MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

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

Issue 6, 25 July 2024

(Supplementary to MS ISO 15189)

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

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Introduction

The purpose of SC 2 is to provide clarification including supplementary requirements to MS ISO 15189 in the Malaysian context. This document should be read in conjunction with the MS ISO 15189 standard and accreditation criteria documents published by the Department of Standards Malaysia (JSM). The clause numbers correspond to those in the standard but since not all clauses require supplementary requirements, the numbering may not continuous.

Compliance with 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 document will apply to all applicant and accredited medical laboratories assessed under *Skim Akreditasi Makmal Malaysia* (SAMM).

2 Normative references

MS ISO 15189 - Medical Laboratories - Requirements for quality and competence.

3 Terms and definitions

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

3.33 authorised requestor
a medically-qualified practitioner or his/her authorised designee or a person acting under a medicolegal directive.

3.34 collection centre
a place which is administratively under the main laboratory where primary samples are collected and/or prepared for sending to the laboratory.

3.35 person authorised to receive laboratory result and report
the person authorised to receive the laboratory test result or report shall be the authorised requestor or his/her authorised designee.

3.36 report
interpretative report issued (usually by pathologist) containing clinical diagnosis and advice from test results or analytical findings.

3.37 result
data without clinical interpretation and may have a descriptive or automated comment.

Examples of descriptive or automated comments:

i) Chemical Pathology
   a. Sample haemolysed
   b. High
   c. Low

ii) Haematology
   a. Blood film shows hypochromic microcytic RBC

iii) Medical Microbiology
   a. Malaria parasites seen

b. Escherichia coli isolated, sensitive to ciprofloxacin
c. CSF direct smear shows pus cells and gram-positive cocci
d. Scrub typhus antibody titre IgG 1280
e. Hepatitis A Virus IgM-reactive
f. Anti HBs <2 IU/L

Note:
1) Further example of comments may be stipulated in the relevant Specific Technical Requirements (STRs).
2) Histopathology - no example given because only reports are issued.

3.38 Subject Matter Experts (SME)
a person with knowledge and expertise in a specific subject or technical area.

3.39 health service provider
centre or organisation or facility that provides healthcare support services for patients (e.g. dialysis centre, rehabilitation centre, nursing home).

3.40 healthcare provider
a professionally qualified individual or entity that provides medical care or treatment. (e.g. doctor, nurse practitioner, midwife, radiologist, laboratory, hospital, clinic).

4 General requirements

4.1 Impartiality

d) The monitoring process or initiative may be as follows:

i) Turnaround time (TAT) between the customers/users, urgent result processing, specific trends of TAT/complaint/customer feedback regarding delayed/unsatisfactory results.

ii) Staff suggestions/feedback.

iii) Evaluation of vendors/suppliers and referral laboratories and consultants.

4.2 Confidentiality

Same as MS ISO 15189.

4.2.2 Release of information

The nature of information and to whom the information is to be released need to be addressed by laboratory.

4.3 Requirements regarding patients

Note: Where applicable the laboratory may refer to MOH policy on patient and family rights.

5 Structural and governance requirements

5.1 Legal entity

Same as MS ISO 15189.

5.2 Laboratory director

The laboratory director (however named) should be the person-in-charge of the laboratory services and shall be resident in 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 be competent to assume responsibility for all the services provided. Where national regulations apply, the laboratory shall comply with statutory requirements in regards to competence, qualifications and experience of the laboratory director (person-in-charge).

Note: Resident connotes the laboratory is a place of his/her professional practice and the laboratory director works in house up to the duration stipulated.

A person shall not be a laboratory director for more than one (1) medical testing laboratory, under one SAMM number. A laboratory director shall be responsible for a maximum of four (4) branches under one SAMM number.

For laboratory with branches, the laboratory director may delegate his/her responsibilities to a deputy laboratory director (however named) at the branch. Nevertheless, the laboratory director remains ultimately responsible.

Note: Refer Accreditation Policy (AP) 3 - Policy for the Accreditation of Branches or Sites of Conformity Assessment Bodies.

The qualification of the laboratory director is related to the scope of accreditation of a laboratory as follows:

i) For a laboratory that 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. 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; or

   b. A person with a Medical Degree, 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; or

   c. 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.

