



STANDARDS
MALAYSIA

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)
LABORATORY ACCREDITATION SCHEME OF MALAYSIA

**SC 2 - SPECIFIC CRITERIA
FOR ACCREDITATION IN THE FIELD OF
MEDICAL TESTING**

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(Supplementary to MS ISO 15189)



MS ISO 15189

JABATAN STANDARD MALAYSIA
Department of Standards Malaysia

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SPECIFIC CRITERIA FOR ACCREDITATION IN THE FIELD OF MEDICAL TESTING

Introduction

The purpose of SC 2 is to clarify the main standard MS ISO 15189 in the Malaysian context. This document should be read in conjunction with the MS ISO 15189 standard. Clause numbers correspond to those in the standard which require elaboration.

Compliance to this document does not in any way exempt laboratories from or diminish their responsibilities in observing/complying with existing national laws and regulations/guidelines currently enforced in the country.

1 Scope

This will apply to all medical laboratories assessed according to MS ISO 15189 Medical Laboratories - Requirements for Quality and Competence.

2 Normative references

Examples but not limited to:

- 2.1 Pathology Laboratory Act 2007 (Act 674)
- 2.2 Human Tissue Act 1974 (Act 130)
- 2.3 National Archives Act 2003 (Act 629)
- 2.4 Private Healthcare Facilities and Services Act 1998 (Act 586)

3 Terms and definitions

For the purpose of this document the terms and definition given in MS ISO 15189 and the following apply.

- i. Collection centre - a place which is administratively under the main laboratory where primary samples are collected and/or prepared for sending to the laboratory.
- ii. Result - data without clinical interpretation and may have a descriptive comment.

Examples of descriptive comments:

- (a) Chemical Pathology
 - Sample haemolysed
 - High

- Low
- (b) Haematology - Blood film shows normochromic microcytic RBC
- (c) Medical Microbiology - Malaria parasites seen
 - *Escherichia coli* isolated, sensitive to gentamicin
 - CSF direct smear shows pus cells and gram positive cocci
 - Scrub typhus antibody titre IgG 1280
- (d) Virology - Dengue IgM positive
 - No virus isolated
- (e) Cytopathology - Within normal limits

Note: Histopathology - no example given because descriptive comments are not allowed.

- iii. Report - interpretative report issued (usually by pathologist) containing clinically relevant inferences from test results or analytical findings.
- iv. Authorised requester (Clause 5.4.3b of MS ISO 15189)

A medically-qualified practitioner or his/her authorised designee or a person acting under a medicolegal directive.
- v. Person authorised to receive laboratory test result and report (Clause 5.9.1 of MS ISO 15189)
 - The person authorised to receive the laboratory test result or report shall be the authorised requester or his/her authorised designee.
- vi. Subject Matter Experts (SME) is a person with knowledge and expertise in a specific subject or technical area

4 Management requirements

4.1 Organisation and management responsibility

4.1.1.4 Laboratory director

The laboratory director shall be the person-in-charge of the services of the laboratory and should be resident to the laboratory. There may be more than one laboratory director if the scope of services provided by the laboratory extends over more than one specialty of pathology such that a single laboratory director may not have the competence to assume responsibility for all the services provided. Where

national regulations apply, statutory requirements with regard to competence, qualifications and experience of the laboratory director (person-in-charge) shall be complied with.

Note: 'Resident' connotes that the laboratory director works in-house and the laboratory is the main place of professional practice.

The requirements for the laboratory director are related to the scope of accreditation of a laboratory:

- (i) For a laboratory which provides clinical consultation and/or clinical interpretation for tests accredited under the scope of accreditation, the laboratory director shall be a medically-qualified pathologist (i.e. a medical practitioner registered with the Malaysian Medical Council, with a postgraduate qualification in pathology approved by the Government of Malaysia) and a minimum of three years working experience as a pathologist.
- (ii) For a laboratory accredited for testing-only services (i.e. no clinical consultation or interpretation services), the laboratory director shall be a medically-qualified pathologist, as defined in (i) above; or a person with a Bachelor of Science Degree or Bachelor of Biomedical Science Degree or an equivalent in a relevant field, with a minimum of five years working experience in a pathology laboratory in the appropriate area of the scope of accreditation, three of which shall have been at a supervisory level.

4.1.1.4c) Sufficiency of staff to meet needs

The number of staff, skill mix and case mix will vary from laboratory to laboratory. The adequacy of staff numbers and the appropriateness of the skill mix in relation to the scope of services, case mix and the workload in any laboratory shall be scrutinised at assessment. Indicators assessed shall include staff numbers, workload, annual leave, extended hours of work, on-call roster duties, staffing resources for quality management issues and back-up support. Where appropriate, reference should be made to national professional guidelines.

