinations or contracts shall ensure that

a) requirements, including the methods to be used, are adequately defined, documented and understood (see 5.5);

b) the laboratory has the capability and resources to meet the requirements, and

c) appropriate procedures selected are able to meet the contract requirements and clinical needs (see 5.5).

In reference to b), the review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary, for the performance of the examinations in question. The review may also encompass results of earlier participation in external quality assurance schemes using samples of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

4.4.2 Records of reviews, including any significant changes and pertinent discussions, shall be maintained (see 4.13.3).

4.4.3 The review shall also cover any work referred by the laboratory (see 4.5).

4.4.4 Clients (e.g. clinicians, health care bodies, health insurance companies, pharmaceutical companies) shall be informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected parties.

4.4.H HOKLAS Policy on Review of contracts

When reviewing contracts, laboratories shall ensure that the examinations requested relate to the needs of clients for the intended purposes. As far as practicable, laboratories should give advice to clients and help them to determine their needs. In this regard, the requirement in clause 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 contract and the requirements of this clause apply. The communication may be in the form of memorandum, manual, letter, etc.

4.5 Examination by referral laboratories

4.5.1 The laboratory shall have an effective documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinions for histopathology, cytology and related disciplines. Laboratory management, with the advice of users of laboratory services where appropriate, shall be responsible for selecting and monitoring the quality of referral laboratories and consultants and shall ensure that the referral laboratory or referral consultant is competent to perform the requested examinations.

4.5.2 Arrangements with referral laboratories shall be reviewed periodically to ensure that

a) requirements, including the pre-examination and post-examination procedures, are adequately defined, documented, and understood,

b) the referral laboratory is able to meet the requirements and that there are no conflicts of interest,

c) selection of examination procedures is appropriate for the intended use, and

d) respective responsibilities for the interpretation of examination results are clearly defined.

Records of such reviews shall be maintained in accordance with national, regional or local requirements.

4.5.3 The laboratory shall maintain a register of all referral laboratories that it uses. A register shall be kept of all samples that have been referred to another laboratory. The name and address of the laboratory responsible for the examination result shall be provided to the user of laboratory services. A duplicate of the laboratory report shall be retained in both the patient record and in the permanent file of the laboratory.

4.5.4 The referring laboratory and not the referral laboratory shall be responsible for ensuring that referral laboratory examination results and findings are provided to the person making the request. If the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory, without alterations that could affect clinical interpretation.

NOTE National regional and local regulations may apply.

However, this does not require that the referring laboratory report include every word and have the exact format of the referral laboratory report, unless national/local laws or regulations require it. The referring laboratory director may elect to provide additional interpretative remarks to those, if any, of the referral laboratory, in the context of the patient and the local medical environment. The author of such added remarks should be clearly identified.

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 selection and referring examinations to other laboratories and consultants. For accredited examinations, the referral laboratory shall be accredited by HOKLAS, or be a laboratory accredited under a scheme with which HOKLAS has a mutual recognition arrangement (MRA), for the examinations concerned. Relevant HOKLAS regulations governing the subcontracting of work and reporting of results from subcontractors given in HKAS 002 are applicable to examination by referral laboratories. HKAS will only grant accreditation to a laboratory only for those activities that the laboratory itself is competent to carry out.

Where a sample is intended to be examined by another laboratory, as requested by the clinicians of a hospital, and the pathology laboratory of the hospital merely acts as a distribution centre on behalf of the hospital, the requirement of this clause does not apply. However, the examination results of such samples shall not be issued under the name of the hospital's pathology laboratory and the laboratory shall not make any statement on its accreditation status regarding the examination results.

4.6 External services and supplies

4.6.1 Laboratory management shall define and document its policies and procedures for the selection and use of purchased external services, equipment and consumable supplies that affect the quality of its service. Purchased items shall consistently meet the laboratory's quality requirements. National, regional or local regulations may require records of purchased items. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials.

4.6.2 Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable. Documentation of the supplier's conformance with its quality management system may also be used for verification.

4.6.3 There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies and purchased products shall be established and maintained for a period of time, as defined in the quality management system. This system should include the recording of lot numbers of all relevant reagents, control materials and calibrators, the date of receipt in the laboratory and the date the materials is placed in service. All of these quality records shall be available for laboratory management review.

4.6.4 The laboratory shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examinations and shall maintain records of these evaluations and list those approved.

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 supply source.

(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-sale 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

Appropriate laboratory professional staff shall provide advice on choice of examinations and use of the services, including repeat frequency and required type of sample. Where appropriate, interpretation of the results of examinations shall be provided.

There should be regular documented meetings of professional staff with the clinical staff regarding the use of the laboratory services and for the purpose of consultation on scientific matters. The professional staff should participate in clinical rounds, enabling advice on effectiveness in general as well as in individual cases.

4.8 Resolution of complaints

The laboratory shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients or other parties. Records of complaints and of investigations and corrective actions taken by the laboratory shall be maintained, as required (see 4.13.3).

NOTE Laboratories are encouraged to obtain both positive and negative feedback from the users of their services, preferably in a systematic way (e.g. surveys).

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 substance of the complaint immediately. Reference should be made to HKAS 002.

4.9 Identification and control of nonconformities

4.9.1 Laboratory management shall have a policy and procedure to be implemented when it detects that any aspect of its examinations does not conform with its own procedures or the agreed upon requirements of its quality management system or the requesting clinician. These shall ensure that

a) personnel responsible for problem resolution are designated,

b) the actions to be taken are defined,

c) the medical significance of the nonconforming examinations is considered and where appropriate, the requesting clinician informed,

d) examinations are halted and reports withheld as necessary,

e) corrective action is taken immediately,

f) the results of nonconforming examinations already released are recalled or appropriately identified, if necessary,

g) the responsibility for authorisation of the resumption of examinations is defined, and

h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals by laboratory management to detect trends and initiate preventive action.

NOTE Nonconforming examinations or activities occur in many different areas and can be identified in many different ways, including clinician complaints, quality control indications, instrument calibrations, checking of consumable materials, staff comments, report and certificate checking, laboratory management reviews, and internal and external audits.

4.9.2 If it is determined that nonconforming examinations could recur or that there is doubt about the laboratory's compliance with its own policies or procedures as given in the quality manual, procedures to identify, document and eliminate the root cause(s) shall be promptly implemented (see 4.11).

4.9.3 The laboratory shall define and implement procedures for the release of results in the case of nonconformities, including the review of such results. These events shall be recorded.

4.10 Corrective action

4.10.1 Procedures for corrective action shall include an investigative process to determine the underlying cause or causes of the problem. These shall, where appropriate, lead to preventive actions. Corrective action shall be appropriate to the magnitude of the problem and commensurate with the risks encountered.

4.10.2 Laboratory management shall document and implement any changes required to its operational procedures resulting from corrective action investigations.

4.10.3 Laboratory management shall monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems.

4.10.4 When the identification of nonconformance or the corrective action investigation casts doubt on compliance with policies and procedures or the quality management system, laboratory management shall ensure that appropriate areas of activity are audited in accordance with 4.14. The results of corrective action shall be submitted for laboratory management review.

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 non-conforming 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. Hence, it is important that the Quality Manager or other designated staff members shall coordinate the work arising from such corrective actions.

4.11 Preventive action

4.11.1 Needed improvements and potential sources of nonconformities, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.11.2 Procedures for preventive action shall include the initiation of such actions and application of controls to ensure that they are effective. Apart from the review of the operational procedures, preventive action might involve analysis of data, including trend- and risk-analyses and external quality assurance.

NOTE Preventive action is a pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.

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 client feedback and complaints.

4.12 Continual improvement

4.12.1 All operational procedures shall be systematically reviewed by laboratory management at regular intervals, as defined in the quality management system, in order to identify any potential sources of nonconformance or other opportunities for improvement in the quality management system or technical practices. Action plans for improvement shall be developed, documented and implemented, as appropriate.

4.12.2 After action has been taken resulting from the review, laboratory management shall evaluate the effectiveness of the action through a focused review or audit of the area concerned.

4.12.3 The results of action following the review shall be submitted to laboratory management for review and implementation of any needed changes to the quality management system.

4.12.4 Laboratory management shall implement quality indicator for systematically monitoring and evaluating the laboratory's contribution to patient care. When this programme identifies opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management shall ensure that the medical laboratory participates in quality improvement activities that deal with relevant areas and outcomes of patient care.

4.12.5 Laboratory management shall provide access to suitable educational and training opportunities for all laboratory personnel and relevant users of laboratory services.

4.13 Quality and technical records

4.13.1 The laboratory shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records.

4.13.2 All records shall be legible and stored such that they are readily retrievable. Records may be stored on any appropriate medium subject to national, regional or local legal requirements (see Note, 4.3.1). Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.

4.13.3 The laboratory shall have a policy that defines the length of time various records pertaining to the quality management system and examination results are to be retained. Retention time shall be defined by the nature of the examination or specifically for each record.

NOTE National, regional and local regulations may apply.