5.2.2 Laboratory director responsibilities

The laboratory director (or designate/s) shall:

i) Provide effective leadership of the medical laboratory services, including budget planning and financial management, in accordance with institutional assignment of such responsibilities;

ii) Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and patient population served, and providers of formal agreements, when required;

iii) Ensure that there are appropriate number of staffs with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users;

iv) Ensure an effective management system and implementation of the quality policy;

v) Implement a safe laboratory environment in compliance with good practice and applicable requirements;

Note: The laboratory director must ensure compliance with OSHA and national, federal, state (or provincial), and local laws and regulations, as well as other applicable safety regulations.

vi) Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate;

vii) Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;

viii) Select and monitor laboratory equipment, product, services and suppliers with respect to quality;

ix) Select the referral laboratories and consultants and, monitor the quality of their services (see 6.8.2);

x) Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations;

xi) Define, implement and monitor standards of performance and quality improvement of the medical laboratory service(s);

Note: This may be done within the context of the various quality improvement committees of the parent organisation, as appropriate, where applicable.

xii) Monitor all work performed in the laboratory to determine that clinically relevant information is being generated;

xiii) Address any complaint, request or suggestion from patients, users and staff of laboratory services;

xiv) Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable; and

Note: The contingency plan should be periodically tested.

xv) Plan and direct research and development, where appropriate.

5.3 Laboratory activities

5.3.1 General

The laboratory shall indicate the permanent location, branches, sites, points of care testing sites and collection centres where applicable in its institution within its responsibilities.

For the purpose of accreditation under SAMM, a laboratory with branch(es) may apply for accreditation for up to maximum four (4) branches under one (1) SAMM number. The branch(es) shall be located within the same region, either in Peninsular or East Malaysia, where the Central Laboratory is located. Laboratory with branch(es) located in both regions shall apply to JSM for separate accreditation (under different SAMM number).

Note: Sites other than main location include mobile laboratories, Emergency Department, wards, outpatient clinics, etc.

5.3.3 Advisory activities

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 to meet the needs of patients and users. 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 tests remains the responsibility of the reporting pathologist(s).

5.4 Structure and authority

5.4.1 General

a) The laboratory director and his/her designees are regarded as key personnel that shall be defined in the organisation and management structure. Key personnel (however named) shall normally be:

   a. Quality manager
   b. Technical manager
   c. Document controller
   d. Clinical personnel (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 (however named) 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 that suits the laboratory's circumstances 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 JSM 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 the JSM promptly. This is the responsibility of the laboratory management; and

   v) Where a laboratory loses the services of a key personnel for all or part of his/her scope of accreditation and no new appointment is made by the laboratory management, the laboratory's accreditation (or part thereof) will be suspended until such time as a new appointment is approved by JSM. When a new key personnel are appointed for all or part of the accreditation, JSM 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.

   Key personnel would be expected to have:

   i) 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;

   ii) A working knowledge of the quality assurance system and operation of the laboratory on a day-to-day basis;

   iii) A working knowledge of and commitment to MS ISO 15189 and SAMM accreditation criteria;

   iv) 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; and

   v) 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.

c) The laboratory shall:

i) Identify all the procedures required to run the tests; and
ii) Include identified procedures as part of the management system.

5.4.2 Quality Management

The management team shall include but is not limited to the following:

a. Laboratory director(s)
b. Quality manager(s)
c. Technical manager(s)
d. Document controller(s)

Quality management responsibilities shall be maintained at all times by the management team or other specified personnel during the absence any member of the management team.

The laboratory shall appoint a quality manager (however named) to carry out and/or coordinate the management system. The scope of responsibility and authority of the quality manager shall be clearly defined and documented, and include the following but are not limited to:

i) Maintenance of the quality manual and associated operations documentation;
ii) Monitoring of laboratory practices to verify continuing compliance with policies and procedures;
iii) Monitoring the evaluation of instrument calibration and maintenance;
iv) Monitoring the validity of methods and procedures;
v) Monitoring the administration of IQC, EQA and evaluation of results;
vi) Selection, training and evaluation of internal auditors;
vii) Scheduling and coordination of management review;
viii) Ensuring and maintaining of training records of laboratory personnel;
ix) Review of feedback received from patients, users and staffs; and
x) Ensuring corrective action and improvements to the management system.

Some of the above responsibilities may be delegated to other persons. However, the quality manager shall ensure that these activities are undertaken in accordance with the procedures and within the time frames specified in the management system.

5.5 Objectives and policies

Same as MS ISO 15189.

5.6 Risk management

Risk management activities shall include both proactive and reactive approaches. As a guidance, potential failures in the laboratory quality management system (hereafter know as management system) including 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 is not limited to an evaluation of the following components:

i) Specimens
ii) Equipment and methodology
iii) Reagents
iv) Environment
v) Personnel

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

Note: Reference may be made to the following documents.

1) MS ISO 31000 – Risk Management – Principles and Guidelines on Implementation.
2) MS IEC/ISO 31010 – Risk Management – Risk Assessment Techniques.
3) MS ISO Guide 73 – Risk Management – Vocabulary.
4) MS 2370 – Medical Laboratories – Reduction of Error Through Risk Management and Continual Improvement.

6 Resource requirements

6.1 General

Same as MS ISO 15189.

6.2 Personnel

6.2.1 General

The laboratory shall determine the adequacy of technical and clinical staff according to the scope of services and workload.

