



**STANDARDS**  
MALAYSIA

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

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

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(Supplementary to MS ISO 15189)



**MS ISO 15189**

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## **TABLE OF CONTENTS**

	<b>Page</b>
<b>1 Introduction</b>	1
<b>2 Scope of accreditation</b>	1
<b>3 Terms and definitions</b>	2
<b>4 Management requirements</b>	2
4.13 Control of records	2
<b>5 Technical requirements</b>	2
5.1 Personnel	2
5.2 Accommodation and environmental conditions	3
5.3 Laboratory equipment, reagents, and consumables	5
5.4 Pre-examination processes	5
5.5 Examination processes	5
5.6 Ensuring quality of examination results	6
5.7 Post-examination processes	6
5.8 Reporting of results	7
5.9 Release of results	7
5.10 Laboratory information management	8
<b>References</b>	9
<b>Acknowledgements</b>	11

## SPECIFIC TECHNICAL REQUIREMENTS FOR ACCREDITATION OF ANATOMICAL PATHOLOGY (HISTOPATHOLOGY) LABORATORIES

### 1 Introduction

- (a) This document describes the specific technical requirements to be complied by histopathology laboratories under the accreditation exercise with Department of Standards Malaysia (Standards Malaysia).
- (b) This document shall be read in conjunction with MS ISO 15189 Medical Laboratories - *Requirements for Quality and Competence* and other accreditation criteria documents published by Standards Malaysia.

**Note:** Other accreditation criteria include SAMM Policies, Specific Criteria 2 and relevant Specific Technical Requirements documents.

- (c) The clause numbers in this document correspond to those in the MS ISO 15189 standard which require elaboration.

### 2 Scope of accreditation

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

- i) Reception of specimens;
- ii) Grossing;
- iii) Processing;
- iv) H&E staining; and
- v) Reporting.

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

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

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

2.1 Diagnostic Histopathology

2.2 Intraoperative Frozen Sections

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

### **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 Management Requirement**

As in MS ISO 15189.

#### **4.13 Control of records**

Records (e.g.: written, audio or video tapes) containing macroscopic description and findings shall be retained at least until the reports have been finalised and the histopathologist has given approval for its discard.

### **5 Technical Requirement**

#### **5.1 Personnel**

##### **5.1.2 Personnel qualifications**

- i) A **histopathologist** shall be a medical practitioner registered with the Malaysian Medical Council with a postgraduate qualification in pathology recognised by the Government of Malaysia and have at least three years of training in histopathology whether as part of the pathology training programme or post-qualification experience and/or be registered with the National Specialist Register.
- ii) A **technical personnel** shall be a person with a (1) Diploma in Medical Laboratory Technology or equivalent or (2) Bachelor of Biomedical Science Degree or equivalent recognised by the Government of Malaysia. The personnel shall have at least six months training in histopathology as part of the training programme or as post-qualification experience.

- iii) **Key technical personnel shall be** a technical personnel with at least five years of working experience in a histopathology laboratory. He/she may be appointed as a supervisory key technical personnel in the histopathology laboratory.
- iv) 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.

### 5.1.6 Competence assessment

As in SC 2 Clause 5.1.6.

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

#### Workload policy

Reference may be made to the following guidelines:

1. Guidelines on staffing and workload for histopathology and cytopathology departments (4<sup>th</sup> edition), The Royal College of Pathologist (September 2015).
2. 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 2006; 59:835–839. doi: 10.1136/jcp.2005.032615

## 5.2 Accommodation and environmental conditions

### 5.2.2 Laboratory and office facilities

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

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

### 5.2.3 Storage facilities

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

Storage of inflammable and dangerous substances shall be stored appropriately in compliant with national regulations.

Reference may be made to the following documents:

- i) Occupational Safety and Health (Use and Standard of Exposure Chemical Hazardous to Health) Regulations 2000 (USECHH Regulations);
- ii) Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations);
- iii) Guidelines on Chemical Management in Health Care Facilities Ministry of Health 2010.

#### **5.2.6 Facilities maintenance and environmental conditions**

- a) 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
- b) 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)
- c) The laboratory shall monitor formaldehyde and xylene vapour concentrations and ensure conformance to DOSH requirements (e.g. Industry Code of Practice on Air Quality 2010). The laboratory shall keep records of monitoring as well as remedial actions taken when exposure exceeded.
- d) All fresh material shall be handled at least in a grossing station.
- e) Dictation of macroscopic and microscopic descriptions shall be in an area free from distraction and noise.
- f) Grossing of specimens shall be performed in a grossing station with adequate extraction of formalin vapours.
- g) 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.