These records may include but are not limited to the following:

a) request forms (including the patient chart or medical record only if used as the request form);

b) examination results and reports;

c) instrument printouts;

d) examination procedures;

e) laboratory work-books or sheets;

f) accession records;

g) calibration functions and conversion factors;

h) quality control records;

i) complaints and action taken;

j) records of internal and external audits;

k) external quality assessment records/interlaboratory comparisons;

l) quality improvement records;

m) instrument maintenance records, including internal and external calibration records;

n) lot documentation, certificates of supplies, package inserts;

o) incident/accident records and action taken;

p) staff training and competency records.

4.13.H HOKLAS Policy on Quality and technical records

(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 system.

(b) Technical records shall include all original observations and raw data and provide a traceable link between the examination specimens as received and the reports which are eventually issued. This applies equally to computer and manual record systems.

(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.

(e) 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.

(f) 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.

(g) 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, preferably by a second person. It is desirable to design workbooks and worksheets so that there is a dedicated place for the signature of the checking person.

(h) The minimum period for retention of original test data, laboratory records and HOKLAS endorsed reports has been set by the 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 client'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 have 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 Internal audits

4.14.1 In order to verify that operations continue to comply with the requirements of the quality management system, internal audits of all elements of the system, both managerial and technical, shall be conducted at intervals defined by the system itself. The internal audit shall progressively address these elements and emphasise areas critically important to patient care.

4.14.2 Audits shall be formally planned, organised and carried out by the quality manager or designated qualified personnel. Personnel shall not audit their own activities. The procedures for internal audits shall be defined and documented and include the types of audit, frequencies, methodologies and required documentation. When deficiencies or opportunities for improvement are noted, the laboratory shall undertake appropriate corrective or preventive actions, which shall be documented and carried out within an agreed-upon time.

The main elements of the quality system should normally be subject to internal audit once every twelve months.

4.14.3 The results of internal audits shall be submitted to laboratory management for review.

4.14.H HOKLAS Policy on Internal audits

HOKLAS policy on internal audits is detailed in HOKLAS Supplementary Criteria No. 7.

4.15 Management review

4.15.1 Laboratory management shall review the laboratory's quality management system and all of its medical services, including examination and advisory activities, to ensure their continuing suitability and effectiveness in support of patient care and to introduce any necessary changes or improvements. The results of the review shall be incorporated into a plan that includes goals, objectives and action plans. A typical period for conducting a management review is once every twelve months.

4.15.2 Management review shall take account of, but not be limited to

a) follow-up of previous management reviews,

b) status of corrective actions taken and required preventive action,

c) reports from managerial and supervisory personnel,

d) the outcome of recent internal audits,

e) assessment by external bodies,

f) the outcome of external quality assessment and other forms of interlaboratory comparison,

g) any changes in the volume and type of work undertaken,

h) feedback, including complaints and other relevant factors, from clinicians, patients and other parties,

i) quality indicators for monitoring the laboratory's contribution to patient care.

j) nonconformities,

k) monitoring of turnaround time,

l) results of continuous improvement processes, and

m) evaluation of suppliers.

Shorter intervals between reviews should be adopted when a quality management system is being established. This will allow early action to be taken in response to those areas identified as requiring amendment of the quality management system or other practices.

4.15.3 The quality and appropriateness of the laboratory's contribution to patient care shall, to the extent possible, be monitored and evaluated objectively.

NOTE Data available will differ according to laboratory type or location (e.g. hospital, clinic or referral laboratory).

4.15.4 Findings and the actions that arise from management reviews shall be recorded, and laboratory staff shall be informed of these findings and the decisions made as a result of the review. Laboratory management shall ensure that arising actions are discharged within an appropriate and agreed-upon time.

4.15.H HOKLAS Policy on Management review

HOKLAS policy on management review is detailed in HOKLAS Supplementary Criteria No. 7.

5 Technical requirements

5.1 Personnel

5.1.1 Laboratory management shall have an organisational plan, personnel policies and job descriptions that define qualifications and duties for all personnel.

5.1.2 Laboratory management shall maintain records of the relevant educational and professional qualifications, training and experience, and competence of all personnel. This information shall be readily available to relevant personnel, and may include

a) certification or license, if required,

b) references from previous employment,

c) job descriptions,

d) records of continuing education and achievements,

e) competency evaluations, and

f) provision for untoward incident or accident reports.

Other records available to authorised persons relating to personnel health may include records of exposure to occupational hazards and records of immunisation status.

5.1.3 The laboratory shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided.

NOTE *Competence* is here understood as the product of basic academic, postgraduate and continuing education, as well as training and experience of several years in a medical laboratory.

5.1.4 The responsibilities of the laboratory director or designees shall include professional, scientific, consultative or advisory organisational, administrative and educational matters. These shall be relevant to the services offered by the laboratory.

The laboratory director or designees for each task should have the appropriate training and background to be able to discharge the following responsibilities:

a) provide advice to those requesting information about the choice of tests, the use of the laboratory service and the interpretation of laboratory data;

b) serve as an active member(s) of the medical staff for those facilities served, if applicable and appropriate;

c) relate and function effectively (including contractual arrangements, if necessary), with

    1) applicable accrediting and regulatory agencies,

2) appropriate administrative officials,

3) the healthcare community, and

4) the patient population served;

d) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

e) implement the quality management system (the laboratory director and professional laboratory personnel should participate as members of the various quality improvement committees of the institution, if applicable);

f) monitor all work performed in the laboratory to determine that reliable data are being generated;

g) ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory;

h) plan, set goals, develop and allocate resources appropriate to the medical environment;

i) provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities;

j) provide educational programs for the medical and laboratory staff and participate in education programs of the institution;

k) plan and direct research and development appropriate to the facility;

l) select and monitor all referral laboratories for quality of service;

m) implement a safe laboratory environment in compliance with good practice and applicable regulations;

n) address any complaint, request or suggestion from users of laboratory services;

o) ensure good staff morale.

The laboratory director need not perform all responsibilities personally. However, it is the laboratory director who remains responsible for the overall operation and administration of the laboratory, for ensuring that quality services are provided for patients.

5.1.5 There shall be staff resources adequate to the undertaking of the work required and the carrying out of other functions of the quality management system.

5.1.6 Personnel shall have training specific to quality assurance and quality management for services offered.

5.1.7 Laboratory management shall authorise personnel to perform particular tasks such as sampling, examination and operation of particular types of equipment, including use of computers in the laboratory information system (see Annex B).

5.1.8 Policies shall be established which define who may use the computer system, who may access patient data and who is authorised to enter and change patient results, correct billing or modify computer programs (see Annexes B and C).

5.1.9 There shall be a continuing education program available to staff at all levels.

5.1.10 Employees shall be trained to prevent or contain the effects of adverse incidents.

5.1.11 The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary.

5.1.12 The personnel making professional judgements with reference to examinations shall have the applicable theoretical and practical background as well as recent experience. Professional judgements can be expressed as opinions, interpretations, predictions, simulations and models and values and should be in accordance with national, regional and local regulations.

Personnel shall take part in regular professional development or other professional liaison.

5.1.13 Confidentiality of information regarding patients shall be maintained by all personnel.

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 should be assessed annually on their competence in performing examinations.

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

(a) Technical personnel

(b) Supervisory personnel

(c) Management personnel

(d) Personnel responsible for providing clinical interpretations

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 by the Hong Kong Medical Laboratory Technologist 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.

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

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 that colour vision problems will not affect validity of results.

HOKLAS Policy on Supervisory and Management Personnel

The need for supervisory and management 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 and the number 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.

Supervisory personnel 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 continuous experience in the relevant 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.

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, 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 Laboratory Director who 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 technical operation and technical management of the laboratory. The requirements for Laboratory Director are related to the Scope of Accreditation of a laboratory.

A laboratory which provides clinical consultation and/or clinical interpretation for a wide spectrum of tests accredited under the scope of accreditation shall have a qualified pathologist as Laboratory Director who takes overall responsibility for the operation of the laboratory.

For a laboratory accredited for testing-only services and/or limited tests that require clinical interpretation by a qualified pathologist, the Laboratory Director shall be

A. a qualified pathologist; OR

B. a person with
   (i) a Doctoral degree in medical sciences or related subjects after obtaining a Bachelor's degree in medical sciences or related subjects, and
   (ii) at least 5 years of relevant medical testing experience, three of which shall be at a supervisory level; OR

C. a person with
   (i) a Master degree in medical sciences or related subjects after obtaining a Bachelor's degree in medical sciences or related subjects, and
   (ii) at least 8 years of relevant medical testing experience, three of which shall be at a supervisory level.

Note: *A person who has obtained the following minimum qualifications before 1 July 2003 may also be acceptable as Laboratory Director of laboratories accredited for testing-only services and/or limited tests that require clinical interpretation:*

(i) a Bachelor's degree in medical sciences or related subjects, 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 whole discipline such as anatomical pathology, chemical pathology, haematology, immunology, or microbiology.

HKAS will critically review the requirements for Laboratory Director regularly.