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.

a) Sufficiency of staff numbers, 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 the laboratory shall be considered at the assessment. Parameters assessed may 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 local guidelines relevant to the profession.

   The adequacy of engaged technical and clinical personnel shall fulfill the following:

   i) 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 specialty of pathology. If the resident pathologists are unable to cover all the services offered, suitably qualified and experienced visiting pathologists shall be engaged;

   ii) 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, part-time qualified and competent technical personnel shall be engaged;

   iii) Where there is no resident clinical personnel to provide the clinical input or advisory services required in (see 5.3.3), the services of a visiting pathologist shall be engaged; and

   iv) There shall be at least one technical personnel present in the laboratory, during working hours.

b) External personnel shall include part-time, contract and visiting personnel.

c) The laboratory shall also communicate with the laboratory personnel changes related to laboratory operation; e.g. SOP, disruption, LIS, transition of laboratory services.

d) The introductory programme shall also include professionalism, ethical and awareness related to MS ISO 15189 principle and requirements.

6.2.2 Competence requirements

a) 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.

b) i) 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.

ii) 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.

c) 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 (STRs)) are expected to undergo reassessment and retraining if necessary. Records of training and competency attainment shall be endorsed by both trainer and trainee.

d) Competency assessment for six (6) categories of personnel as follows shall be performed:

(1) Technical 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

b. 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);

ii) Records of evaluation of competence in the tasks assigned to the person; and

iii) Compliance with existing national regulatory requirements.

Note: Laws of Malaysia Act 774, Allied Health Professions Act 2016, provides for registration of persons based on qualification and experience (Section 46).

Trainee technical personnel are those undergoing training programme such as Diploma MLT and BSc in a relevant field of medical laboratory technology. They can perform technical work, provided that they are under the direction and supervision of a technical person fulfilling criteria i) 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) 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.

(2) 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).

For laboratories with such interpretative or consultation services, only those that fulfil the specific requirements for the appropriate clinical personnel may be accredited for such a service(s).

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 under his/her supervision.

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 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 laboratory 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.

JSM shall be informed of departure or changes in the availability of the persons approved for giving interpretations as soon as possible (see 5.4.1). JSM 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.

(3) 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:

i) The qualifications and professional experience of persons with management and supervisory roles;
ii) The workload of the laboratory and the range of tests offered;
iii) The technical complexity and nature of the testing involved;
iv) The contact that managers and supervisors maintain with subordinate staff; and
v) 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.

(4) Persons with supervisory roles

Persons with supervisory roles shall be authorised and possess suitable, skills and experience to train and supervise subordinate personnel.

(5) Contract personnel

When a laboratory uses contract personnel, irrespective of the duration of the contract and whether the contract personnel is employed full-time or part-time, the laboratory shall ensure that the requirements for staff competence are met. The competency evaluation of these staffs shall be carried out and recorded. Where necessary, training shall be provided, particularly with regard to those parts of the laboratory management system which are relevant to their assigned duties. Direct supervision may be required initially to ensure that the contract personnel are competent in carrying out their duties.

(6) 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 are unable to adequately discharge the responsibilities appropriate to the laboratory services. These services may include supervision, providing clinical interpretation of examination/test results, performing examinations, or providing 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 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.

6.2.4 Continuing education and professional development

Continuing education and continuing professional development are important for maintaining competence of clinical and technical personnel. These educational activities should also include aspects of professional conduct and ethics. Example of such activities including online, in-house or external activities as listed below:

External

i) Attendance at professional conferences, seminars and lectures;
ii) Educational attachments or visits to other laboratories; and
iii) Participation in training courses and workshops.

Internal

i) Regular educational presentations;
ii) Journal article reviews;
iii) Case presentations including multidisciplinary team discussions;
iv) Review of QAP educational material; and
v) Review of interesting/abnormal cases (histological slides, smears, blood films, culture, etc.).

As a guideline, all clinical personnel would be expected to spend at least 10 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 on a pro-rata basis. 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.

6.2.5 Personnel records

Personnel records shall include but are not limited to:

i) Educational and professional qualifications;
ii) Laboratory personnel license or certification, where applicable;
iii) Previous work experience;
iv) Job descriptions;

v) Introduction of new staff to the laboratory environment;
vi) Training in current job tasks;
vii) List of authorisation based on competency assessments;
viii) Records of continuing education and achievement;
ix) Review of staff performance;
x) Work-related incident and/or accident records; and
xi) Immunisation status, when relevant to assigned duties.

6.3 Facilities and environmental conditions

6.3.2 d) Safety facilities and devices shall be readily accessible to the personnel.