The appropriateness of technical and clinical personnel engaged shall be interpreted using the following guidelines:

- (a) For a laboratory which provides clinical consultation and/or clinical interpretation for tests accredited under the scope of accreditation, the laboratory shall engage the services of medically-qualified pathologist(s) trained in that speciality of pathology. If the resident pathologists are unable to cover all the services offered, suitably qualified and experienced visiting pathologists shall be engaged.
- (b) The laboratory shall engage the services of technical personnel trained in each specialty of pathology accredited under the scope of accreditation. Where resident technical personnel are

unable to cover all the services offered, suitably qualified and experienced part-time technical personnel shall be engaged.

- (c) Where there is no resident clinical personnel to provide the clinical input or advisory services required in Clause 4.7, the services of a visiting pathologist shall be engaged.
- (d) There shall be at least one technical personnel present in the laboratory, during all working hours.

4.1.2.5 Responsibility, authority and interrelationships

Responsibilities of the laboratory director and designees

The standard prescribes a number of responsibilities for the “laboratory director” (person or persons). Each of these responsibilities can be formally designated to a person(s) (designee(s)) with appropriate qualifications and experience to assume those responsibilities. The laboratory director and his designees are regarded as key personnel. Key personnel shall normally be:

- (a) All laboratory directors (however named);
- (b) Quality manager;
- (c) Technical manager;
- (d) Document controller;
- (e) Medically qualified pathologists providing clinical interpretative reports.

It is recognised that in smaller laboratories individuals can have more than one function and that it could be impractical to appoint deputies for every function.

In this regard, the following issues shall be addressed:

- (i) The designation of key personnel will be the responsibility of the laboratory director. Laboratories are required to have a documented person/position specification for key personnel and a documented and formal process for their qualification and appointment.
- (ii) The laboratory shall maintain a list of current key personnel, including the scope of their areas of responsibility. This list may be listed in the laboratory’s quality manual or as a separate document, but shall be maintained as up-to-date at all times. The technical and/or clinical scope for each key personnel will be described in a manner to suit the laboratory’s circumstance and organisational structure, but there shall be at least one key personnel appointed for each specialty of pathology in the laboratory’s scope of accreditation.

- (iii) The list of key personnel and their individual scope of responsibility shall be notified to Standards Malaysia prior to the assessment. The list will also be reviewed with the laboratory during assessment.
- (iv) Changes to key personnel listings (including individuals who have left the laboratory, new key personnel appointments, or changes in the scope of responsibility) shall also be notified to Standards Malaysia. This is the responsibility of the laboratory management.
- (v) Where a laboratory loses a key personnel for all or part of their scope of accreditation, and no new appointment is made by the laboratory management, then the laboratory's accreditation (or part thereof) will be suspended until such time as a new appointment is approved by Standards Malaysia. Where new key personnel appointments are made outside of routine assessments, and particularly when a new appointment is the sole key personnel for all or part of the accreditation, Standards Malaysia reserves the right to conduct an on-site assessment of the laboratory to be assured that the laboratory's system, and the integrity of the laboratory's test results, will continue to be maintained.

Responsibilities of key personnel

- (i) Key personnel would be expected to have:
 - (a) A position in the staff organisational plan which provides for the authority to implement necessary changes in the laboratory operation to ensure the integrity of test results is maintained.
 - (b) A working knowledge of the quality assurance system and operation of the laboratory on a day-to-day basis.
 - (c) A working knowledge of and commitment to the requirements for SAMM accreditation, including the quality and technical management principles embodied in MS ISO 15189 and relevant Specific Criteria.
 - (d) The necessary expertise and experience to be aware of, and understand, any limitation of the test procedures, and to understand fully the scientific basis of the procedures.
- (ii) Key personnel can be given both the responsibility and authority to:
 - (a) Develop and implement new operational procedures.
 - (b) Design quality control programmes, set action criteria and take corrective action when these criteria are exceeded.

- (c) Identify and resolve problems.
 - (d) Take responsibility for the validity of the outputs.
- (ii) Clinical and technical personnel who are not engaged full-time could also be appointed as key personnel. However, the circumstances in which they are called upon to exercise their key personnel responsibilities and their access to and knowledge of the laboratory's operations, should be such that they are able to take full responsibility for the work they undertake, authorise or oversee.

4.2 Quality management system

As in MS ISO 15189.

4.3 Document control

As in MS ISO 15189.

4.4 Service agreements

4.4.1 Establishment of service agreements

Where a laboratory is a part of a hospital and provides in-house services to the hospital, the internal arrangement between the hospital management and the laboratory management may be considered as an agreement and the requirements of this clause apply. The agreement may be in the form of a request form, memorandum, manual, circular, letter, minutes of a meeting, etc. which shall be controlled.