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.

HOKLAS Policy on Personnel responsible for giving clinical interpretations of examination results

Clinical interpretations 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.

Laboratories fulfilling the specific requirements for professional staff who provide consultations and clinical interpretations of examination results may be accredited for such service. The person who provides clinical interpretation may or may not be the Laboratory Director himself/herself.

The availability of such consultant and clinical interpretation of examination results service will be delineated in the Scope of Accreditation of a laboratory.

Personnel responsible for giving clinical interpretations of examination results shall have in-depth knowledge of the relevant disciplines. They shall comply with the competence requirements given in clause 5.1.12 of this document for the specialty areas they cover. The laboratory shall have effective procedures to ensure that responsible specialists 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 interpretations 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 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 interpretations on a specimen, if necessary.

An applicant laboratory shall provide a written confirmation letter from HKCPath that the proposed pathologist is qualified to give clinical interpretation for the scope given in the laboratory's Scope of Accreditation.

The person who provides clinical interpretations may or may not be the Laboratory Director who takes the overall responsibility of the operation of the laboratory. However, persons providing clinical interpretations shall have the authority to make decisions on the operations of the laboratories with respect to matters relating to clinical interpretations.

Where giving such clinical interpretations is 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 providing clinical interpretations and 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 persons of the laboratory approved for giving consultation and clinical interpretation. The responsibility for clinical interpretation of laboratory's examination results remains with the approved person(s). This responsibility cannot be delegated to other persons. The person giving the interpretations 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 consultation and clinical interpretation service, or suspension of the laboratory's accreditation, depending on the circumstances.

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 the HKAS Executive to sign such reports.

A person nominated for Approved Signatory shall be competent in making a 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 and in HKAS 002.

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 report containing clinical interpretations 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.

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,
ii) registered pathologist trainees under supervision of a qualified pathologist, or
iii) persons who are MLT Part I registered (or persons with equivalent qualifications and exempted by the Supplementary Medical Professions Ordinance Cap. 359) with at least 1 year post Part I experience plus at least 3 years experience in related specialty areas in which he/she is approved.

(b) position in the staff structure;
(c) familiarity with technical procedures and awareness of the basic concepts behind the procedures and any limitations;
(d) knowledge of the procedures for recording, reporting and checking results;
(e) awareness of the needs for periodic recalibration of equipment;
(f) awareness of the regulations and criteria of HOKLAS, and particularly those related to reports.

In case of Signatory for clinical interpretations, the requirements given in the last section apply.

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 these 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 in carrying out their duties.

Consulting pathologists

A consulting pathologist is a qualified pathologist who periodically visits a laboratory and

provides specialist services in areas where the Laboratory Director, or other staff members of the laboratory, cannot adequately discharge the responsibilities that are appropriate to the services provided by the laboratory.

The service of a consulting pathologist is necessary when the Laboratory Director, or other staff members of the laboratory, cannot provide clinical interpretation of examination results as well as for performance of some examinations or other services.

The consulting pathologist needs to be qualified in the specialty area where he/she is providing consultation and clinical interpretation of examination results.

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

i) a close and effective working relationship between the Laboratory Director and consulting pathologist is established;
ii) advice and recommendations of the consulting pathologist are being acted upon within the required 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. As a minimum, the consulting pathologist shall visit the laboratory once a month;
iv) a written report is provided by the consulting pathologist on a quarterly basis. As 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.

Responsibilities shall be delegated to the consulting pathologist in areas where the Laboratory Director, or other staff members of the laboratory, cannot discharge adequately. These include, for example, the provision of clinical 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 such as interpretation of examination results.

5.2 Accommodation and environmental conditions

5.2.1 The laboratory shall have space allocated so that its workload can be performed without compromising the quality of work, quality control procedures, safety of personnel or patient care services. The laboratory director shall determine the adequacy of this space. The resources shall be of a degree necessary to support the activities of the laboratory. Laboratory resources shall be maintained in a functional and reliable condition. Similar provisions should be made for primary sample collection and examinations at sites other than the permanent laboratory facility.

5.2.2 The laboratory shall be designed for the efficiency of its operation, to optimise the comfort of its occupants and to minimise the risk of injury and occupational illness. Patients, employees and visitors shall be protected from recognised hazards.

5.2.3 When primary sample collection facilities are provided, consideration shall be given to the accommodation of patient disabilities, comfort and privacy, in addition to the optimization of collection conditions.

5.2.4 The laboratory design and environment shall be suitable for the tasks carried out therein. The environment in which the primary sample collection or examinations or both are undertaken shall not invalidate the results, or adversely affect the required quality, of any measurement.

Laboratory facilities for examination should allow correct performance of examinations. These include, but are not limited to, energy sources lighting, ventilation, water, waste and refuse disposal, and environmental conditions. The laboratory should have procedures for checking that the environment does not adversely affect the performance of specimen collection and equipment.

5.2.5 The laboratory shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the results. Attention should be paid to sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature and sound and vibration levels, as appropriate to the technical activities concerned.

5.2.6 There shall be effective separation between adjacent laboratory sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

EXAMPLE Where examination procedures pose a hazard (mycobacteriology, radionuclides etc.); work could be affected or influenced by not being separated, such as nucleic acid amplifications; an environment conducive to quiet and uninterrupted work is required, such as for cytopathology screening; or where work requires a controlled environment, such as for large computer systems.

5.2.7 Access to, and use of, areas affecting the quality of the examinations shall be controlled. Appropriate measures shall be taken to safeguard samples and resources from unauthorised access.

5.2.8 Communication systems within the laboratory shall be those appropriate to the size and complexity of the facility and the efficient transfer of messages.

5.2.9 Relevant storage space and conditions shall be provided to ensure the continuing integrity of samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records and results.

5.2.10 Work areas shall be clean and well maintained. Storage and disposal of dangerous materials shall be those specified by relevant regulations.

Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures and training for personnel could be necessary to that end.

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. 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.

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, fumes and other factors, which may affect the integrity of the samples (such as excessive temperature, humidity and direct sunlight). 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 recommended periods in conditions designed to maintain their integrity.

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

Accommodation and environmental conditions 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. 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 set by the 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.

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 should be adequately trained and their health situation be closely monitored and documented.

5.3 Laboratory equipment

NOTE For the purpose of this International Standard, instruments, reference materials, consumables, reagents and analytical systems are included as laboratory equipment, as applicable.

5.3.1 The laboratory shall be furnished with all items of equipment required for the provision of services (including primary sample collection, and sample preparation and processing, examination and storage). In those cases where the laboratory needs to use equipment outside its permanent control, laboratory management shall ensure that the requirements of this International Standard are met.

When selecting equipment, account should be taken of the use of energy and future disposal (care of the environment).

5.3.2 Equipment shall be shown (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.

Laboratory management shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have a documented and recorded programme of preventive maintenance (see 4.2.5), which, at a minimum, follows the manufacturer's recommendations.

When manufacturer's instructions, operator's manuals or other documentation are available, they may be used to establish requirements, for compliance with relevant standards or to specify requirements for periodic calibration, as appropriate, to fulfil part or all of this requirement.

5.3.3 Each item of equipment shall be uniquely labelled, marked or otherwise identified.

5.3.4 Records shall be maintained for each item of equipment contributing to the performance of examinations. These records shall include at least the following:

a) identity of the equipment;

b) manufacturer's name, type identification and serial number or other unique identification;

c) manufacturer's contact person and telephone number, as appropriate;

d) date of receiving and date of putting into service;

e) current location, where appropriate;

f) condition when received (e.g. new, used or reconditioned);

g) manufacturer's instructions, if available, or reference to their retention;

h) equipment performance records that confirm the equipment's suitability for use;

i) maintenance carried out and that planned for the future;

j) damage to, or malfunction, modification or repair, of the equipment;

k) predicted replacement date, if possible.

The performance records referred to in h) should include copies of reports/certificates of all calibrations and/or verifications including dates, time and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, together with the frequency of checks carried out between maintenance/calibration, as appropriate, to fulfil part or all of this requirement. Manufacturer's instructions may be used to establish acceptance criteria, procedures and frequency of verification for maintenance or calibration or both, as appropriate, to fulfil part or all of this requirement.

These records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by law or regulation.

5.3.5 Equipment shall be operated by authorized personnel only. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) shall be readily available to laboratory personnel.

5.3.6 Equipment shall be maintained in a safe working condition. This shall include examination of electrical safety, emergency stop devices and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons. Manufacturer's specifications or instruction or both shall be used, as appropriate.

5.3.7 Where equipment is found to be defective, it shall be taken out of service, clearly labelled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria. The laboratory shall examine the effect of this defect on previous examinations and institute the procedure given in 4.9. The laboratory shall take reasonable measures to decontaminate equipment prior to service, repair or decommissioning.

5.3.8 A list of the measures taken to reduce contamination shall be provided to the person working on the equipment. The laboratory shall provide suitable space for repairs and appropriate personal protective equipment.