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

a. WHO Laboratory Biosafety Manual;
b. College of Pathologists, Academy of Medicine Malaysia guidelines;
c. Guidance documents available from other accreditation bodies (e.g. HOKLAS, SANAS, IANZ, NATA, etc.);
d. Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations (USECHH Regulations);
e. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations (CLASS Regulations);
f. Guidelines on Chemical Management in Health Care Facilities Ministry of Health; and
g. Handbook on Setting up of Private Hospital in Malaysia.

ii) 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.

iii) The laboratory shall comply with the requirements set by the national authorities regulating the occupational health and safety. The laboratory shall also comply with the safety instructions and advice in accordance with the test procedures.

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

v) 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 adversely affected or influenced by not being segregated (e.g. tissue culture, prenatal sequencing; and
c. Where a quiet and uninterrupted work environment is required (e.g. cytology screening).

vi) There should be demarcation between "clean" areas, i.e. areas used for clerical aspects of laboratory work and "dirty" areas, e.g. tissue grossing, cytogenetic processing.

vii) Access to the work areas shall be controlled.

viii) Areas with public engagement shall be clearly segregated from the work areas.

6.4 Equipment

6.4.2 Equipment requirements

b) 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 and fulfill the intended needs.

In the event where tests need to be outsourced temporarily, such as reagent shortage or analyser breakdown, the laboratory should consider the same metrological traceability to ensure results consistency. All outsourced tests shall be communicated to the users.

Where applicable, this may be achieved by assessing equipment records such as but not limited to:

i) Method Verification;
ii) Calibration or Performance checking;
iii) Maintenance and Service;
iv) IQC & EQA/PT;
v) Comparability testing; and
vi) Nonconforming work related to the equipment.

6.4.3 Equipment acceptance procedure

Where applicable before being placed into use, equipment acceptance shall be demonstrated by the following examples:

i) Equipment such as balance, pipette, incubator, water bath - calibration certificate;
ii) Tissue processor and stainer - commissioning records;
iii) Testing analyser - commissioning records; and
iv) LIS/middleware/software - User Acceptance Testing/Authority approved.

Where applicable before being returned into service, equipment acceptance can be demonstrated by the following examples:

i) Equipment such as balance, pipette, incubator, water bath – calibration certificate or checking;
ii) Tissue processer and stainer - performance records;
iii) Testing analyser - performance records; and
iv) LIS/middleware/software - User Acceptance Testing.

6.4.4 Equipment instruction for use

a) Preventing unintended adjustment for analysers and LIS settings (where applicable), include applying security levels or password protections to authorised personnel.

c) Whenever there are changes/alerts/updates on the equipment or software by the manufacturer or other advisory bodies, this shall be communicated to the relevant personnel and appropriate action shall be taken and documented.

6.4.5 Equipment maintenance and repair

a) Whenever equipment PPM is being done internally for example by the concession company or by personnel within the institution, evidence of competence such as certificate or training records of the personnel performing the PPM shall be provided. Refer to Appendix 1.

6.4.7 Equipment records

a) The manufacturer’s instruction shall be in a language commonly understood by the laboratory. Otherwise, a certified translation shall be provided.

6.5 Equipment calibration and metrological traceability

6.5.2 Equipment calibration

c) For testing equipment (analysers) with analytes calibration interval stability exceeding 6 months, the laboratory shall perform calibration verification, or re-calibrate at least every 6 months. Laboratory should also perform calibration verification or re-calibrate after PPM,

replacement of critical parts, where controls exhibit unusual trends/shifts and unacceptable control values that are persistent and not correctable.

e) Where the correction factor arises from the certificate of calibration, it shall be made known to the staff who handle or monitor the equipment. This may be applied for monitoring of temperature of equipment such as ovens, incubators and water baths where data loggers or thermometers are not practical to be used and where temperature is displayed on monitors.

6.5.3 Metrological traceability of measurement results

a) Reference should be made to SAMM Policy (SP) 2 - Policy on the Metrological Traceability of Measurement Results or current Accreditation Policy (AP).

b) 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:

i) JSM accredited calibration laboratories.
ii) Calibration laboratories accredited by one of JSM's Mutual Recognition Agreement (MRA) partners.

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

JSM may expect reduced, or accept extended, calibration intervals based on such factors as history of stability and accuracy 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.

6.6 Reagents and consumables

6.6.1 General

i) All reagents and chemicals shall bear a label which as a minimum, displays 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.

ii) Stocks of dangerous and highly toxic/flammable substances shall be kept separately from other reagents in appropriate cabinets.

6.6.3 Reagents and consumables – Acceptance testing

In principle, new lot verification involves comparison study to identify clinically significant shifts associated with the new reagent lot. The laboratory shall follow a guideline or a procedure that is fit for purpose. Laboratory should consider appropriate sample size or replicates to ensure statistical power is adequate.

Note: Examples of guidelines are CLSI, NOKLUS and P-smile website from John Hopkins University.