4.5 Examination by referral laboratories

4.5.1 Selecting and evaluating referral laboratories and consultants

In exceptional circumstances where an examination is sought on an esoteric or unusual condition, and the request is urgent, one-off or ad-hoc in nature, the examination may be referred to a laboratory or a second opinion sought from an individual, without prior management evaluation. The reasons for such a referral shall be documented by the appropriate laboratory director or key personnel, to show why this referral is in the best interest of patient care.

This clause does not apply where a sample is to be examined by another laboratory, as arranged by a requester and the pathology laboratory merely acts as a handling centre on behalf of the requester. The examination results of such samples shall not be issued under the name of the

pathology laboratory and the laboratory shall not make any statement on its accreditation status regarding the examination results.

The referring laboratory shall ensure that request form sent to the referral laboratories comply with Clause 5.4.3 of MS ISO 15189.

4.5.2 Provision of examination results

The referring laboratory may discharge the responsibility for reporting as follows:

- (a) By forwarding the original report in its entirety to the requester.
- (b) By instructing the referral laboratory to send the original report (paper or electronic) directly to the requester and a copy to the referring laboratory.
- (c) Where the referring laboratory has already performed related tests, any additional tests performed by the referral laboratory may be reported as part of a composite report issued by the referring laboratory. In this case the laboratory/pathologist responsible for performing each test in the composite report shall be clearly identified.

4.5.3 Transcription of result/report from the referral laboratories is not encouraged.

4.6 External services and supplies

As in MS ISO 15189.

4.7 Advisory services

Pathologist(s) and/or appropriate specialist(s) shall be available to provide clinical advice prior to test ordering and to advise on the interpretation of all test results. Other appropriate advice may be provided by Subject Matter Experts (SME). This may entail referring the clinician to an appropriate specialist in another laboratory or institution. A laboratory handbook, developed in conjunction with an appropriate pathologist(s) or specialist(s), may be seen as a convenient means of providing guidance to clinician(s) on the choice of tests, etc.

The technical and scientific personnel may give advice on technical matters. However clinical interpretation of laboratory test results remains the responsibility of the supervising pathologist(s).

4.8 Resolution of complaints

As in MS ISO 15189.

4.9 Identification and control of nonconformities

As in MS ISO 15189.

4.10 Corrective action

As in MS ISO 15189.

4.11 Preventive action

As in MS ISO 15189.

4.12 Continual improvement

The laboratory shall review periodically its contribution to patient care. The aspects that may be monitored include the following:

- (a) test repertoire, including standard testing profiles, reflex testing, procedures for follow up and confirmatory testing;
- (b) methodology and instrumentation considerations, including specificity, sensitivity and uncertainty of results in relation to clinical decision making;
- (c) appropriateness and timelines of interpretations provided, including automatic-comment generation, if relevant;
- (d) follow up of significantly abnormal test results;
- (e) follow up of adverse incidents after corrective action has been taken;
- (f) quality of pre-examination services (e.g. number of re-collections, incorrect samples, poor-quality samples, mislabelled samples, rejected samples);
- (g) clinically relevant turnaround times i.e. from time of sampling to result sent-out; and
- (h) systematic collection and evaluation of clinically relevant feedback e.g. customer satisfaction survey.

Compliance with this clause imposes on the laboratory a need to develop close links with clinical users of its services, to include full and active participation in audit processes that connect the technical output of the laboratory to outcomes of patient care.

4.13 Control of records

- 4.13.1 A copy of examination results and reports issued shall be kept in the record system or it shall allow one to be reproduced upon request.

4.13.2 Minimum retention periods for patient records and specimens shall conform to relevant national guidelines / regulations where available such as College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.

4.14 Evaluation and audits

4.14.2 Periodic review of requests, and suitability of procedures and sample requirements

Authorised personnel (pathologist/SME) shall periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received.

4.14.5 Internal audit

Auditors shall have adequate knowledge in MS ISO 15189 and receive relevant training to conduct internal audit.

A checklist may be useful to ensure complete coverage of the important aspects of the audit which includes both managerial and technical components. The elements to be audited may include the following:

- (a) staff awareness of the quality manual;
- (b) analytical procedure selection, control and validation;
- (c) control of reagents and standards;
- (d) equipment calibration and maintenance records;
- (e) proficiency testing and inter-laboratory collaborative trials;
- (f) audit trails in quality and technical records;
- (g) personnel training records;
- (h) handling of deficiencies and remedial action; and
- (i) laboratory housekeeping and health and safety measures.

All activities of the laboratory under the quality management system including its collection centers shall be subjected to internal audit.

4.14.6 Risk management

As a guidance, potential failures in laboratory quality management system including the pre-examination, examination and post examination work processes which affect examination results may be identified using methods such as Failure Mode and Effect Analysis (FMEA) or similar risk assessment tools. It may include, but not limited to an evaluation of the following components:-

- (a) Specimen
- (b) Test system (Equipment and methodology)
- (c) Reagents
- (d) Environment
- (e) Personnel

Evaluation of the risk and mitigation to reduce the risk shall be documented. Effectiveness of the actions shall be evaluated during the assessment.