5.3.9 Whenever practicable, equipment under the control of the laboratory which requires calibration or verification shall be labelled or otherwise coded to indicate the status of calibration or verification and the date when recalibration or reverification is due.

5.3.10 When equipment is removed from the direct control of the laboratory or is repaired or serviced, the laboratory shall ensure that it is checked and shown to be functioning satisfactorily before being returned to laboratory use.

5.3.11 When computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory shall ensure that

a) computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility,

b) procedures are established and implemented for protecting the integrity of data at all times,

c) computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data, and

d) computer programmes and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorised persons.

See also Annex B.

5.3.12 The laboratory shall have procedures for safe handling, transport, storage and use of equipment, to prevent its contamination or deterioration.

5.3.13 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures for ensuring that copies of prior correction factors are correctly updated.

5.3.14 Equipment, including hardware, software, reference materials, consumables, reagents and analytical systems shall be safeguarded from adjustments or tampering that might invalidate examination results.

5.3.H HOKLAS Policy on Laboratory equipment

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 their calibration and maintenance.

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

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

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

5.4 Pre-examination procedures

5.4.1 The request form shall contain information sufficient to identify the patient and the authorized requester, as well as providing pertinent clinical data. National, regional or local requirements shall apply.

The request form or an electronic equivalent should allow space for the inclusion of, but not be limited to, the following:

a) unique identification of the patient;

b) name or other unique identifier of physician or other person legally authorised to request examinations or use medical information together with the destination for the report. The requesting clinician's address should be provided as part of the request form information when it is different from that of the receiving laboratory.

c) type of primary sample and the anatomic site of origin, where appropriate;

d) examinations requested;

e) clinical information relevant to the patient, which should include gender and date of birth, as a minimum, for interpretation purposes;

f) date and time of primary sample collection;

g) date and time of receipt of samples by the laboratory.

The format of the request form (e.g. electronic or paper) and the manner in which requests are to be communicated to the laboratory should be determined in discussion with the users of laboratory services.

5.4.2 Specific instructions for the proper collection and handling of primary samples shall be documented and implemented by laboratory management (see 4.2.4) and made available to those responsible for primary sample collection. These instructions shall be contained in a primary sample collection manual.

5.4.3 The primary sample collection manual shall include the following:

a) copies of or references to

   1) lists of available laboratory examinations offered,

   2) consent forms, when applicable,

   3) information and instructions provided to patients in relation to their own preparation before primary sample collection, and

   4) information for users of laboratory services on medical indications and appropriate selection of available procedures;

b) procedures for

1) preparation of the patient (e.g. instructions to caregivers and phlebotomists),

2) identification of primary sample, and

3) primary sample collection (e.g. phlebotomy, skin puncture, blood, urine and other body fluids), with descriptions of the primary sample containers and any necessary additives;

c) instructions for

1) completion of request form or electronic request,

2) type and amount of the primary sample to be collected,

3) special timing of collection, if required,

4) any special handling needs between time of collection and time received by the laboratory (transport requirements, refrigeration, warming, immediate delivery, etc.),

5) labelling of primary samples,

6) clinical information (e.g. history of administration of drugs),

7) positive identification, in detail, of the patient from whom a primary sample is collected,

8) recording the identity of the person collecting the primary sample, and

9) safe disposal of materials used in the collection;

d) instructions for

1) storage of examined samples,

2) time limits for requesting additional examinations,

3) additional examinations, and

4) repeat examination due to analytical failure or further examinations of same primary sample.

5.4.4 The primary sample collection manual shall be part of the document control system (see 4.3.1).

5.4.5 Primary samples shall be traceable, normally by request form, to an identified individual. Primary samples lacking proper identification shall not be accepted or processed by the laboratory.

Where there is uncertainty in the identification of the primary sample or instability of the analytes in the primary sample (cerebrospinal fluid, biopsy, etc.), and the primary sample is irreplaceable or critical, the laboratory may choose initially to process the sample but not release the results until the requesting physician or person responsible for the primary sample collection takes responsibility for identifying and accepting the sample, or for providing proper information, or all these. In such an instance, the signature of that person taking responsibility for the primary sample identification should be recorded on, or traceable to, the request form. If this requirement is not met for any reason, the person responsible should be identified in the report if the examination is carried out. Samples to be set aside for future examination (e.g. viral antibodies, metabolites relevant to the clinical syndrome) should also be identifiable.

5.4.6. The laboratory shall monitor the transportation of samples to the laboratory such that they are transported

a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned,

b) within a temperature interval specified in the primary sample collection manual and with the designated preservatives to ensure the integrity of samples, and

c) in a manner that ensures safety for the carrier, the general public and the receiving laboratory, in compliance with national, regional or local regulatory requirements.

5.4.7 All primary samples received shall be recorded in an accession book, worksheet, computer or other comparable system. The date and time of receipt of samples, as well as the identity of the receiving officer, shall be recorded.

5.4.8 Criteria shall be developed and documented for acceptance or rejection of primary samples. If compromised primary samples are accepted, the final report shall indicate the nature of the problem and, if applicable, that caution is required when interpreting the result.

5.4.9 The laboratory shall periodically review its sample volume requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.

5.4.10 Authorized personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.

5.4.11 The laboratory shall, if relevant, have a documented procedure for the receipt, labelling, processing and reporting of those primary samples received by the laboratory and specifically marked as urgent. The procedure shall include details of any special labelling of the request form and primary sample, the mechanism of transfer of the primary sample to the examination area of the laboratory, any rapid processing mode to be used and any special reporting criteria to be followed.

5.4.12 Sample portions shall also be traceable to the original primary sample.

5.4.13 The laboratory shall have a written policy concerning verbal requests for sample examinations.

5.4.14 Samples shall be stored for a specified time, under conditions ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations.

5.4.H HOKLAS Policy on Pre-examination procedures

Both the examination request document and the specimen submitted shall bear the unique identification of the patient. This identification may include, for example, the name of the patient, as well as the number of his/her identity document, such as identity card or passport number.

5.5 Examination procedures

NOTE Some of the following might not be applicable to all disciplines in the scope of laboratory medicine.

5.5.1 The laboratory shall use examination procedures, including those for selecting/taking sample portions, which meet the needs of the users of laboratory services and are appropriate for the examinations. Preferred procedures are those that have been published in established/authoritative textbooks, peer-reviewed texts or journals, or in international, national or regional guidelines. If in-house procedures are used, they shall be appropriately validated for their intended use and fully documented.

5.5.2 The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use. The validations shall be as extensive as are necessary to meet the needs in the given application or field of application. The laboratory shall record the results obtained and the procedure used for the validation.

The methods and procedures selected for use shall be evaluated and found to give satisfactory results before being used for medical examinations. A review of procedures by the laboratory director or designated person shall be undertaken initially and at defined intervals. Such a review is normally carried out annually. These reviews shall be documented.

5.5.3 All procedures shall be documented and be available at the workstation for relevant staff. Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in the laboratory.

Card files or similar systems that summarise key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.

The procedure shall be based in whole or in part on the instructions for use (e.g. package insert) written by the manufacturer, provided that they are in accordance with 5.5.1 and 5.5.2 and that they describe the procedure as it is performed in the laboratory and are written in the language commonly understood by the staff of the laboratory. Any deviation shall be reviewed and documented. Additional information that could be required to perform the examination shall also be documented. Each new version of examination kits with major changes in reagents or procedure shall be checked for performance and suitability for intended use. Any procedural changes shall be dated and authorised as for other procedures.

In addition to document control identifiers, documentation should include, when applicable, the following :

a) purpose of the examination;

b) principle of the procedure used for examinations;

c) performance specifications (e.g. linearity, precision, accuracy expressed as uncertainty of measurement, detection limit, measuring interval, trueness of measurement, sensitivity and specificity);

d) primary sample system (e.g. plasma, serum, urine);

e) type of container and additive;

f) required equipment and reagents;

g) calibration procedures (metrological traceability);

h) procedural steps;

i) quality control procedures;

j) interferences (e.g. lipemia, hemolysis, bilirubinemia) and cross reactions;

k) principle of procedure for calculating results, including measurement uncertainty;

l) biological reference intervals;

m) reportable interval of patient examination results;

n) alert/critical values, where appropriate;

o) laboratory interpretation;

p) safety precautions;

q) potential sources of variability.

Electronic manuals are acceptable provided that the above-specified information is included. The same requirements for document control should also apply to electronic manuals.

The laboratory director shall be responsible for ensuring that the contents of examination procedures are complete, current and have been thoroughly reviewed.

5.5.4 Performance specifications for each procedure used in an examination shall relate to the intended use of that procedure.

5.5.5 Biological reference intervals shall be periodically reviewed. If the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population, then an investigation shall be undertaken, followed, if necessary, by corrective action. A review of biological reference intervals shall also take place when the laboratory changes an examination procedure or pre-examination procedure, if appropriate.

5.5.6 The laboratory shall make its list of current examination procedures, including primary sample requirements and relevant performance specifications and requirements, available to users of laboratory services upon request.

