1. Purpose

This Supplement requirements are specific requirements for surgical pathology laboratory.

2. Application

This supplement requirements are specified the requirements that the surgical pathology laboratory shall establish the policy and procedure to ensure that the surgical pathology laboratory complies with this supplement requirements and ISO 15189.

3. References

☞ 3.1 Royal College of Pathologists of Thailand. (2018). Curriculum and training criteria for residency program in anatomical pathology leading to the diploma of the Thai board of anatomical pathology (B.E. 2561). Bangkok, Thailand: Royal College of Pathologists of Thailand.

☞ 3.2 College of American Pathologists. (2023). Anatomic Pathology (ANP) checklist. Northfield, IL: College of American Pathologists. Retrieved from https://www.cap.org/laboratory-improvement/accreditation/checklists

☞ 3.3 Department of Pathology, Institute of Pathology, Phramongkutklao Medical Center. (2024). Curriculum for Diploma of Thai Board of Anatomical Pathology (B.E. 2567). Bangkok, Thailand: Department of Pathology, Institute of Pathology, Phramongkutklao Medical Center.

☞ 3.4 ISO 15189:2022 Medical laboratories — Requirements for quality and competence.

☞ 3.5 ISO 15190:2020 Medical laboratories — Requirements for safety.

4. Definition and abbreviation

Surgical pathology is the pathological diagnosis of tissue by gross and microscopic to investigate of cell and tissue combine with clinical information from doctor diagnosis or confirm the diagnosis of patient.

5. Associated Documents

5.1 N 07 15 001 Policy and requirements for acceptance the measurement result of calibration equipment

5.2 N 07 15 011 Supplement requirements for medical laboratory

6. Procedures

Supplement Requirements

6.1 Personnel

6.1.1 Staffs who are responsible for the surgical pathology must contain least.

1) Pathologist, in the appropriate quantity and quality of work. One Pathologist is responsible only pathological diagnosis without any other work cannot exceed 20 per day (6 hours / day). If needed for other work such as teaching, training, management, quality control, increasing professional knowledge research, the pathological work load should reduce by proportion.

2) Undergraduate and minimum degree officer which are knowledgeable, and experience should be suitable with quantity and quality of work.

6.1.2 Staff from article 6.1.1 should be evaluated knowledge by appropriate timing to qualify with the responsibilities of work as following,

1) Pathologist are required Continuing Medical Education (CME) by The Medical Council role or practice of surgical pathology at least 300 cases per year.

2) Related staff should continue academic activities as appropriate.

☞ 6.2 Accommodation and Environmental Conditions

To ensure that the physical environment, accommodation, and facilities of the surgical pathology laboratory are appropriately designed, equipped, and maintained to support safe, efficient, and high-quality performance of all procedures, in compliance with ISO 15189:2022 (Clause

6.3), ISO 15190:2020, and the College of American Pathologists (CAP) Anatomic Pathology (ANP) Checklist (2023).

The working areas shall be clearly divided into functional sections appropriate for service and operations, including at least the following areas:

1) Pathologist office

A designated, secure, and ergonomic area for slide review, diagnostic interpretation, and report preparation, ensuring confidentiality and adequate lighting, ventilation, and workspace.

2) Pathology laboratory

The main technical area for specimen processing, gross examination, embedding, sectioning, staining, and related analytical procedures, equipped with appropriate ventilation, safety devices, and environmental controls to maintain safe and standardized working conditions.

3) The document office

A separate area for the storage, control, and management of laboratory records, quality system documents, and administrative files, with restricted access to maintain document integrity and confidentiality.

4) Storage area for block and slide

A controlled environment for the preservation, organization, and traceability of paraffin blocks, glass slides, and archival materials, ensuring proper environmental conditions and long-term retrievability.

☞ **6.3 Laboratory equipment, reagents, and consumables**

6.3.1 pre-pre-examination processes

6.3.1.1 The laboratory shall be equipped with all necessary items of equipment, instruments, consumables, reference materials, and reagents required for the provision of services. Purchased items must consistently meet the laboratory’s requirements. There shall be

procedures for handling, storage, maintenance, and a regular monitoring program.

6.3.1.2 The laboratory is responsible for ensuring that manufacturers' performance claims are met, and that calibration services provided by manufacturers fulfill the laboratory's requirements. The suitability for the intended use must also be verified.

6.3.1.3 When laboratories use different equipment or examination methods, the comparability of these various examination systems must be ensured.

6.3.1.4 The laboratory shall have firefighting equipment, chemical and hazardous materials protection equipment, and a first aid kit readily available in case of accidents, where necessary and appropriate

☞ **6.3.2 Pre-examination processes**

6.3.2.1 The laboratory shall establish a procedure for customers to follow. This procedure shall include details on the test analysis, patient preparation, sample collection, sample container requirements, sample handling, completion of request forms, turnaround times, criteria for acceptance or rejection of primary samples, safety protocols for collection and handling of samples, and the receiving/sending of test reports.

