MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

STR 2.2 - SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF ANATOMICAL PATHOLOGY (HISTOPATHOLOGY) LABORATORIES

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(Supplementary to MS ISO 15189)

SKIM AKREDITASI MAKMAL MALAYSIA (SAMM)

LABORATORY ACCREDITATION SCHEME OF MALAYSIA

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Introduction

This document describes the specific technical requirements to be complied by histopathology laboratories. This document should be read in conjunction with MS ISO 15189 *Medical laboratories - Requirements for quality and competence* and other accreditation criteria documents published by 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 be 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

The minimum activities required for accreditation as a histopathology laboratory shall include the following processes:

i) Reception of specimens
ii) Macroscopic examination (grossing)
iii) Tissue processing
iv) Haematoxylin (H&E) and eosin staining
v) Microscopic examination and reporting

If the laboratory offers frozen sections, the frozen sections shall be part of the accreditation scope.

The areas for which accreditation shall be offered are listed below:

1.1 Diagnostic histopathology using haematoxylin and eosin stain including ancillary tests performed necessary for diagnoses

Note: For laboratory to state the test in their scope.

1.2 Intraoperative frozen section

1.3 Digital pathology

Whenever the activities are referred externally, they shall be performed in an accredited laboratory.

All ancillary tests (e.g. immunohistochemistry) performed in the laboratory and incorporated in the histopathology reports shall be part of the accreditation scope.

2 Normative references

i) MS ISO 15189 - Medical Laboratories - Requirements for quality and competence.
ii) SC 2 - Specific Criteria for Accreditation in the Field of Medical Testing.

3 Terms and definitions

3.1 Diagnostic histopathology

Refers to examination of human tissue (macroscopic and microscopic) for the diagnosis and monitoring of disease. In relevant circumstances, this is supplemented by the use of special stains and/or other forms of examination, such as histochemistry, immunohistochemistry, immunofluorescence, enzyme histochemistry, electron microscopy and molecular techniques.

3.2 Intraoperative frozen sections

Refers to the examination of human tissues removed during a surgical operation for the purpose of immediate patient management. This examination involves smears and/or fresh tissues sections. This shall be followed by examination of routine paraffin sections made from the tissue, where relevant.

4 General requirements

Same as MS ISO 15189 and SC 2.

5 Structural and governance requirements

Same as MS ISO 15189 and SC 2.

6 Resource requirements

6.2.1 General

a) The laboratory shall determine the overall workload policy for technical and clinical staff.

Reference may be made to the following guidelines:

i) Guidelines on staffing and workload for histopathology and cytopathology departments, The Royal College of Pathologist.

ii) The Warwick system of prospective workload allocation in cellular pathology - an aid to subspecialisation: a comparison with the Royal College of Pathologists' system, J Clin Pathol; 59:835–839. doi: 10.1136/jcp.2005.032615.

iii) Operational Policy in Pathology Services (Ministry of Health Malaysia).

6.2 Personnel

6.2.2 Competence requirements

a) Personnel qualifications

i) An **anatomical pathologist** (hereafter refer as **histopathologist**) shall be a medical practitioner registered with the Malaysian Medical Council (MMC) with a postgraduate qualification in pathology recognised by the Government of Malaysia and have at least three (3) years of training in histopathology whether as part of the pathology training programme or post-qualification experience and be registered with the National Specialist Register (NSR) and have an active Annual Practicing Certificate (APC).

ii) A **medical officer** in anatomic pathology shall be a person who is medically qualified and has an active APC. He/she could be;

a. Fresh graduate of Master of Pathology or equivalent undergoing gazettement.
b. Medical officer undergoing postgraduate anatomic pathology programme.
c. Medical officer posted in pathology laboratory.

iii) A **technical personnel** shall be a person with a Diploma in Medical Laboratory Technology or equivalent or Bachelor of Biomedical Science Degree or equivalent recognised by the Government of Malaysia. The personnel shall have at least six (6) months training in histopathology as part of the training programme or as post-qualification experience.

iv) A **key technical personnel** shall be a technical personnel with minimum three (3) years of working experience in a histopathology laboratory. He/she may be appointed as supervisory key technical personnel in the histopathology laboratory.

v) A **technical assistant** in histopathology shall be a person with appropriate practical experience and specific training to assist the technical personnel in the reception and registration of specimens, paraffin block microtomy, H&E staining, labeling and cross-checking of stained sections against the corresponding paraffin blocks.

c) Competence assessment

i) Where the number of tests (e.g. frozen sections, renal biopsies etc.) are too few/insufficient or rather infrequent, the laboratory shall take part in documented supplementary activities designed to maintain expertise or should institute activities to increase competency.

ii) Medical officers/pathology trainees servicing the laboratory shall have regular competency assessment.