5.5.7 If the laboratory intends to change an examination procedure such that results or their interpretations could be significantly different, the implications shall be explained to users of the laboratory services in writing, prior to the introduction of the change.

NOTE This requirement can be accomplished in any of several different ways, depending on local circumstances. Some methods include directed mailings, laboratory newsletters or part of the examination report itself.

5.5.H HOKLAS Policy on Examination procedures

For some examinations, a laboratory may be accredited for examinations only. However, for some examinations, due to their nature, accreditation will only be granted when clinical interpretation of the examination results is also provided. Some examples of these types of examinations are given in relevant HOKLAS Supplementary Criteria.

5.6 Assuring quality of examination procedures

5.6.1 The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results. It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions. Special attention should be paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc.

5.6.2 The laboratory shall determine the uncertainty of results, where relevant and possible. Uncertainty components which are of importance shall be taken into account. Sources that contribute to uncertainty may include sampling, sample preparation, sample portion selection, calibrators, reference materials, input quantities, equipment used, environmental conditions, condition of the sample and changes of operator.

5.6.3 A programme for calibration of measuring systems and verification of trueness shall be designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference. Where none of these are possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

a) participation in a suitable programme of interlaboratory comparisons;

b) use of suitable reference materials, certified to indicate the characterisation of the material;

c) examination or calibration by another procedure;

d) ratio or reciprocity-type measurements;

e) mutual consent standards or methods which are clearly established, specified, characterised and mutually agreed by all parties concerned;

f) documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.

5.6.4 The laboratory shall participate in interlaboratory comparisons such as those organised by external quality assessment schemes. Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled. Interlaboratory comparison programs shall be in substantial agreement with ISO/IEC Guide 43-1.

External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.

5.6.5 Whenever a formal interlaboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. Whenever possible, this mechanism shall utilize externally derived challenge materials such as exchange of samples with other laboratories. Laboratory management shall monitor the results of this mechanism of interlaboratory comparison and participate in the implementation and recording of corrective actions.

5.6.6 For those examinations performed using different procedures or equipment or at different sites, or all these, there shall be a defined mechanism for verifying the comparability of results throughout the clinically appropriate intervals. Such verification shall be performed at defined periods of time appropriate to the characteristics of the procedure or instrument.

5.6.7 The laboratory shall document, record and, as appropriate, expeditiously act upon results from these comparisons. Problems or deficiencies identified shall be acted upon and records of actions retained.

5.6.H HOKLAS Policy on Assuring the quality of examination procedures

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 HOKLAS requirements on participation in proficiency testing activities are stated in HKAS Regulations for Accreditation. Specific requirements, if any, for each discipline are given 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), duplicates, blanks, spikes, etc. Control samples shall be of a similar matrix as the patients' samples. Correlation of results in a sample shall be reviewed, where relevant.

Quality control samples, external proficiency testing and other alternative performance assessment samples shall be examined in exactly the same procedures as patient samples and analysed by personnel who routinely examined patient samples.

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

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

materials are available, for evaluation of the accuracy being achieved at various concentration levels.

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

(c) Regular examinations of the same sample by two or more persons. This allows for the estimation of precision between staff members being achieved in the laboratory and for identifying any significant biases evident in an individual's results.

(d) Programmed examination of the same sample by different examination techniques or two different items of the same apparatus type. This allows for estimation of any technique-dependent bias or equipment bias in the laboratory's results.

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

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

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.

(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 has been set. These recommendations are given in HOKLAS Supplementary Criteria No. 2. Laboratories shall note that any recommendation on calibration, including re-calibration intervals are 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 is to be performed by a "competent calibration body". The HKAS Executive will, for the time being, accept as evidence of traceability to SI units, calibrations which have been performed by :

(i) The Government of the HKSAR Standards and Calibration Laboratory;

(ii) Nominated primary standards institutions referred to in Supplementary Criteria No. 2.

(iii) Laboratories accredited by 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 HOKLAS 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 the HKAS Executive from time to time.

(d) Some items of equipment may be able to be calibrated by accredited laboratories without the services of external calibration bodies, provided the laboratories have the necessary reference standards and materials and the calibration procedures do not demand specialist techniques which are outside the capabilities and experience of the laboratory staff. However, the uncertainty of calibration shall meet the requirements of the applications.

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

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

ISO Guide 32 gives guidelines on calibration in analytical chemistry and use of certified reference materials. Laboratories should follow these guidelines for equipment calibration. When using CRMs for assessment of a measurement process, the guidelines given in ISO Guide 33 should be followed.

Reference material (RM) : Material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

NOTE : A reference material may be in the form of a pure or mixed gas, liquid or solid. Examples are water for the calibration of viscometers, sapphire as a heat capacity calibrant in calorimetry, and solutions used for calibration in chemical analysis.

Certified reference material (CRM) : Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

NOTES :
1. *A reference material certificate is defined as document accompanying a certified reference material stating one or more property values and their uncertainties, and confirming that the necessary procedures have been carried out to ensure*

their validity and traceability.

2. *CRMs are generally prepared in batches for which the property values are determined within stated uncertainty limits by measurements on samples representative of the whole batch.*

3. *The certified properties of reference materials are sometimes conveniently and reliably realised when the material is incoporated into a specially fabricated device, e.g. a substance of known triple-point into a triple-point cell; a glass of known optical density into a transmission filter; spheres of uniform particle size mounted on a microscope slide. Such devices may also be considered as CRMs.*

4. *All CRMs lie within the definition of measurement standards or etalons given in the International vocabulary of basic and general terms in metrology (VIM).*

5. *Some RMs and CRMs have properties which, because they cannot be correlated with an established chemical structure or for other reasons, cannot be determined by exactly defined physical and chemical measurement methods. Such materials include certain biological materials such as vaccines to which an international unit has been assigned by the World Health Organisation.*

Where laboratories are undertaking calibrations of equipment through the use of certified reference materials or reference materials, the onus will be on the laboratories to demonstrate to the HKAS Executive :

(i) that sufficient reference materials are held by the laboratory to calibrate the relevant items of equipment over their intended measurement ranges;

(ii) that full records are kept of the identity and source of each certified reference material and/or reference material;

(iii) in cases where certified reference materials are used, that these materials are supplied by a recognised national institution. Full documentation of the certified values of these materials and the mode of validation of the certified values shall be held;

(iv) in cases where it is necessary to use commercially prepared chemical standards as reference materials, that the claimed values of each batch of these chemicals are verified before use and records of verification are held;

(v) that, where necessary, all precautions have been taken to match the matrices of the reference materials to those encountered in the laboratory's test samples or that the laboratory has determined and accounted for the effects of any non-matching of matrices.

Laboratories are asked to advise the HKAS Executive of any doubts about the assigned values of reference materials and laboratories are encouraged to refer all such doubts, together with supporting technical details, to the producers of the materials concerned.

(f) 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 5.6.H(c)(i) to (v) but which should be competent.

(g) Designated officers of the laboratory shall be assigned the responsibility for the

calibration of equipment and management of reference materials.

(h) 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.

5.7 Post-examination procedures

5.7.1 Authorized personnel shall systematically review the results of examinations, evaluate them in conformity with the clinical information available regarding the patient and authorize the release of the results.

5.7.2 Storage of the primary sample and other laboratory samples shall be in accordance with approved policy.

5.7.3 Safe disposal of samples no longer required for examination shall be carried out in accordance with local regulations or recommendations for waste management.

5.8 Reporting of results

5.8.1 Laboratory management shall be responsible for formatting reports. The format of the report form (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory should be determined in discussion with the users of laboratory services.

5.8.2 Laboratory management shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval.

5.8.3 Results shall be legible, without mistakes in transcription and reported to persons authorized to receive and use medical information. The report shall also include, but not be limited to the following:

a) clear, unambiguous identification of the examination including, where appropriate, the measurement procedure;

b) the identification of the laboratory that issued the report;

c) unique identification and location of the patient, where possible, and destination of the report;

d) name or other unique identifier of the requester and the requester's address;

e) date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory;

f) date and time of release of report, which, if not on the report, shall be readily accessible when needed;

g) source and system (or primary sample type);

h) results of the examination reported in SI units or units traceable to SI units (see ISO Guide 31), where applicable;

i) biological reference intervals, where applicable;

j) interpretation of results, where appropriate;

k) other comments (e.g. quality or adequacy of primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure); the report should identify examinations undertaken as part of a development programme and for which no specific claims on measurement performance are made, and, where applicable, information on detection limit and uncertainty of measurement should be provided upon request;

l) identification of the person authorizing the release of the report;

m) if relevant, original and corrected result;

n) signature or authorization of the person checking or releasing the report, where possible.

NOTE In reference to i), under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.

5.8.4 As appropriate, the description of examinations performed and their results should follow the vocabulary and syntax recommended by one or more of the following organisations:

- International Council for Standardization in Haematology (ICSH);
- International Society of Haematology (ISH);
- International Federation of Clinical Chemistry and Laboratory Medicine (IFCC);
- International Union of Pure and Applied Chemistry (IUPAC);
- International Society of Thrombosis and Haemostasis (ISTH)
- European Committee for Standardisation (CEN).