IQC may be used for acceptance testing in the following conditions:

i) Commutability of the IQC material is evident;
ii) Unstable analytes (e.g., ammonia, blood gases);
iii) High biological risk sample (e.g., SARS CoV-2, HIV); and
iv) Tests that leave little or no specimen after initial analysis.

Note: Commutability means stability and characteristics of the material are maintained throughout the analysis, such that the results remain equivalent.

For the same measurement procedure/method in different laboratory/sites, whenever the reagent has the same lot number, shipment and stored in the same warehouse, it suffices just to verify in one site, provided the procedure and acceptance criteria of new lot verification is the same. Other sites should have access to the verification findings.

In the event the reagent is depleted before new lot verification can be performed and no other sites have evaluated the new lot, laboratory may ensure the new lot performance by order listed below:

i) Running previous EQA sample if the sample is stable.
ii) Ensuring QC has no significant shift.

Records of such review shall be retained (see 8.4.3).

6.6.4 Reagents and consumables – Inventory management

Laboratory shall have a process in place for identification of new lots of reagents before acceptance testing.

6.7 Service agreements

6.7.1 Agreements with laboratory users

i) 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 shall be a controlled document which may be in the form of a request form, memorandum, manual, circular, letter, minutes of a meeting, etc.

ii) An official agreement shall be made with other laboratories or healthcare providers that send samples to the laboratory for examination. The agreement shall be a controlled document which may be in the form of memorandum, contract or documentation of negotiated request(s).

iii) The laboratory shall not enter into financial arrangements with referring practitioners or healthcare providers where such arrangements poses as an inducement for the referral of samples for examination or interfere with practitioner's independent assessment of what is best for the patient.

iv) The requirements of user and provider of laboratory services shall be adequately specified and documented.

v) When there is a directive from the higher authority, that constitutes an agreement.

6.7.2 Agreements with POCT operators

The laboratory should comply with the latest National Point of Care Testing - Policy and Guidelines and established institutional policies where applicable.

6.8 Externally provided products and services

6.8.1 General

Note:
1) Services include, e.g. sample collection services, pipette and other calibration services, facility and equipment maintenance services, EQA programmes, referral laboratories and consultants.
2) Products include, e.g. *approved reagents, consumables, equipment, test kits, laboratory hardware and software.

*Nationally or internationally benchmarked.

6.8.2 Referral laboratories and consultants

i) The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretations for testing in any discipline.

ii) 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.

iii) This clause does not apply where a sample is to be examined by another laboratory, as arranged by a requestor and the pathology laboratory merely acts as a handling centre on behalf of the requestor. 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.

iv) The referring laboratory shall ensure that the request form sent to the referral laboratory complies with clause 7.2.3 of MS ISO 15189.

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

a. By forwarding the original report in its entirety to the requestor;
b. By instructing the referral laboratory to send the original report (paper or electronic) directly to the requestor and a copy to the referring laboratory; and
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.

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

vii) When there is a directive from the higher authority, that constitutes an agreement.

6.8.3 Review and approval of externally provided products and services

A current list of selected and approved suppliers of equipment, reagents, consumables, software, external laboratories and consultants shall be maintained.

7 Process requirements

7.1 General

Same as MS ISO 15189.

7.2 Pre-examination processes

7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

b) 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.

7.2.4 Primary sample collection and handling

i) 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.

ii) Collection centres shall be audited internally at least once a year by the central laboratory. Collection centres shall be assessed regularly within each accreditation cycle (5 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 workload, types of samples and audit reports of the collection centres.

iii) 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 7.2.4 and 7.2.5 of MS ISO 15189.

7.2.4.3 Patient consent

a) The responsibility for obtaining consent for procedures (e.g. FNA) shall be in accordance with the laboratory policy.

7.2.4.4 Instruction for collection activities

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

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

d) All patient specimens accepted by the laboratory for testing shall be labelled in accordance with procedures defined. The specimen label shall carry the following but not limited to:

i) Two unique identifiers (e.g. name of patient and patient identification number);
ii) Type and site of sample where relevant (e.g. serum, plasma, CSF, renal biopsy, upper lobe of right lung); and
iii) Date and where relevant time of sampling.

7.2.5 Sample transportation

c) Sample transportation systems include porter, courier services, pneumatic, robotic and drone systems. Evaluation criteria to ensure adequacy of sample transportation may include turnaround time, temperature and impact on sample integrity.

Personnel who are directly involved in sample preparation and transportation shall be trained on sample transportation requirements including risks and factors that affect the sample integrity.

7.2.6 Sample receipt

7.2.6.1 Sample receipt procedure

a) 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 always distinguish samples from each other.