Reference may be made to the following documents:

- (a) MS ISO 31000 – Risk Management – Principles and Guidelines on Implementation
- (b) MS IEC/ISO 31010 – Risk Management – Risk Assessment Techniques
- (c) MS ISO Guide 73 – Risk Management – Vocabulary
- (d) MS 2370 – Medical Laboratories – Reduction of Error Through Risk Management and Continual Improvement

4.15 Management review

As in MS ISO 15189.

5 Technical requirements

5.1 Personnel

The laboratory personnel policy(ies) shall include recruitment, appointment and assignment of all clinical and technical personnel, and their performance appraisals based on predetermined individual targets. The recruitment and qualifications of laboratory personnel shall be in compliance with relevant existing laws in the country.

The competency of personnel is a major aspect of each laboratory assessment as the standard of performance depends heavily on the competence of the laboratory's personnel.

Four categories of personnel will be assessed. They are:

- (a) Technical personnel;
- (b) Clinical personnel;
- (c) Management personnel; and
- (d) Supervisory personnel.

Technical personnel refer to staff who perform the scientific and technical work of the laboratory. They shall have suitable qualifications and training and have sufficient experience and ability to perform the scientific and technical work required by the scope of the accreditation. This shall be evidenced by:

- (i) a Bachelor of Science Degree or a Bachelor of Biomedical Science Degree or an equivalent in a relevant field, recognised by the Government of Malaysia , and at least 6 months of supervised training in the relevant area of laboratory service (whether as part of the degree programme or as post-degree training); or
- (ii) a Diploma in Medical Laboratory Technology or an equivalent, recognised by the Government of Malaysia and at least 6 months of supervised training in the relevant area of the laboratory service (whether as part of the diploma programme or as post-diploma training); and
- (iii) Records of evaluation of competence in the tasks assigned to the person.

Trainee technical personnel who are undergoing supervised training in the relevant area of the laboratory service, can also perform technical work, provided that they are under the direction and supervision of a technical person fulfilling criteria (i) or (ii) above, in the relevant area of laboratory service. A system shall be in place to cross examine and verify the trainee's performance.

Technical assistants are personnel without the formal qualifications as in (i) or (ii) above but possess appropriate practical experience, specific training and with competency assessed, to undertake work of a repetitive nature. Such work shall not involve analytical testing, measurements or validation of results.

The laboratory shall ensure that technical personnel assigned to perform new or rarely used techniques undergo appropriate training. Records of training and assessments of competence shall be kept. These shall include records of results of examinations/tests performed during training and competence assessments. The validity

of results produced by technical personnel, particularly in the first six months after completion of training in new techniques shall be monitored.

Mental and physical challenges (e.g. mental illness, colour blindness and other physical handicaps) may affect the performance of certain types of laboratory tests. It is the responsibility of the laboratory management to assign duties in a manner that will ensure the validity of results and laboratory safety without being compromised by personnel with these challenges.

Clinical personnel

Clinical personnel are those who provide clinical interpretations (or professional opinions or consultations) of laboratory test results for the purpose of medical diagnosis or treatment of persons suffering from, or believed 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.

Personnel providing such clinical interpretations or professional judgement shall possess such qualification, training and experience, relevant to the specialty of pathology in which they practice (e.g. histopathology, haematology, chemical pathology and medical microbiology).

Only laboratories with such interpretative or consultation services that fulfil the specific requirements for the appropriate clinical personnel may be accredited for such a service. Laboratories must meet the relevant requirement for personnel with interpretative or consultative capabilities before they may be accredited for providing such services of interpretations or professional judgement relevant to the specialty of pathology in which they practice (e.g. histopathology, haematology, chemical pathology and medical microbiology)

Only medically-qualified pathologists can provide clinical interpretations of laboratory test results or consultations in the pathology specialty in which he/she is qualified. Qualification is evidenced by a post-graduate qualification in pathology approved by the Government of Malaysia, with at least 3 years of training or working experience in the relevant pathology specialty(ies) whether as part of the pathology qualification training programme or as post-qualification experience.

Medical practitioners working in the laboratory or undergoing formal training in pathology can also provide clinical interpretation provided that they are under the direction and supervision of a medically-qualified pathologist in that specialty. A system shall be in place to cross examine and verify the medical practitioner's interpretations. The supervising pathologist is held responsible for the reports of the medical practitioner that he supervises.

All clinical personnel shall satisfy the requirements of the Malaysian Medical Council to practice in Malaysia.

Under defined circumstances, interpretation of results may be provided by technical personnel with suitable training and working experience (e.g. cytopathology, cytogenetics and immunology). Such interpretation may be a prepared text or comment based on accepted criteria or algorithm but should not include advice on clinical diagnosis and management. Exceptions to this are stated in the Specific Technical Requirements (STRs).