6.3 Facilities and environmental conditions

6.3.2 Facility controls

i) Microtomes when not in use shall be covered with safety knife shields.

ii) The laboratory staff shall be equipped with appropriate Personal Protective Equipment (PPE) e.g. laboratory shoes, masks, protective aprons and goggles.

iii) There shall be an enclosed room with adequate ventilation/fume extraction system for macroscopic examination and cutting (grossing) of fresh tissue as well as formalin-fixed specimens**.**

iv) Appropriate extraction systems shall be in place to minimise the level of noxious vapours in accordance to national regulations (e.g. Department of Safety and Health, DOSH, Malaysia).

v) The laboratory shall monitor formaldehyde and xylene vapour concentrations and ensure conformance to DOSH requirements (e.g. Industry Code of Practice on Air Quality, Malaysia). The laboratory shall keep records of monitoring as well as remedial actions taken when exposure exceeded.

vi) All fresh tissues shall be handled in biosafety cabinet.

vii) Grossing of specimens shall be performed in a grossing station with adequate extraction of formalin vapours. The grossing station shall have an exhaust ventilation system and equipped with a minimum of two filters, which may include carbon filters, potassium permanganate filters, or a combination of both.

viii) Dictation of macroscopic and microscopic descriptions shall be in an area free from distraction and noise.

ix) Exhaust pipes of fume hoods shall open above the roof of the building where the laboratory is located and shall not cause harm to the environment as required by national regulations.

6.3.3 Storage facilities

There shall be adequate ventilated space for the storage of formalin-fixed specimens.

Storage of inflammable and dangerous substances (e.g. alcohol) shall be stored appropriately in compliance with national regulations.

Reference may be made to the following:

i) Portal Rasmi Jabatan Keselamatan dan Kesihatan Pekerjaan Kementerian Sumber Manusia.

ii) Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations (CLASS Regulations).

iii) Guidelines on Chemical Management in Health Care Facilities Ministry of Health.

6.4 Equipment

6.4.5 Equipment maintenance and repair

The fume hood shall have its airflow regularly monitored, its filters changed when saturated and the extraction ducting checked for leakage according to manufacturer's specifications.

6.6 Reagents and consumables

6.6.4 Reagents and consumables - Inventory management

The laboratory shall maintain a proper inventory list of antibodies used currently for immunohistochemistry (IHC), which shall include the dilutions and expiry date of the antibodies. This list shall be authorised and regularly updated. Validation and verification records of the antibodies shall be kept.

In the event expired antibodies are being used, validation and verification records shall be kept.

7 Process requirements

7.2 Pre-examination processes

7.2.3 Requests for providing laboratory examinations

7.2.3.1 General

Requests for intraoperative frozen sections, electron microscopic examinations and examinations by any special techniques shall be approved by the attending histopathologist.

Laboratory which uses digital microscopy for diagnostic purposes shall have relevant procedures and supporting documentation, training and validation in place.

Reference may be made to the following documents:

i) The Royal College of Pathologists - Best Practice Recommendations for Implementing Digital Pathology.

ii) The Royal College of Pathologists of Australasia (RCPA) - Guidelines for Digital Microscopy in Anatomical Pathology and Cytology.

7.2.4.2 Information for pre-collection activities

Instructions for pre-collection activities shall include requirement to itemise all specimens included in each request form.

7.2.7 Pre-examination handling, preparation, and storage

7.2.7.1 Sample protection

i) Harmful chemicals such as formalin, xylene, diaminobenzidine, tissues and effluents such as cysts and intestinal contents for discard, shall be disposed of as required by national regulatory requirements.

ii) The period for retention of specimens including slides and paraffin blocks shall comply with national and regional guidelines. Reference may be made to College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.

iii) Tissue disposal shall follow national and/or regional guidelines (some states in Malaysia require burial permit for resected limbs/organs).

iv) There shall be proper records of storage and subsequent disposal of waste and surplus wet tissue.

v) Surplus wet tissue no longer required after examination and infectious material shall be disposed in accordance with local or national regulations and shall not contaminate the environment or endanger the public.

vi) In cases where specimens are archived for academic purposes (teaching and research), proper documentation shall be available.

vii) The laboratory shall have a procedure for the release of tissue blocks, slides, specimens to third parties (e.g. other laboratories or other clinicians or patients/next of kin).

7.3 Examination processes

7.3.1 General

The laboratory shall have a policy on specimen handling.

i) Sampling of the primary specimen shall be performed by histopathologist(s) or medical officer(s) who has undergone supervised training and approved as competent to undertake the task.

ii) Transferring of small specimens that do not require any orientation into cassettes may be carried out by competent technical personnel.

iii) Processing fresh tissue for intraoperative frozen section shall be carried out by competent technical personnel.

iv) Sampling of the specimen shall be adequate for complete reporting according to established specimen sampling guidelines.

v) The procedures of the laboratory shall include steps to prevent mix up of specimens and cross contamination (e.g. the floatation bath shall be cleaned regularly).

vi) The personnel authorised and responsible for each stage of the process from the receipt of the specimen till the production of the stained section shall be identified and the records maintained.