7.2.6.2 Sample acceptance exceptions

a) Additional examples of compromised sample may include:

i) Samples deemed to be precious (e.g. CSF, fluid, tissue, bone marrow and paediatric samples) will not be discarded by the laboratory. Results will include a comment relating to the condition of the sample (e.g. sample unlabeled, inadequate sample);

ii) In exceptional circumstances (i.e. urgent conditions), prothrombin time and fibrinogen assay may be analysed in blood coagulation tubes filled up to 70% of their nominal volume;

iii) Serum and lithium-heparin plasma may be interchangeable, provided that the assays are validated for use on either biological matrix and the decisional thresholds overlap; and

iv) Remove fibrin strands or clots from serum or plasma samples before use for automated analyses.

7.2.7 Pre-examination handling, preparation, and storage

7.2.7.3 Sample stability

Information on analyte stability shall be readily available.

7.3 Examination processes

7.3.1 General

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

ii) 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. For hardcopy inserts that are not provided with the reagent/kit and only available online, laboratory shall always refer to the latest version online. If the insert is to be printed for use, this shall be authorised and controlled.

iii) 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.

b) The source and rationale performance specifications shall be documented and authorised.

7.3.2 Verification of examination methods

a) The laboratory shall be responsible for the verification process, including planning the experimental design, sample preparation, sample analysis, data collection, analysis and interpretation.

For verification procedures, the laboratory may refer to National Guidelines, CLSI, Westgard, Eurachem, NATA Technical Notes or other appropriate protocols.

c) The extent of the verification of examination methods shall be as follows:

i) For quantitative tests, minimum components to be verified may include:

a. Precision
b. Method comparison (with previous method or current method)
   - If more than 2 instruments are used for the same analyte, comparison between the 2 instruments/methods need to be performed.
c. Linearity (measurement or reportable range).
d. Analytical Sensitivity (LOB/LOD/LOQ/FS) if there is clinical significance at low concentration.
e. Reference interval verification
   - For the same measurement procedure/method in different laboratory within the same reference population demographics and geographic location, it is sufficed just to verify in one laboratory/site, however, the other laboratory will need to review the ranges and decide on the acceptability.

f. Verification of all the above may be extended in the following cases:
   - When a test needs to be diluted beyond manufacturer recommendations, dilution verification shall be performed. This information shall be made available on request.
   - Whenever carry over is known or suspected, carry over study shall be performed.

ii) For qualitative tests (tests which give two possible responses i.e., negative or positive, present or absent, reactive or non-reactive) minimum components required to be verified may include:

a. Repeatability/Reproducibility
b. Sensitivity & Specificity
c. Verification at cut-off value
d. Method comparison with previous method, where applicable.

As the difference in components and materials used in collection devices can significantly impact laboratory analysis, collection devices shall also be verified. However, for sites with the same method/instrument, verification of the same collection device of one site is sufficient. Other sites may review the findings and decide on their acceptability.

Note: The sites can be different labs, hospitals and departments that use the same method/ instrument.

7.3.4 Evaluation of measurement uncertainty (MU)

As in SAMM Policy 5 and national guidelines. Reference also can be made to MS ISO/TS 20914.

If laboratory uses more than one equipment for the same analyte, MU needs to be estimated separately and combined appropriately (refer to MS ISO/TS 20914).

The laboratory that chooses to include bias may do so with caution. MU for bias can only be included if the laboratory performs correction to the bias (i.e., apply correction factor). Assessment of bias using EQA also needs to be done with caution as bias could arise from the use of different calibrators or reagents. If bias correction/correction factor is applied, effective bias monitoring shall be in place.

b) MU shall be reviewed at least yearly or whenever there is a change in SD or MU calibrator. When the change is significant, MU shall be re-estimated.

7.3.6 Documentation of examination procedures

a) If an abbreviated/simplified/extracted document used at the workbench is taken from a procedure, the abbreviated/simplified/extracted document shall indicate the source of where it is taken from i.e., procedure name/ID. Where such a procedure is internally controlled, the abbreviated/simplified/extracted document at the workbench shall be authorised.

7.3.7 Ensuring the validity of examination results

7.3.7.2 Internal quality control (IQC)

a) The laboratory shall identify the person(s) to be responsible for quality control activities.

3) For third party QC, the target value and SD shall be reestablished.

b) 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.

7.3.7.3 External quality assessment (EQA)

a) i) The laboratory shall subscribe to at least one EQA programme for each test or each related group of tests or each related test method where relevant (as stipulated by the relevant STRs) under the scope of accreditation.

JSM encourages a risk based approach to determine appropriate EQA frequencies and EQA programme.

a. The order of preference for choosing an EQA programme should be:
   - An EQA programme accredited to ISO/IEC 17043.
   - Recognised EQA programme.
   - Interlaboratory comparison between accredited laboratories.
   - Interlaboratory comparison between non-accredited laboratories.

b. The laboratory may be invited to participate in EQA programme organised by APAC/ILAC. If the laboratory is unable to participate it may seek exemption from the Director of Accreditation of JSM.

ii) Another purpose of EQA is to supplement continuing professional development. Consequently, slides and samples may be examined, tested and discussed for educational purposes, following use in proficiency testing.

b) Where a pathologist has responsibilities in more than one laboratory, participation in an appropriate EQA 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.