The person who provides clinical interpretations, who may or may not be the laboratory director, shall have the authority to make decisions on the operations of the laboratories with respect to matters relating to clinical interpretations.

Where appropriate, certain clinical personnel may also serve as key personnel or designees of the laboratory director.

Where the provision of consultations or interpretations is included in the scope of accreditation, the assessment/reassessment will include the evaluation of the personnel and relevant records and reports produced by them.

Approvals for providing interpretations and signing *Skim Akreditasi Makmal Malaysia* (SAMM) endorsed reports containing interpretations will be granted to those personnel who are found to fulfill the relevant requirements. The responsibility for interpretation of the laboratory's test results remains with the approved person(s) and cannot be delegated to other persons. The person giving the interpretations shall be deemed to authorise the release of the report containing his/her interpretation personally.

Department of Standards Malaysia (Standards Malaysia) shall be informed of departure or changes in the availability of the persons approved for giving interpretations as soon as possible. Standards Malaysia will take the necessary actions such as amendment of the scope of accreditation of the laboratory regarding the availability of consultation and interpretation services, or suspension of the laboratory's accreditation, depending on the circumstances.

Management and Supervisory Roles

Some technical and clinical personnel may assume management and/or supervisory roles.

The suitability of personnel, including the laboratory director, in performing their management and supervisory roles, shall be assessed. Aspects which will be considered include:

- (a) the qualifications and professional experience of persons with management and supervisory roles;
- (b) the workload of the laboratory and the range of tests offered;
- (c) the technical complexity and nature of the testing involved;

- (d) the contact that managers and supervisors maintain with subordinate staff; and
- (e) the involvement of managers and supervisors in the development of methodology and adoption of new methodology within the laboratory.

The management team shall include all laboratory directors and at least a medically qualified pathologist who may be a visiting pathologist.

Persons with supervisory roles shall be stated to have sufficient authority, skills and experience to train and supervise subordinate personnel.

Contracted personnel

When a laboratory uses contracted personnel irrespective of the duration of the contract and whether the contracted personnel 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 that the contracted personnel are competent in carrying out their duties.

Visiting pathologists

A visiting pathologist is a medically-qualified pathologist who periodically visits a laboratory and provides services in areas where the laboratory director, or other personnel of the laboratory, cannot adequately discharge the responsibilities that are appropriate to the services provided by the laboratory. These services may be supervisory or the provision of clinical interpretation of examination/test results or the performance of examinations or other services.

The visiting pathologist shall be qualified in the specialty where he/she is providing services and shall comply with the competence requirements of clinical personnel.

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

- (i) an effective working relationship between the laboratory director and visiting pathologist is established;
- (ii) advice and recommendations of the visiting pathologist are acted upon within the required timeframe;

- (iii) the frequency and duration of visits are defined and appropriate to the volume and scope of work undertaken by the visiting pathologist. This may take into account the availability of electronic links, which enable remote supervision of laboratory output;
- (iv) the functions, roles and activities of the visiting pathologist as well as his/her authorities and responsibilities are clearly defined;
- (v) records of input by the visiting pathologist including the dates and duration of visits, topics and issues discussed, interactions with on-site staff, recommendations, advice or instructions given, are kept;
- (vi) the means by which the visiting 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 visiting pathologist within a timescale appropriate to the clinical situation is in place; and
- (viii) liabilities of the examination results and their interpretations are clearly defined.

5.1.6 Competence assessment

Personnel competency

The competency of all clinical and technical personnel to perform assigned tasks shall be reassessed, at least once in two years. Personnel who undertake duties after a long period of absence (as specified in the relevant specific technical requirements) are expected to undergo reassessment and retraining if necessary. Records of training and competency attainment shall be endorsed by both trainer and trainee.

Where personnel are expected to work in areas other than those in which they would normally work (e.g. when working on-call or at weekends) a programme of regular refresher training shall be established and records retained.

Personnel who work only “out-of-hours” shall have regular contact with routine staff and in particular supervisory staff. As a guide, one day per month spent in the laboratory during normal working hours would be appropriate.

5.1.8 Continuing education and professional development

Continuing education and continuing professional development are important for maintaining competence of clinical and technical personnel. These include in-house and external activities and use of appropriate reference texts and journals. Examples are:

External

- (a) Attendance at professional conferences, seminars and lectures.
- (b) Educational attachments or visits to other laboratories.
- (c) Participation in training courses and workshops.

Internal

- (a) Regular educational presentations.
- (b) Journal article reviews.
- (c) Case presentations.
- (d) Review of QAP educational material.
- (e) Review of interesting/abnormal cases (histological slides, smears, blood films, culture, etc.).

