1. INTRODUCTION

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

b) This document shall be studied in conjunction with ISO 15189 Medical laboratories–Particular requirements for quality and competence, other MEDICAL Series Technical Notes published by PNAC-MLAS and other Guidance Notes such as "ISO 15190 Medical Laboratories–Requirements for Safety".

2. GENERAL TECHNICAL NOTE : MEDICAL G-23/01

2.1 Please refer to **General Technical Note: Medical- G-23/01** for the following:

- PERSONNEL
- COLLECTION AND HANDLING OF SPECIMENS
- PHYSICAL FACILITIES
- REAGENTS
- REFERENCE MATERIALS
- REQUISITIONS, TEST METHODS AND METHOD VALIDATION
- MAINTENANCE OF EQUIPMENT
- CALIBRATION OF EQUIPMENT
- QUALITY CONTROL AND PROFICIENCY TESTING
- LABORATORY SAFETY
- RETAINED SAMPLES
- WASTE DISPOSAL
- REPORTING OF RESULTS

3. EQUIPMENT

3.1 All equipment must be maintained and serviced regularly. Calibration of equipment shall be performed by PNAC-MLAS accredited calibration laboratory, wherever possible. Records must be kept of such calibration, maintenance and servicing.

4. SAFETY

4.1 Refer to Laboratory safety in **General Technical Note: Medical G-23/01**. In addition to that, the histopathology laboratory should comply with the following:-

4.2 A safety procedure manual shall be available on the workbench and a safety officer shall be appointed to ensure safety measures as contained in the manual are implemented.

4.3 Fire extinguishers, eyewash and shower stations and first-aid kits shall be installed in areas which are readily accessible to staff in the event of an accident, fire or injury.

4.4 Safety protocol on the handling of infectious materials including HIV/AIDS, Creutzfeld-Jacob disease, etc. must be available.

4.5 Personal Protection equipment e.g. gowns, masks, goggles shall be made available to staff who require such protection when at work.

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

4.7 Biological Safety cabinets shall be available for handling of infectious materials.

5. PERSONNEL

5.1 Refer to Personnel in **General Technical Note: Medical - G-23/01.** In addition to that, the number of technical, clerical and professional staff to be employed must be sufficient for the workload of the histopathology laboratory.

5.2 The staff must be suitably qualified as determined by the laboratory/organization. In addition, there shall be compliance to relevant regulatory requirements.

6. REPORTING OF TEST RESULTS

6.1 Refer to Reporting of test results in **General Technical Note: Medical G-23/01.** In addition to that the following is applicable to histopathology laboratory.

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

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

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

6.5 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.

7. QUALITY CONTROL AND PROFICIENCY PROGRAMME

7.1 Refer to Quality control and proficiency programmes in **General Technical Note: Medical - G-23/01.** In addition to the above, quality control measures must be in place and documented to ensure good technical quality of slides produced.

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

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

8. RETENTION OF MATERIALS AND REPORTS

8.1 All materials and reports should be retained for a minimum period as stated below:-

RETENTION OF LABORATORY RECORDS AND MATERIALS

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.

Microfilm and electronic records in place of hard copies are acceptable provided they are maintained securely, are readily accessible and are the exact duplicates of the reports sent out.

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	10 years	10 years	

blocks)			
Slides	10 years	10 years	5-years
IMF Slides	7-years	7-years	7-years

Records

Reports	20-years	20-years	20-years