Whenever the program has issues, this needs to be escalated to the EQA provider. Laboratory shall monitor if the issue has been resolved.

g) For any late/missed result submission that is not included in the EQA report, the laboratory shall review and compare its EQA results with appropriate target values or diagnosis.

7.3.7.4 Comparability of examination results

b) When sample size is small (<20), analysis using linear regression and t-test is not applicable. The laboratory may use other methods such as range test or may compare directly to analytical performance specification (APS).

c) Periodicity of comparison of examination results shall be based on risks and may be but not limited to the following frequencies:

i) Frequent monitoring – daily or weekly with few samples/replicates.

ii) Periodic monitoring – 2 to 4 times/year for stable and low risk of non-comparability. More samples/replicates than (i) above.

iii) Special cause testing – due to alert or triggering event i.e., Fail EQA issue, shift in Patient Moving Averages or equivalent. More samples/replicates than (ii) above but less than number performed during initial verification.

Note: Reference may be made to CLSI-EP31A and National Guidelines.

7.4 Post-examination processes

7.4.1 Result reporting

7.4.1.1 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.

7.4.1.3 Critical result reports

b) Example of verification of accuracy of communication may be applying read back policy.

c) Escalation procedure encompasses notifying laboratory to the next level of responsibility at the requesting site, so that the patient's needs are attended to.

7.4.1.6 Requirements for reports

l) Critical results shall be clearly highlighted regardless of the medium of the report (electronic or printed).

7.4.1.7 Additional information for reports

d) Such additional information can only be issued by the authorised personnel.

7.4.2 Post-examination handling of samples

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.

c) The storage container shall be leak proof, and easily retrievable.

7.5 Nonconforming work

Nonconformity work shall apply to any pre-examination, examination and post post-examination processes.

7.6 Control of data and information management

7.6.1 General

The laboratory shall indicate which data management systems (computerised and non computerised) are used to manage the laboratory activities e.g. use of a masterlist to indicate activities against the data system.

7.6.2 Authorities and responsibilities for information management

The laboratory shall define the authorities and responsibilities of all personnel who use the system, in particular those who:

i) Access patient data and information;
ii) Enter patient data and examination results;
iii) Change patient data or examination results;
iv) Authorize the release of examination results and reports; and
v) Maintain and modify the system.

7.7 Complaints

Same as MS ISO 15189.

7.8 Continuity and emergency preparedness planning

Same as MS ISO 15189.

8 Management system requirements

8.1 General requirements

8.1.2 Fulfilment of management system requirements

All policies and procedures established to meet the criteria detailed in these accreditation requirements shall be documented. A management system shall provide laboratory management with continuing confidence that results and reports are valid and reliable. The success of the management system is dependent on the commitment of management and the active participation of every member of the laboratory staff. To make sure that everyone fully understands what the expectations are, all elements of the management system shall be clearly explained and documented such as in a quality manual.

8.2 Management system documentation

Same as MS ISO 15189.

8.3 Control of management system documents

Same as MS ISO 15189.

8.4 Control of records

8.4.3 Retention of Records

Minimum retention periods for patient records and specimens shall conform to the relevant latest version of the national guidelines where available, such as Guidelines on Retention of Pathology Records and Materials by the College of Pathologists, Academy of Medicine of Malaysia, and the Ministry of Health Malaysia.

8.5 Actions to address risks and opportunities for improvement

Same as MS ISO 15189.

8.6 Improvement

8.6.1 Continual improvement

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

i) Test repertoire, including standard testing profiles, reflex testing, procedures for follow up and confirmatory testing;
ii) Methodology and instrumentation considerations, including specificity, sensitivity and uncertainty of results in relation to clinical decision making;
iii) Appropriateness and timelines of interpretations provided, including automatic-comment generation, if relevant;
iv) Follow up of significantly abnormal test results;
v) Follow up of adverse incidents after corrective action has been taken;
vi) Quality of pre-examination services (e.g. number of re-collections, incorrect samples, poor-quality samples, mislabeled samples, rejected samples);
vii) Clinically relevant turnaround times i.e. from time of sampling to result sent-out; and
viii) 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.

8.7 Nonconformities and corrective actions

Nonconformities may arise from any aspect of the management systems including pre-examination, examination and post-examination processes.

8.8 Evaluations

8.8.3 Internal audit

8.8.3.2 The laboratory shall:

a) All activities of the laboratory under the management system including its collection centres shall be subjected to internal audit.

c) 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:
   i) Staff awareness of the policies and procedures;
   ii) Examination procedure selection, development, modification and validation;
   iii) Management of reagents, consumables and equipment;
   iv) Management and understanding of IQC, EQA and results comparability;
   v) Management of personnel training, competency evaluation and performance;
   vi) Management of data and records;
   vii) Action on non-conformities;
   viii) Laboratory housekeeping;
   ix) Management of health and safety issues;
   x) Risk management and contingency plans;
   xi) Impartiality and confidentiality; and
   xii) Waste management.