As a guideline for a minimum level of participation, all clinical personnel would be expected to spend at least 15 hours in each 3 months period and all technical personnel would be expected to spend at least 5 hours in each 3 months period participating in these activities, unless otherwise directed by the accreditation body following a peer-review assessment.

For part-time staff, the minimum level of participation should be pro-rata. Detailed records of participation in these activities shall be kept, in addition to records of competency in the performance of key tasks in the laboratory.

5.2 Accommodation and environmental conditions

The laboratory should be designed to ensure a comfortable and safe working environment. Reference may be made to the following documents:

- i. WHO Laboratory Biosafety Manual;
- ii. College of Pathologists, Academy of Medicine Malaysia guidelines;
- iii. Guidance documents available from other accreditation bodies (e.g. HOKLAS, SANAS, IANZ, NATA, etc.);
- iv. Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations);

- v. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations);
- vi. Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010.

Safety

While safe laboratory practice forms an important part of providing a quality service and will be necessary to achieve the standards required for accreditation, an assessment does not constitute a formal safety audit.

National authorities are responsible for occupational health and safety in laboratories. However, it is an expectation of the standard that all applicable standards and guidelines relating to medical laboratories in Malaysia, and recognised best practice, shall be implemented. Attention shall be drawn to any unsafe practices that are encountered. Where instruction and advice related to safety are written into test methods covered by accreditation, these shall also be observed.

A safety manual detailing the laboratory's policies and procedures in relation to health and safety shall be readily available to staff.

Due consideration shall be given to separating certain procedures from the main work area for the safety of workers and the protection of the environment. Such procedures include but are not limited to:

- (a) those that may pose a hazard to other staff (e.g. tests using radioactive isotopes, mycobacteriology);
- (b) those procedures which may be affected or influenced by not being segregated (e.g. tissue culture, polymerase chain reaction (PCR) work); and
- (c) where a quiet and uninterrupted work environment is required (e.g. cytology screening).

There shall be demarcation between "clean" areas, i.e. areas used for clerical aspects of laboratory work and "dirty" areas, i.e. areas used for testing procedures. Access to the work areas shall be controlled and areas for members of the public shall be clearly segregated from the work areas.

5.3 Laboratory equipment, reagents, and consumables

5.3.1 Equipment

5.3.1.1 General

In cases where the laboratory needs to use equipment outside of its permanent control, such as when sharing specialised equipment, management shall ensure that the requirements of this standard are met. This could be achieved as follows:

- (a) access to records of equipment calibration and maintenance.
- (b) verify equipment performance at each time of use.

5.3.1.4 Equipment calibration and metrological traceability

Reference should be made to SAMM Policy 2. Test or calibration equipment that has a significant effect on the reported results and associated uncertainties of measurement (including, where relevant, instruments used for monitoring environmental conditions) shall be calibrated by (one or more) of the following:

- (a) Standards Malaysia accredited calibration laboratories.
- (b) Calibration laboratories accredited by one of Standards Malaysia's Mutual Recognition Agreement (MRA) partners.

Note: An endorsement relating only to ISO 9001 certification is not acceptable.

Standards Malaysia may expect reduced, or accept extended, calibration intervals based on such factors as history of stability and accuracy and precision requirements. It is the responsibility of the laboratory to provide clear evidence that its calibration and maintenance system ensures confidence that the equipment is maintained. Recommended calibration and/or performance check interval are available in Appendix 1. Reference may also be made to ILAC G 24- Guidelines for the determination of calibration intervals of measuring instruments.

5.3.2 Reagents and consumables

All reagent and chemical shall bear a label which as a minimum, display reagent/chemical name, date of preparation/date opened, strength, solvent, any special precautions or hazards and date of expiry. A barcoded label with the above information is acceptable. The person responsible for the preparation of the reagent shall be identifiable either from the label or from records.

Dangerous and highly toxic/flammable substances shall be kept separately from other reagents in appropriate cabinets.

5.4 Pre-examination processes

The importance of proper collection and transportation of primary samples is emphasised. Where the laboratory undertakes collection of samples by its own employees, this aspect shall be formally assessed.

Collection centres shall be assessed for every cycle of the accreditation period (3 years). The selection of collection centre to be assessed shall be based on their geographical location and shall normally not be less than 10% of the total number of collection centres. Consideration will also be given to work load, types of samples and audit reports of the collection centres.

In cases where laboratory personnel are not directly involved in sample collection, the laboratory maintains responsibility for instructing and monitoring so that collections are carried out correctly, and so that samples are transported to the laboratory in compliance with Clause 5.4.4.3 and 5.4.5 of MS ISO 15189.

5.4.3 a) Each sample received shall be uniquely identified and matched to the accompanying request form by at least two unique identifiers. Where two or more samples accompany a request form, these shall be distinguishable from each other in both the labels and request form.