As appropriate, the description and results should follow the nomenclature recommended by one or more of the following organisations:

- International Union of Biochemistry and Molecular Biology (IUBMB);
- International Union of Microbiological Societies (IUMS);
- International Union of Immunological Societies (IUIS);
- SNOMED International (College of American Pathologists);
- World Health Organisation (WHO).

NOTE National, regional and local regulations may require the name and location of the examining (or referral) laboratory to be shown in the final report.

5.8.5 The report shall indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the result.

5.8.6 Copies or files of reported results shall be retained by the laboratory such that prompt retrieval of the information is possible. The length of time that reported data are retained may vary; however, the reported results shall be retrievable for as long as medically relevant or as required by national, regional or local requirements.

5.8.7 The laboratory shall have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results for critical properties fall within established "alert" or "critical" intervals. This includes results received on samples sent to referral laboratories for examination.

5.8.8 In order that local clinical needs can be served, the laboratory shall determine the critical properties and their "alert/critical" intervals, in agreement with the clinicians using the laboratory. This applies to all examinations, including nominal and ordinal properties.

5.8.9 For results transmitted as an interim report, the final report shall always be forwarded to the requester.

5.8.10 Records of actions taken in response to results in the critical intervals shall be maintained. These shall include date, time, responsible laboratory staff member, person notified and examination results. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.

5.8.11 Laboratory management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs.

There shall be a policy for notifying the requester when an examination is delayed. Turnaround times as well as any feedback from clinicians in relation to it shall be monitored, recorded and reviewed by laboratory management. Where necessary, corrective action shall be taken to address any problems so identified.

This does not mean that the clinical personnel are to be notified of all delays in examination, but only in those situations where the delay could compromise patient care. This procedure should be developed in collaboration between clinical and laboratory personnel.

5.8.12 When examination results from a referral laboratory need to be transcribed by the referring laboratory, procedures for verifying the correctness of all transcriptions shall be in place.

5.8.13 The laboratory shall have clearly documented procedures for the release of examination results, including details of who may release results and to whom. The procedures shall also include guidelines for the release of results directly to patients.

5.8.14 The laboratory shall establish policies and practices for ensuring that results distributed by telephone or other electronic means reach only authorized receivers. Results provided verbally shall be followed by a properly recorded report.

5.8.15 The laboratory shall have written policies and procedures regarding the alteration of reports.

When altered, the record must show the time, date and name of the person responsible for the change.

Original entries shall remain legible when alterations are made.

Original electronic records shall be retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.

Results that have been available for clinical decision-making and revised shall be retained in subsequent cumulative reports and be clearly identified as having been revised. If the reporting system cannot capture amendments, changes or alterations, an audit log shall be used.

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 significantly abnormal examination results. Moreover, there shall be a hierarchical method of review of examination results, that is, a sequential review of 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 testing-only, the laboratory shall fully understand its limitation. It shall, where necessary, indicate on the test report that clinical interpretation by a qualified pathologist is recommended.

Where possible, age- and sex-specific biological reference intervals should be provided when reporting results, where relevant. Generally, such reference intervals shall be verified or determined 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.

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

(a) Numerical expression of results and rounding of numbers

Laboratories are advised to obtain a copy of either British Standard 1957 or 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 client 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 and HKAS Supplementary Criteria No. 1.

(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.

(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 HKAS 002.

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

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

(ii) Appropriate documentation is provided to the laboratory including :

HKAS 002	Regulations for HKAS Accreditation
HOKLAS 015	Technical Criteria for Laboratory Accreditation (Medical Laboratories)
HOKLAS 005	Application Form for Laboratory Accreditation
HOKLAS 006/013	Schedule of Accreditation Fees for Hong Kong Laboratories/Laboratories located outside Hong Kong.
HOKLAS 016	Assessment / Reassessment Questionnaire (Medical Laboratories)
HOKLAS 009	Directory of Accredited Laboratories

Relevant HKAS and HOKLAS Supplementary Criteria and Information Notes

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

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

(b) A completed Assessment / Reassessment Questionnaire (HOKLAS 016)

(c) The documents specified in the Assessment / Reassessment Questionnaire

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

STEP 2 - PRELIMINARY ADVICE TO LABORATORY

(i) Following examination of the documentation submitted by the laboratory, the 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

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

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

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

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

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

STEP 4 - ASSESSMENT OF LABORATORY

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

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

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

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

STEP 5 - ADVICE OF ASSESSMENT OUTCOME

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 the HKAS Executive. Any amendment to the assessment report will be issued to the laboratory within 10 working days of the assessment.

For intial assessments for a test category or a major test area, the assessment will be reviewed by the HKAS Executive as well as AAB. The reviewed assessment results will be issued to the laboratory in the form of an outcome letter.

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

STEP 6 - REMEDIAL ACTIONS (if required)

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

(ii) Assuming the remedial actions are found acceptable, a recommendation for accreditation will normally follow. A formal notification letter and a Certification of Accreditation will be issued.

(iii) If a laboratory is unsuccessful in achieving accreditation, it has the right to appeal (See Disputes, Complaints and Appeals in HKAS 002).

STEP 7 - AFTER ACCREDITATION

(i) 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.

(ii) 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.

(iii) Laboratories are required from time to time to participate in HOKLAS proficiency testing programmes (where appropriate).

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

This includes notification of such changes as :

(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, assessors involved

in the assessment and members of AAB (except where a conflict of interest arises). 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

TEST CATEGORIES

HOKLAS accreditation is currently available in the test categories detailed below. Additional test categories may be added as the system develops and submissions from laboratories for including additional test categories may be considered by the HKAS Executive. Technical criteria for all test categories other than medical testing are given in HOKLAS 003 Technical Criteria for Laboratory Accreditation. Medical testing laboratories shall also comply with technical criteria given in HOKLAS 015 Technical Criteria for Laboratory Accreditation (Medical Laboratories).

The test categories are :

CALIBRATION SERVICES

Accreditation is available, for example, for :

- calibration undertaken for instruments used in applied physics area such as acoustic and vibration measurement, optics and photometry, heat and temperature measurement;
- calibration undertaken for engineering metrology purposes (size, angle, shape, relative positioning, etc.);
- calibration undertaken for physical metrology purposes (mass, volume, force, pressure, fluid flow, etc.) and calibration of the instruments and machines used in these measurements (balances, extensometers, tensile and compression testing machines, pressure gauges, etc.);
- calibration of electrical measuring instruments.

CHEMICAL TESTING

Accreditation is available, for example, for :

- pharmaceutical analysis;
- precious metal testing;
- dangerous goods testing;
- corrosion testing;
- coal and ash testing;
- natural gas testing.

CHINESE MEDICINE

- toxic elements testing;
- pesticide residues testing;
- microbiological tests;
- aflatoxins testing.

CONSTRUCTION MATERIALS

Accreditation is available, for example, for chemical and physical testing associated with :

- cube testing;
- core testing;
- curing of concrete specimens;
- constituent materials (cement, PFA, aggregates, admixtures, water) testing;
- tensile testing of steel;
- bend testing of steel;
- repair mortar testing;
- building components (door, collapsible gate, cooking bench, sink unit) testing;
- soil and rock testing;
- bituminous materials;
- non-destructive testing;
- pile tests.

Consideration will also be given to the provision of accreditation for a wide range of other tests both physical and chemical on concrete and steel or their constituents and the associated site services for sampling of materials, making and storage of specimens and applicable tests on site.

ELECTRICAL AND ELECTRONIC PRODUCTS

Accreditation is available, for example, for :

- electrical performance tests on appliances;
- other performance tests on appliances (such as mechanical, energy consumption, temperature characteristics, etc., tests);
- approval tests (national and international specifying bodies) for electrical and electronic appliances, and components;
- measurements and tests on electrical measuring instruments (covered also under Calibration Services test category) and on conductors, insulating materials and insulators, capacitors, inductors and transformers, cells and batteries, communications equipment, electrical machines and auxiliary apparatus (motors, generators, starters, controllers, regulators, etc.), circuit switching devices, cables and feeders;
- safety tests;
- electromagnetic compatibility testing;
- telecommunication equipment tests;
- environmental tests.

ENVIRONMENTAL TESTING

Accreditation is available, for example, for :

- air testing;
- asbestos testing;
- noise testing;
- solid/liquid waste testing;
- water testing;
- sediment/biota testing;
- sampling.

FOOD

Accreditation is available, for example, for :

- sampling of food and beverages to recognised standard methods;
- chemical tests on food, beverages and food additives;
- microbiological tests on food, beverages and food additives;
- physical tests on food, beverages and food additives;
- chemical and microbiological tests on water used in food processing;
- chemical, physical and microbiological tests on food packaging materials and receptacles;
- insect infestation tests on food;
- tests for pesticides, mycotoxins, heavy metals, etc., residues in food.

MEDICAL TESTING (Technical Criteria are given in HOKLAS 015)

- Anatomical Pathology;
- Chemical Pathology;
- Clinical Microbiology and Infection;
- Haematology;
- Immunology.

