ACCREDITATION SCHEME FOR LABORATORIES

Technical Note MED 002

Specific Criteria for Histopathology Section

Technical Note MED 002- Histopathology, 26 November 2021
The SAC Accreditation Programme is managed by Enterprise Singapore

1. Introduction & Scope

1.1 a) This document describes the specific requirements to be complied by histopathology section to be accredited.

b) The International Standard 'ISO 15189 Medical laboratories – Particular requirements for quality and competence', other MEDICAL Series Technical Notes published by SAC-SINGLAS shall be studied in conjunction with this document.

2. Accommodation and Environmental Conditions

2.1 Safety

2.1.1 The Laboratory shall maintain the quantity of flammable and dangerous chemicals within the allowable limit, as stipulated in its SCDF license and NEA certification.

2.1.2 Appropriate extraction systems shall be in place to minimize the levels of noxious vapours.

2.1.3 The Laboratory should measure the level of formalin vapour annually, to ensure the environment is maintained within the recommended safe level.

3 Pre-examination Procedures

3.1 For specimen transportation, the laboratory should have a documented contingency protocol to handle formalin leakage.

4 Examination Procedures

4.1 If digital pathology is used, the laboratory shall have evidence of validation.

5 Assuring Quality of Examination Procedures – Quality Control and Proficiency Testing

5.1 Quality control measures must be in place and documented to ensure good technical quality of slides produced.

5.2 If the laboratory is performing immunohistochemical stains, it shall be enrolled in a quality assurance programme for immunohistochemistry.

5.3 Workload statistics, audit activities and work improvement activities shall be documented and monitored regularly.

6 Post-examination Procedures

6.1 The table below refers to the minimum retention period for materials and records. Laboratories are to retain records and materials for a longer period of time than specified, especially when patient care needs so warrant it.

6.2

MATERIALS	SURGICAL PATHOLOGY	POST MORTEM	CYTOLOGY
Wet Tissue	4 weeks after final report	3 months after final report	-
Cytologic material e.g. sputum, fluid	-	-	7 days
Paraffin blocks (include E/M blocks)	10 years	10 years	-
Slides	10 years	10 years	5 years
IMF Slides	7 days	7 days	7 days
Records & Reports	15 years	15 years	15 years

7 Reporting of Results

7.1 All reports must be documented in writing. This includes intraoperative consultation.

7.2 A Pathologist or a designated qualified physician must verify all reports.

7.3 The reports must be timely and relevant to the medical management of the patients.

7.4 All intra-departmental and extra-departmental consultation of cases shall be recorded. All reports shall be easily retrievable by name or identification number or accession number.