5.4.4 Instructions on safety precautions shall be available to those responsible for sample collection.

5.4.4.3 a) On presentation for collection, patients shall be positively identified by the collector, using open questions wherever possible (e.g. What is your name?).

5.4.4.3 e) All patient specimens accepted by the laboratory for testing shall be labelled in accordance with procedures defined. As a minimum, the specimen label shall carry the following:

(a) Two unique identifiers (e.g. name of patient and patient identification number);

(b) Type of sample (e.g. urine, blood, CSF, renal biopsy, right middle toe); and

(c) Date of sampling.

5.4.6 Sample reception

Samples and associated records (worksheets, slides, etc.) shall be uniquely identified at all stages of testing. This may be achieved by the use of unique laboratory numbers. This is usually the most practical option especially where large numbers of specimens are processed. Alternatively, samples and

associated records may be uniquely identified by the use of two patient identifiers (e.g. patient's name and date of birth or medical record number).

The uniqueness of a numbering system shall be such that it can distinguish samples from each other even over a long period of time.

5.5 Examination processes

5.5.1.1 General

Each procedure shall be authorised and dated by the responsible key personnel.

Review of methods shall be documented. Where there are no changes after a review, a date and signature will be sufficient for record purposes. Some manufacturers provide method documentation (product inserts) with their product and these may be included in method manuals. These shall be authorised as above.

Where this information is not sufficiently detailed to cover all required elements it shall be supplemented by the laboratory. Inserts for new batches received shall be checked for changes in procedure and a copy of the new insert placed in the manual. Product updates shall be reviewed for relevance to the laboratory and if relevant, appropriate action taken shall be documented and controlled accordingly.

5.5.1.4 Measurement uncertainty of measured quantity value

As in MS ISO 15189 and SAMM Policy 5.

5.6 Ensuring quality of examination results

5.6.2 Quality control

- (a) Laboratories shall identify person(s) to be responsible for quality control activities.
- (b) The quality control programme in the laboratory should address the following:
 - i. The internal QC material used shall cover the analysis or analytical concentrations encountered. Low, normal and high, normal and abnormal, positive and negative controls, as appropriate for the test, shall be performed at least every day or every batch of analysis. Its performance shall be reviewed based on acceptance or rejection criteria and the analytical problems rectified.
 - ii. For special stains, positive controls shall be performed. Where possible, positive control slides shall be retained so that they are traceable to the relevant patient slides.

- iii. The use of controls independent of those produced by the manufacturer of the test or analyser is preferable.
- iv. Where calibration of an assay is required, appropriate material shall be used as calibrator. If the material selected is not intended for use as a calibrator, ascribed calibration values shall be substantiated.
- v. Acceptable ranges shall be defined for internal quality control material. These ranges shall be statistically valid and clinically relevant.
- vi. Means and standard deviations supplied by manufacturers of QC material should be validated to ensure that adequate control of assays is achieved. Laboratories should determine means and standard deviations using their own data.
- vii. Control material should be matrix matched e.g. urine based control should be used for assay of urine analytes.
- viii. A protocol for action to be taken where quality control results fall outside acceptable ranges shall be documented. Criteria for acceptance or rejection of a QC run shall be established.
- ix. Internal QC results shall be recorded and reviewed.
- x. Graphical presentation of numerical QC results should be considered, to assist the early detection of trends.
- xi. Details of action taken on unacceptable results shall be recorded.
- xii. The laboratory shall have a system of long-term monitoring of internal quality control results to assess method performance against the quality specification as stated in method verification/validation. A record of remedial action shall be maintained if the performance does not meet the quality specification.

5.6.3 Interlaboratory comparisons

- (a) The purpose of Interlaboratory Comparisons (ILC) programmes (such as EQA or PT) is to provide information on aspects of uncertainty associated with genuine patient samples, including the competency of personnel carrying out testing work. Thus, external quality control samples should, wherever possible, be treated as patient samples. Hence, all personnel who are directly involved in testing patient samples shall

participate in the testing of external quality control samples. Record of their participation shall be maintained, to include an evaluation of performance for the purposes of continuing quality improvement.

- (b) A secondary purpose of ILC is to provide a challenge to personnel for purposes of continuing professional development. Consequently, slides and samples may be examined, tested and discussed for educational purpose, following use in proficiency testing.
- (c) Where a pathologist has responsibilities in more than one laboratory, participation in an appropriate ILC programme in one of the laboratories may be acceptable. However, each laboratory shall itself subscribe to an appropriate programme thus ensuring that technical personnel of the laboratory are able to participate in the technical challenges provided.
- (d) The laboratory shall subscribe to at least one ILC programme for each test or each related group of test or each related test method where relevant under the scope of accreditation.
- (e) Subscription to the ILC shall be current and sustained.
- (f) Standards Malaysia encourages a risk based approach to determine appropriate ILC frequencies.
- (g) The order of preference for choosing an ILC programme should be:
 - i) An EQA programme accredited to ISO/IEC 17043
 - ii) Recognised EQA programme
 - iii) Interlaboratory comparison between accredited laboratories
 - iv) Interlaboratory comparison between non-accredited laboratories

Note: List of PT Providers is available in Standards Malaysia website.