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

8.9 Management reviews

Same as MS ISO 15189.

Annex A
(normative)

Additional requirements for Point-of-Care Testing (POCT)

A.1 The laboratory shall comply with the requirements in Annex A of MS ISO 15189 when POCT is included in the scope of accreditation. The laboratory should refer to the latest version of the National Policy and Guidelines for Point of Care Testing and where applicable, established institutional policies (6.7.1).

Only POCTs within the scope of accreditation shall be assessed during each SAMM assessment.

During assessment, all critical areas i.e. ICU, NICU, HDW, CCU, OT, ED, shall be assessed. For non-critical areas, at least 20% shall be assessed.

A.3 The laboratory shall be responsible for the management system of POCTs. This may include establishing a POCT committee, coordinators, procedures, processes and activities to comply with the requirements of this standard.

A.4 The laboratory shall ensure the appointed person-in-charge (however named) and operators at POCT sites shall be trained, assessed and deemed competent. The list of persons in charge and operators shall be kept up to date.

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	**Calibration:** Initial calibration	
		Intermediate check: 3 monthly	Accuracy of and repeatability at volumes in use
2.	Balances	**Calibration:** a) Initial calibration b) Re-calibration when required (such as every repair, moving of equipment, one point or repeatability checks fail, etc.)	By accredited calibration laboratory (Refer SP2)
		Intermediate check: a) Each weighing b) *Monthly c) *6 monthly **Calibration using traceable certified masses or using statistical process control (SPC)*	Zero check. One-point checks 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)	**Calibration:** a) Initial calibration b) Recalibration 5 yearly	By accredited calibration laboratory (Refer SP2)
4.	i) Biological Safety Cabinets ii) Laminar Flow iii) Fume Hood/ Cabinet	**Certification:** Yearly certification or according to manufacturer's instruction	By a certified body
5.	Centrifuges	Follow manufacturer's instruction.	By accredited calibration laboratory (Refer SP2) Tachometer (mechanical, stroboscope or light cell type, or by other approved means) where operating speed is specified Note: Calibration of the timing device and, where appropriate, the temperature measurement device will also be required
6.	Sterilisers/ Autoclaves	**Calibration:** a) Initial calibration b) 15 monthly certification or as required by DOSH	By accredited calibration laboratory (Refer SP2) By Department of Safety and Health (DOSH)
		Intermediate check: a) Monthly intermediate check b) Each use	Use biological indicator Use physical indicator (autoclave tape/strip etc.)
	Hot Air Sterilising Ovens	**Calibration:** Initial calibration	By accredited calibration laboratory (Refer SP2)

No	Type of equipment	Maximum period between successive calibrations and/or intermediate check	Procedures
		Intermediate check: Each use	Use physical indicator (heat indicator tape/ strip etc.)
7.	pH Meter	**Intermediate check:** Each use	Calibrate using at least two appropriate standard buffers for intended use as per manufacturer instruction
8.	Refrigerators/Chillers/ Freezer/Cold Room	**Intermediate check:** Minimum daily	Monitor temperature using a calibrated thermometer
9.	Thermostatically Controlled Equipment (Incubators, Water Baths, Ovens)	**Calibration:** Initial calibration; 3 spatial uniformities, 1 temperature sensor **Intermediate check:** Working days	By accredited calibration laboratory (Refer SP2) or calibrated thermometer according to relevance (Refer STRs) Monitor temperature using a calibrated thermometer. Monitor temperature at a minimum 1 point
10.	Thermometers (Liquid in Glass) i) Reference ii) Working	**Calibration:** 5 yearly (complete) **Intermediate check:** a) As recommended by the manufacturer or indicated by the risk assessment b) Initial	By accredited calibration laboratory (Refer SP2) Check at ice point and at points of use Check against reference thermometer / thermocouple across working range or at points of use
11.	Thermometers (Digital) i) Reference ii) Working	**Calibration:** 2 yearly **Intermediate check:** a) 6 monthly b) Initial	By accredited calibration laboratory (Refer SP2) Check against reference device at the temperature of use
12.	Timing Devices (related to examination) (Stopwatch/Clock/ Timers)	**Intermediate check:** 6 monthly	Check against https://mst.sirim.my/ (The Malaysian Standard Time). Two measurements separated by an appropriate interval
13.	Volumetric Glassware (Flasks/Pipettes/ Burettes)	Initial (on commissioning) 10 years (borosilicate) 5 years (soda-lime)	Using distilled water at critical graduations.

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