6.3.2.2 The laboratory shall provide such documents to the customers, and records of the handling or receipt of these documents shall be maintained by the laboratory.

6.3.2.3 Laboratory staff may not collect all or any samples for examination. However, the laboratory is still responsible for ensuring that the samples received are not compromised

☞ **6.4 Examination processes for surgical pathology laboratory**

The surgical pathology laboratory shall ensure that all examination processes are conducted under appropriate supervision and in compliance with ISO 15189:2022 (Clause 7.4) and professional standards established by the Royal College of Pathologist of Thailand.

1) The gross examination of surgical specimens may be performed by medical residents, medical technologists, or other authorized personnel under the direct supervision of a qualified pathologist. All gross descriptions, specimen labeling, and tissue selection for processing shall be reviewed and verified by the supervising pathologist before final reporting.

2) The microscopic examination and diagnosis of surgical pathology specimens shall be performed exclusively by a licensed pathologist. The pathologist is responsible for interpreting the histopathological findings, correlating them with clinical and gross information, and issuing the final diagnostic report.

3) When trainees or residents are involved, the pathologist must review, verify, and co-sign the final report to ensure diagnostic accuracy and patient safety.

☞ **6.5 Ensuring quality of examination results for surgical pathology laboratory**

To ensure the accuracy, reliability, and consistency of examination results, the surgical pathology laboratory shall establish and maintain a systematic quality assurance program in accordance with ISO 15189:2022 (Clause 7.7), CAP ANP checklist (2023), and the Practical Guideline for Anatomic Pathology (Royal College of Pathologist of Thailand).

The QA program shall include continuous monitoring, assessment, and documentation of analytical and diagnostic processes, as well as participation in external quality assessment (EQA) or proficiency testing (PT) schemes, when available. The laboratory shall also ensure periodic internal reviews, inter-observer

correlation, and performance evaluations to support continual improvement and maintain diagnostic consistency across all examination activities.

☞ **6.6 post-examination processes**

The laboratory shall ensure that all medical evidence, examination records, and materials are properly collected, preserved, and retained within the specified timeframe to maintain traceability, quality, and legal compliance.

The minimum retention requirements are as follows:

1.Specimen Log Book – shall be retained for 10 years after the date of reporting.

2.Gross Specimens and Effusion Fluids (including cases where the specimen container is unavailable) – shall be retained for 2 weeks after reporting, after which proper disposal procedures must be followed.

3.Paraffin Blocks – shall be stored for at least 5 years in an appropriate, Temperature - controlled area to ensure integrity and retrievability.

4.Glass Slides – shall be stored for a minimum of 5 years from the date of reporting.

5.Duplicate Copies of Reports and Requests – shall be maintained for 10 years to ensure traceability and case review capability.

6.Cytological Reports, including both internal and external consultation cases a complete copy of the report, together with the original, shall be kept for 10 years.

All evidence and documents listed above may be preserved either in physical or electronic formats, such as scanned reports, digitized slides, or other validated electronic archival systems, provided that retrievability and data integrity are ensured throughout the retention period.

☞ **6.7 Reporting of results**

The surgical pathology report shall contain sufficient and relevant information to support accurate clinical interpretation and patient management.

Each report shall include, at a minimum:

1.Gross examination findings — describing the specimen type, size, appearance, and key pathological features.

2.Paraffin block information — indicating the block number(s) and tissue location or site corresponding to each block.

3.Microscopic findings and final diagnosis — prepared, reviewed, and approved by a qualified pathologist.

All diagnostic pathology results must be reviewed, authorized, and signed by the responsible pathologist before release. When electronic reporting systems are used, the laboratory shall ensure proper authentication, traceability, and data security in accordance with ISO 15189:2022 (Clause 7.9) and BLQS policy on report control. The final report shall be retained and retrievable for the defined retention period, as specified in Section 6.6 (Post-Examination Processes).

7. Data record and Used document

-

8. Supplementary notes

-

9. History of change

Revision	Document Changes	Prepared / Revised by	Date Issued
00	Initial document	-	-
01	-	Mr. Surasak Muenphon	-
02	Change detail in Supplement requirement	Mr. Surasak Muenphon	-
03	- Change format and detail in Procedures (clause 6) - Add clause 7 and 8	Miss Nattakarn Laieddee	10 November 2017
04	- Add Reference in clause 3.2 - Edit storage time of Specimen	Misss. Sirimas Khamsai	12 March 2024

Revision	Document Changes	Prepared / Revised by	Date Issued
	log book and report 10 years in clause 6.7.1 - Change format		
05	- Add Reference in clause 3.1-3.5 -Edited the text to be concise and academically accurate in Clause 6.2 Accommodation and Environmental Conditions 6.3 Laboratory equipment, reagents, and consumables 6.3.2 Pre-examination processes 6.4 Examination processes for surgical pathology laboratory 6.5 Ensuring quality of examination results for surgical pathology laboratory 6.6 post-examination processes 6.7 Reporting of results	Misss. Sirimas Khamsai	