Where such ILC programmes are not available, the laboratory shall develop appropriate quality control activities in compliance to MS ISO 15189 Clause 5.6.3.2.

- (h) The laboratory shall participate in any ILC programme when directed by Standards Malaysia e.g. ILC organised by APLAC/ILAC. If the laboratory is unable to participate it

may seek exemption from Standards Malaysia. Standards Malaysia may grant exemption of participation in a PT subject to the Director of Accreditation's discretion.

5.7 Post-examination processes

All samples shall be retained in accordance with national guidelines e.g. College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.

5.8 Reporting of results

5.8.1 General

Manual transcriptions of data or results or reports are strongly discouraged. When data has to be transcribed manually, into an electronic database or otherwise, there shall be a means of checking the accuracy of transcriptions and entries. Wherever relevant, checking should be performed by an independent operator.

5.9 Release of results

As in MS ISO 15189.

5.10 Laboratory information management

As in MS ISO 15189.

Appendix 1

Recommended calibration and/or performance check interval for Medical Testing Laboratories

No.	Type of equipment	Maximum period between successive calibrations and/or intermediate check	Procedures
1.	Automatic Burettes, Dispensers and Pipettors	Three monthly intermediate check	Accuracy of and repeatability at volumes in use.
2.	Balances	Initial calibration (such as every repair, moving of equipment, etc.) (a) Each weighing (b) *One month (c) *Six months *Calibration using traceable certified masses or Using statistical process control (SPC)	By an accredited calibration laboratory. Zero check. One point check using a known mass close to balance capacity. Repeatability checks at the upper and lower ends of the scale.
3.	Masses (Integral, stainless steel, or nickel-chrome alloys)	Initial calibration Five years recalibration	By an accredited calibration laboratory. By an accredited calibration laboratory.
4.	<ul style="list-style-type: none"> • Biological Safety Cabinets • Laminar Flow • Fume Hood/Cabinet 	Yearly certification or according to manufacturer's instruction Intermediate check or performance check	By a certified body.

Recommended calibration and/or performance check interval for Medical Testing Laboratories

No.	Type of equipment	Maximum period between successive calibrations and/or intermediate check	Procedures
8.	Refrigerators/Chillers/Freezer/Cold Room	Minimum daily	Monitor temperature using calibrated thermometer.
9.	Thermometers (Liquid in Glass) Reference Working	Five years (complete) Six months Initial Six months	By an accredited calibration laboratory. Check at ice point and at points of use. Check against reference thermometer / thermocouple across working range or at points of use. Check at ice point and at points of use.
10.	Thermostatically Controlled Equipment (Incubators, Water Baths, Ovens)	Initial calibration Working days	By an accredited calibration laboratory Monitor temperature using calibrated thermometer
11.	Volumetric Glassware (Flasks, Pipettes, Burettes)	Initial only	Using distilled water at critical graduations.
12.	Timing Devices (Stop Watch/Clock/Timers)	Six months	Test against Malaysia standard time. Two measurements separated by an appropriate interval

References:

1. College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials
2. Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010 (http://www.moh.gov.my/images/gallery/Garispanduan/Guidelines_on_Chemical-1.pdf)
3. ILAC G 24 - Guidelines for the Determination of Calibration Intervals of Measuring Instruments
4. MS 2370 - Medical Laboratories -- Reduction of Error Through Risk Management and Continual Improvement
5. MS IEC/ISO 31010 - Risk Management -- Risk Assessment Techniques
6. MS ISO 15189 - Medical Laboratories -- Requirements for quality and competence'
7. MS ISO 31000 - Risk Management -- Principles and Guidelines on Implementation
8. MS ISO Guide 73 - Risk Management -- Vocabulary
9. Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations) (<http://www.dosh.gov.my/index.php/en/legislation/regulations-1/osha-1994-act-154/522-pua-131-2000-1/file>)
10. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations) (http://www.federalgazette.agc.gov.my/outputp/pua_20131011_P%20U%20%20%28A%29%20310-peraturan-peraturan%20keselamatan%20dan%20kesihatan%20pekerjaan%20%28pengelasan%20pelabelan%20dan%20helaian%20data%20keselamatan%20bahan%20kimia%20berbahaya%29%202013.pdf)
11. SAMM Policy 2 (SP 2) - Policy on the Traceability of Measurement Results
12. SAMM Policy 5 (SP 5) - Policy on Measurement Uncertainty Requirements for SAMM Testing Laboratories
13. WHO Laboratory Biosafety Manual (<http://www.who.int/en/>).

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