7.3.7 Ensuring the validity of examination results

7.3.7.2 Internal quality control (IQC)

i) The laboratory shall have IQC for H&E and ancillary stains. Controls shall be performed for each batch run, and the records maintained. The control shall be traceable to the batch of staining. All stained tissue section slides shall be dated.

ii) IQC slides for H&E stain shall be run before performing H&E staining on test slides.

iii) Control tissue for ancillary stain can be performed in batches or inserted together with the test section on the same slide.

iv) It is recommended for HER2 immunohistochemistry to have 0, 1+, 2+ and 3+ control tissue in one section for each batch.

7.3.7.3 External quality assessment (EQA)

i) The laboratory shall participate in inter-laboratory comparison, which shall include at least one EQA (national or international).

ii) This shall include a general diagnostic module which covers the case mix of the laboratory and at least one technical module for routine and ancillary test. The laboratory shall monitor individual and overall performance and implement corrective actions where necessary.

iii) Participation in EQA should reflect usual diagnostic practice in the laboratory. Individual pathologist performance in EQA shall be monitored.

iv) When a histopathologist reports in more than one laboratory, it is sufficient for the histopathologist to participate in at least one EQA (a diagnostic module) which covers the case mix of the laboratories concerned.

7.4 Post-examination processes

7.4.1 Reporting of results

7.4.1.1 General

The laboratory shall have policy on reporting of results.

i) The histopathologist(s) shall be responsible for the content of the histopathology examination Histopathological Examination (HPE) reports.

ii) Histopathologist(s) under gazettement is/are not allowed to validate HPE reports independently except simple cases such as uncomplicated appendix, product of conception etc.

iii) Histopathologist(s) who has/have completed gazettement satisfactorily can validate reports once credentialed by the hospital.

iv) Medical officer(s) is/are not allowed to validate HPE reports.

v) Histopathologist(s) reporting using digital microscopy shall have relevant training and credentialing.

7.4.1.2 Result review and release

i) There shall be a documented policy on the release of all histopathology reports including verbal, preliminary and supplementary reports.

ii) The histopathology reports shall be issued to authorised requesters.

iii) All verbal and preliminary reports (e.g. frozen section reports) shall be followed by final reports.

iv) There shall be a system that allows retrieval of patients' previous histopathology and/or other related reports.

7.4.1.3 Critical result reports

The laboratory shall have policy on handling critical result reports.

The laboratory shall have a list of critical diagnoses which have significant impact which require urgent notification to the clinician(s) to facilitate rapid intervention or treatment (e.g. unexpected malignancy, removal of wrong organ, finding fat in endometrial curettage etc.).

7.4.1.6 Requirements for reports

i) Histopathology reports shall contain at least macroscopy, microscopy and interpretation of the findings. Other information such as clinical history, comments, references may be added as necessary.

ii) A record of the block selection which records each cassette's labelling and the site of sections submitted should be included in the macroscopic description.

iii) HPE reports for resected malignant tumour specimens (e.g. mastectomy and colectomy) should include pathology staging.

8 Management system requirements

8.4 Control of records

The laboratory shall have policy on control of records pertaining to its activities.

Records (e.g. written, audios or videos) containing macroscopic descriptions and findings shall be retained at least until the reports have been finalised and the histopathologist(s) has/have given approval for their discard.

Reference may be made to College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.

Bibliography

1. MS ISO 15189 Medical Laboratories - Requirements for Quality and Competence.

2. SC 2 - Specific Criteria for Accreditation in the Field of Medical Testing.

3. Akta [50] Perubatan 1971.

4. Guidelines on Chemical Management in Health Care Facilities Ministry of Health Malaysia.

5. Portal Rasmi Jabatan Keselamatan dan Kesihatan Pekerjaan Kementerian Sumber Manusia Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health).

6. The Royal College of Pathologists Guidelines on Staffing and Workload for Histopathology and Cytopathology Departments.

7. College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.

8. Industry Code of Practice on Indoor Air Quality, Malaysia.

9. Guidelines on Staffing and Workload for Histopathology and Cytopathology Departments, The Royal College of Pathologist.

10. The Warwick System of Prospective Workload Allocation in Cellular Pathology - an Aid to Subspecialisation: A Comparison with the Royal College of Pathologists' System, Journal of Clinical Pathology.

11. The Royal College of Pathologists - Best Practice Recommendations for Implementing Digital Pathology.

12. The Royal College of Pathologists of Australasia (RCPA) - Guidelines for Digital Microscopy in Anatomical Pathology and Cytology.

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