MISCELLANEOUS

- other tests not readily accommodated in other test categories.

TEXTILES AND GARMENTS

Accreditation is available, for example, for tests on fibres, yarns, fabrics, webbing, carpets, fasteners, down, leather goods, garments, etc. for :

- physical and mechanical tests;
- chemical tests;

- colourfastness tests;
- flammability tests;
- resistance to insect damage;
- quantitative analysis of mixtures and blends;
- washing tests;
- dimensional change tests;
- resistance to fungal growth.

TOYS AND CHILDREN'S PRODUCTS

Accreditation is available, for example, for :

- tests for compliance with constructional requirements;
- hazard tests (sharp edges or points, ingestion, inhalation, bite tests, penetration of projectiles, etc.);
- normal use testing;
- abuse testing;
- flammability tests;
- noise level tests;
- toxicology tests (coating materials, modelling materials, tests for composition for detection of prohibited substances, etc.);
- electrical safety tests (also available under Electrical and Electronics test category);

Examples of typical expressions of the "Scope of Accreditation" are shown in the HOKLAS Directory of Accredited Laboratories available in CD version or published in the HKAS website www.info.gov.hk/itc/hkas.

Appendix C
(Informative)

BIBLIOGRAPHY

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)

Information Series (I series)

ILAC I1 : 1994	Legal Liability in Testing
ILAC I2 : 1994	Testing, Quality Assurance, Certification and Accreditation
ILAC I3 : 1996	The Role of Testing and Accreditation in International Trade
ILAC I4 : 1996	Guidance Documents for the Preparation of Laboratory Quality Manuals

Guidance Series (G series)

ILAC G2 : 1994	Traceability of Measurements
ILAC G3 : 1994	Guidelines for Training Courses for Assessors
ILAC G4 : 1994	Guidelines on Scopes of Accreditation
ILAC G7 : 1994	Accreditation Requirements and Operating Criteria for Horseracing Laboratories
ILAC G8 : 1996	Guidelines on Assessment and Reporting of Compliance with Specification
ILAC G9 : 1996	Guidelines for the Selection and Use of Certified Reference Materials
ILAC G10 : 1996	Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories
ILAC G11 : 1998	Guidelines on Assessor Qualification and Competence

ILAC G12 : 2000	Guidelines for the Requirements for the Competence of Reference Materials Producers
ILAC G13 : 2000	Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
ILAC G14 : 2000	Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status
ILAC G15 : 2001	Guidance for Accreditation to ISO/IEC 17025
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 : 2002	The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing
ILAC G19 : 2002	Guidelines for Forensic Science Laboratories
ILAC G20 : 2002	Guidelines on Grading of Non-conformities
ILAC G21 : 2002	Cross Frontier Accreditation – Principles for Avoiding Duplication

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

EA-3/01	EA Conditions for the Use of Accreditation Marks
EA-3/02	The Expression of Uncertainty in Quantitative Testing *(previously EAL-G23)*
EA-3/03	EAC-EAL General Requirements for Bodies Providing Accreditation of Inspection Bodies *(previously EAC/EAL-G28)*
EA-3/04	Criteria for Proficiency Testing in Accreditation *(previously EAL-G6)*
EA-3/05	Guidelines for Training Courses for assessors used by Laboratory Accreditation Schemes *(previously EAL-G7)*
EA-3/06	Guidelines for Selection of Participants to Courses for the Training of assessors Involved in Assessments of Laboratories Applying for Accreditation *(previously EAL-G8)*
EA-3/07	Programme for Course for Tutors for Assessor Training *(previously EAL-G10)*

EA-3/08	Guidelines on the application of EN 45010
EA-3/09	Surveillance and Reassessment of Accredited Organisations
EA-4/02	Expressions of the Uncertainty of Measurements in Calibration *(previously EAL-R2)*
EA-4/05	Accreditation for Chemical Laboratories (with EURACHEM) *(previously EAL-G4)*
EA-4/07	Traceability of Measuring and Test Equipment to National Standards *(previously EAL-G12)*
EA-4/09	Accreditation for Sensory Testing Laboratories *(previously EAL-G16)*
EA-4/10	Accreditation for Laboratories Performing Microbiological Testing *(previously EAL-G18)*
EA-4/12	Accreditation of Medical Laboratories (with ECLM) *(previously EAL-G25)*
EA-10/01	Calibration of Stylus Instruments for Measuring Surface Roughness *(previously EAL-G20)*
EA-10/02	Calibration of Gauge Block Comparators *(previously EAL-G21)*
EA-10/03	Calibration of Pressure Balances *(previously EAL-G26)*
EA-10/04	Uncertainty of Calibration Results in Force measurements *(previously EAL-G22)*
EA-10/05	Co-ordinate Measuring Machine Calibration *(previously EAL-G17)*
EA-10/06	Extent of Calibration for Cylindrical Diameter Standards *(previously EAL-G29)*
EA-10/07	Calibration of Oscilloscopes *(previously EAL-G30)*
EA-10/08	Calibration of Thermocouples *(previously EAL-G31)*
EA-10/09	Measurement and Generation of Small AC Voltages with Inductive Voltage Dividers *(previously EAL-G32)*
EA-10/10	Determination of Pitch Diameter of Parallel Thread Gauges by Mechanical Probing
EA-10/11	Guidelines on the Calibration of Temperature Indicators and Simulators by Electrical Simulation and Measurement

EA-10/12 Guidelines on the Evaluation of Vector Network Analysers (VNA)

EA-10/13 Guidelines on the Calibration of Temperature Block Calibrators

EA-10/14 EA Guidelines on the Calibration of Static Torque Measuring Devices)

EA-10/15 EA Guidelines on the Calibration of Digital Multimeters

EA-10/16 EA Guidelines on the Estimation of Uncertainty in Hardness Measurements

EA-10/17 EA Guidelines on the Calibration of Electromechanical Manometers

C. 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 TC002 APLAC Internal Audits for Laboratories

APLAC TC003 APLAC Management Review for Laboratories

APLAC TC004 APLAC Method of Stating Test Results and Compliance with Specification

Annex B

(informative)

Recommendations for protection of laboratory information systems (LIS)

B.1 General

B.1.1 Results and information are the products of the medical laboratory. Because computer systems can be damaged or subverted in a variety of ways, it is important to establish policies that protect patients from harm caused by loss or change of data.

The recommendations given in this annex ought to result in a high level of data/information integrity for laboratory information systems (LIS).

NOTE They are not applicable to

- desktop calculators,
- small programmable technical computers,
- purchased services and outsourcing,
- computers used solely for word processing, spreadsheets or similar, single-user functions, or
- dedicated microprocessors that are an integral part of an examination instrument.

B.2 Environment

B.2.1 The computer facilities and equipment should be clean, well maintained and in a location and environment that complies with vendor specifications.

B.2.2 Computer components and storage areas should be readily accessible to appropriate fire-fighting equipment.

B.2.3 Wires or computer cables should be protected if located in traffic areas.

B.2.4 There should be provision for an uninterruptible power supply (UPS).

B.2.5 The information facilities should be protected from unauthorized access.

B.3 Procedure manual

B.3.1 A complete computer procedure manual, which may be electronic, should be readily available to all authorized computer users.

B.3.2 The laboratory computer procedure manual should be reviewed and approved at defined intervals by the laboratory director or a person designated for this task.

B.3.3 There should be written procedures for actions necessary to protect the data or computer equipment or both in case of fire or hardware/software failure.

B.4 System security

B.4.1 Computer programs should be adequately protected to prevent alteration or destruction by casual or unauthorized users.

B.4.2 Strict policies should be established for authorizing use the computer system. Policies should define those authorized to access patient data and those authorized to enter patient results, change results, change billing or alter computer programmes.

B.4.3 If data in other computer systems can be accessed through the LIS (e.g. pharmacy or medical records), there should be appropriate computer security measures to prevent unauthorized access to these data through the LIS. The LIS should not be allowed to jeopardize the data security of other systems.

B.5 Data entry and reports

B.5.1 Patient data on reports and video displays should be compared with original input in order to ensure the integrity of data transfer at defined intervals by detecting errors in data transmission, storage or processing.

B.5.2 Whenever multiple copies of tables are maintained within a system (e.g. biological reference interval tables in both the laboratory information system and the hospital information system), they should be periodically compared in order to ensure consistency among all copies in use. Appropriate replication or comparison procedures should be in place.

B.5.3 Documentation should exist stating that calculations performed on patient data by the computer are periodically reviewed.

B.5.4 The LIS output to the medical record constitutes direct patient-care data. Accordingly, the laboratory director should approve and review the content and format of the laboratory reports in order to ensure that they effectively communicate laboratory results and meet the needs of the medical staff.

B.5.5 Data entered into the computer system either manually or by automated methods should be reviewed in order to verify the correctness of the input data before final acceptance and reporting by the computer.

B.5.6 All result entries should be checked against a predefined range of values for a particular examination in order to detect absurd or impossible results before final acceptance and reporting by the computer.