### **5.3 Laboratory equipment, reagents and consumables**

#### **5.3.1.5 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.

#### **5.3.2.4 Reagents and consumables – Inventory management**

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

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

### **5.4 Pre-examination processes**

#### **5.4.1 General**

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

#### **5.4.2 Information for patients and users**

The manual for primary sample collection shall include an instruction that states that specimen submitted for examination be itemised in the request form, if more than one specimen container is submitted per request.

### **5.5 Examination processes**

#### **5.5.1.1 General**

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

- a) The laboratory shall have a policy on who can handle specimens. This policy shall include transferring of small specimens (that do not require any orientation) into cassettes.
- b) 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.

- c) Processing fresh tissue for intraoperative frozen section shall be carried out by competent technical personnel.
- d) The floatation bath shall be cleaned regularly to prevent carry over.
- e) The procedures of the laboratory shall include steps to prevent mix up of specimens and cross contamination, whenever applicable.

## **5.6 Ensuring quality of examination results**

### **5.6.2.2 Quality control materials**

All special stain slides shall show the date when the staining was performed, on the slide label.

Controls shall be performed for each batch, and records maintained.

The control shall be traceable to the batch of staining and shall be retained.

### **5.6.3 Interlaboratory comparisons**

#### **5.6.3.1 Participation**

The laboratory shall participate in inter-laboratory comparison, which includes at least one external quality assurance programme (national or international) as required in Clause 5.6.3 of SC 2 document.

This shall include a general diagnostic module which covers the case mix of the laboratory and one technical module for each test method. The laboratory shall monitor individual and overall performance and implement corrective actions where necessary.

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

## **5.7 Post-examination processes**

### **5.7.2 Storage, retention and disposal of clinical samples**

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



- b) The period for retention of specimens including slides and paraffin blocks shall comply with national guidelines e.g. College of Pathologists, Academy of Medicine Malaysia Guideline on Retention of Pathology Records and Materials.
- c) There shall be proper records of storage and subsequent disposal of waste and unused tissue specimens.
- d) In cases where specimen are archived for academic purposes (teaching and research), proper documentation shall be available.
- e) Surplus wet tissue no longer required after examination and Infectious material shall be disposed in a manner that shall not contaminate or endanger the environment or public and in accordance to local or national regulations.
- f) The laboratory shall have a procedure for the release tissue blocks, slides, specimens to third parties (e.g. other laboratories or other clinicians).

## **5.8 Reporting of results**

### **5.8.1 General**

The histopathologist shall be responsible for the content of the histopathology report and its release.

### **5.8.3 Report content**

The location from which each block is sampled from the primary specimen shall be clearly documented in the final report.

## **5.9 Release of results**

### **5.9.1 General**

The histopathology report shall be issued to an authorised requester.

There shall be a documented policy that frozen section reports are to be transmitted to an authorised requester and that the verbal report is followed by a written report.

There shall be a system that allows retrieval of patients' previous laboratory reports.

### **5.9.3 Revised reports**

If a supplementary/amended report is created, it shall be traceable to the initial report.

## **5.10 Laboratory information management**

If the laboratory information system does not meet the requirements of clause 5.10 MS ISO 15189 or if the system has deficiencies, the laboratory shall have appropriate procedures to address the limitations.

**References:**

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. 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](http://www.moh.gov.my/images/gallery/Garispanduan/Guidelines_on_Chemical-1.pdf)).
4. 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>);
5. Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013 (CLASS Regulations) ([http://www.federalgazette.agc.gov.my/output/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](http://www.federalgazette.agc.gov.my/output/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));
6. The Royal College of Pathologists Guidelines on Staffing and Workload for Histopathology and Cytopathology Departments (4th edition), September 2015
7. HOKLAS Supplementary Criteria No. 25 'Medical Testing' Testing Category- Histopathology, Issue 6, 24 June 2015
8. SANAS TR 31-01 Technical Requirements for the Accreditation of Histopathology in Medical Laboratories, 5 February 2010
9. SAC-SINGLAS Technical Notes Med 002- Specific Criteria for Histopathology Section, August 2013
10. Industry Code of Practice on Indoor Air Quality 2010
11. Guidelines on Staffing and Workload for Histopathology and Cytopathology Departments (4<sup>th</sup> edition), The Royal College of Pathologist (September 2015).

12. 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* 2006; 59:835–839. doi: 10.1136/jcp.2005.032615

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14. Ms. Siti Norehan Ishak Standards Malaysia
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