B.5.7 The reporting system should provide for comments on sample quality that might compromise the accuracy of examination results (e.g. lipaemic, haemolyzed samples) and for comments on interpretation of results.

B.5.8 There should be an audit mechanism allowing the laboratory to identify all individuals who have entered or modified patient data, control files or computer programs.

B.6 Data retrieval and storage

B.6.1 Stored patient result data and archival information should be easily and readily retrievable within a time frame consistent with patient-care needs.

B.6.2 The computer should be able to completely reproduce archived examination results, including the biological reference interval originally given for an examination and any flags, footnotes or interpretative comments attached to the result, as well as the uncertainty of measurement at the time the measurement was made.

B.6.3 Patient and laboratory data should be retrievable, “on-line”, for a designated period of time, depending on the needs of the individual organisation.

B.6.4 Data-storage media, such as tapes and disks, should be properly labeled, stored and protected from damage or unauthorized use.

B.6.5 Efficient back-up should be in place to prevent loss of patient result data in case of hardware or software failure.

B.6.6 Computer alarm systems (usually the main computer console that monitors hardware and software performance) should be monitored and tested regularly to ensure their proper functioning.

B.7 Hardware and software

B.7.1 A written procedure and a complete record of all preventive maintenance for all computer hardware should be readily available.

B.7.2 The system should be checked after each back-up or restoration of data files in order to ensure that no inadvertent alterations have occurred.

B.7.3 Mistakes detected during system backup should be documented, along with corrective action taken, and reported to the responsible person in the laboratory.

B.7.4 Any alterations to the system hardware or software should be verified, validated and completely documented in order to confirm that changes are acceptable and appropriate.

B.7.5 The laboratory director or person designated for the task is responsible for the accurate and effective delivery of examination results to the requesting clinician and should approve all changes in the computer system that may affect patient care.

B.7.6 Programs should be checked for proper performance when first installed and after changes or modifications have been made.

B.7.7 The purpose of a program, the manner of its functioning and its interaction with other programs should be clearly stated. The degree of detail should be adequate to support any troubleshooting, system modification or programming – as applicable – done by the computer operators.

B.7.8 Those interacting with the computer system should be taught how to use a new system or modifications of the old system.

B.7.9 The laboratory should have designated a responsible person to whom all significant computer malfunctions are to be promptly reported.

B.8 System maintenance

B.8.1 “Downtime” for maintenance should be scheduled to minimize interruption of patient-care service.

B.8.2 There should be documented procedures for handling the shutdown and restarting of all or part of the system in order to ensure integrity of the data, uninterrupted delivery of laboratory services and proper functioning of the system after restarting.

B.8.3 There should be written procedures for handling downtime on other systems such as the hospital information system, to ensure the integrity of patient data. Procedures for verifying recovery of the other system and the replacement or updating of data files should be available.

B.8.4 All unscheduled computer downtime, periods of system degradation (response time) and other computer problems should be documented, including the reasons for failure and the corrective action taken.

B.8.5 Written contingency plans should be developed to handle services in the event of a computer system failure such that patient results are reported in

a prompt and useful fashion.

B.8.6 Records should be maintained that document regular maintenance and allow operators to trace any work done on the computer system.

Annex C
(informative)

Ethics in laboratory medicine

C.1 General

The professional personnel of a medical laboratory are bound by the ethical codes of their respective profession. Different countries can have particular rules or requirements for some or all professional personnel which have to be observed. For an example, see [18].

Personnel responsible for the management of medical laboratories should accept that, as with other health professionals, they could have responsibilities over and above the minimum required by law.

Acceptable practice will vary somewhat from country to country. A laboratory will need to determine what is appropriate for their own situation and incorporate the details in their quality manual.

Laboratories shall not engage in practices restricted by law and should uphold the reputation of their profession.

C.2 General principles

C.2.1 The general principle of healthcare ethics is that the patient's welfare is paramount. However, the relationship between the laboratory and the patient is complicated by the fact that there could also be a contractual relationship between the requester and the laboratory. Although this relationship (which is often commercial) can frequently be seen as the more important, the laboratory's obligation should be to ensure that the patient's welfare and interest are always the first consideration and take precedence.

C.2.2 The laboratory should treat all patients fairly and without discrimination.

C.3 Collection of information

C.3.1 Laboratories should collect adequate information for the proper identification of the patient, which enables the requested examinations and other laboratory procedures to be carried out, but should not collect unnecessary personal information.

The patient should be aware of the information collected and the purpose for which it is collected.

C.3.2 Safety of staff and other patients are legitimate concerns when

communicable diseases are possible and information may be collected for these purposes. Billing purposes, financial audit, resource management and utilization reviews are also legitimate management concerns for which information may be collected.

C.4 Collection of primary samples

C.4.1 All procedures carried out on a patient require the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents him- or her-self at a laboratory with a request form and willingly submits to the usual collecting procedure, for example, venipuncture. Patients in a hospital bed should normally be given the opportunity to refuse.

Special procedures, including the more invasive procedures, will require a more detailed explanation and, in some cases, written consent. This is desirable when there is a likelihood of complications following the procedure.

In emergency situations, consent might not be possible and under these circumstances it is acceptable to carry out necessary procedures, provided they are in the patient's best interest.

C.4.2 Some examinations (e.g. certain genetic or serologic examinations) may require special counseling. This would normally be carried out by the clinical staff or requesting physician, but the laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counseling.

C.4.3 Adequate privacy during reception and sampling should be available and appropriate to the type of primary sample being collected and information being requested.

C.4.4 If a primary sample arrives at the laboratory in a condition that is unsuitable for the requested examination, it should normally be discarded and the referring physician notified.

C.5 Performance of examination

All laboratory examinations should be carried out according to appropriate standards and with the level of skill and competence expected of the profession.

Any fabrication of results is completely unacceptable.

In situations where the pathologist or the laboratory can determine the amount of work involved with a requested examination (e.g. the number of blocks that may be cut from a histology specimen), the selection should be reasonable for the particular situation.

C.6 Reporting of results

C.6.1 Results of laboratory examinations that can be attributed to a specific patient are confidential unless disclosure is authorized. Results will normally be reported to the requesting physician and may be reported to other parties with the patient's consent or as required by law. Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

C.6.2 Decisions concerning implied consent for the reporting of results to other parties (e.g. consultant practitioners to whom the patient has been referred) should be made cautiously, taking local customs into account. Laboratories should have written procedures detailing how various requests are handled and this information should be made available to patients on request.

C.6.3 In addition to the accurate reporting of laboratory results, the laboratory has an additional responsibility to ensure that, as far as possible, the examinations are correctly interpreted and applied in the patient's best interest. Specialist advice with regard to the selection and interpretation of examinations is part of the laboratory service.

C.7 Storage and retention of medical records

C.7.1 The laboratory should ensure that the information is stored such that there are reasonable safeguards against loss, unauthorized access or tampering and other misuse.

C.7.2 The retention of medical records can be defined by various statutory and legislative requirements in different countries and these requirements will need to be considered together with any guideline issues by relevant professional bodies.

Local customs, particularly the reliance of clinicians on laboratory records as opposed to their own records, also need to be taken into account.

C.7.3 Concerns regarding legal liability for certain types of procedures (e.g. histology examinations) may require the retention of certain records or materials for much longer periods than for other records or samples.

C.7.4 Laboratories should develop their own protocols for the retention of records, indicating the time various examination results are to be retained. The system should provide ready access, when required, by authorized individuals.

C.8 Access to medical laboratory records

C.8.1 Access to medical laboratory records varies somewhat according to different customs in different parts of the world. Patient access will normally be through the requesting physician. In many countries access will normally be available to

a) the person requesting the examination,

b) laboratory staff, if required for the performance of their duties, and

c) other authorized individuals.

The rights of children and mentally impaired individuals also vary from country to country. Health information can sometimes be withheld from individuals who would normally be expected to be authorized to receive it. This could be for reasons of maintenance of law or individual safety and when access would involve unwarranted disclosure of the affairs of another individual.

C.8.2 The laboratory should develop protocols addressing the handling of different requests in accordance with local laws and customs.

C.9 Use of samples for examination purposes other than those requested

The use of samples for purposes other than those requested without prior consent should occur only if the residual samples are rendered anonymous or have been pooled. Laboratories / institutions should have documented policies for handling unrequested information (e.g. follow-up examinations to clarify previous results) from identifiable samples, taking into account the legal implications. Relevant national, regional and local regulatory and ethical committee requirements should be observed. See [8].

C.10 Financial arrangements

C.10.1 Medical laboratories should not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an inducement for the referral of examinations or patients or interfere with the physician's independent assessment of what is best for the patient.

C.10.2 Where possible, rooms used for primary sample collection should be completely independent and separate from referring practitioners' rooms, but where this is not possible, financial arrangements are to follow normal commercial practice.

C.10.3 Laboratories should try to avoid situations that give rise to a conflict of interest. Where this is not possible, the interests should be declared and steps taken to minimize the impact.

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