## 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 comply with this supplement requirements and ISO 15189.

## 3. References

3.1 Practical Guideline for cytology: Royal College of Pathologist of Thailand.

3.2 Guideline for Gynecological (cervical) Cytology: National Pathology Accreditation Advisory Council, Australia, 1993.

3.3 Cytopathology Checklist for Laboratory Accreditation Program: Commission on Laboratory Accreditation. The College of American Pathologists (CAP), U.S.A., 2006.

## 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 equipments

## 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**

Working area should be dividing to the appropriate area for service, operation at least the following areas,

1) Pathologist office
2) Pathology laboratory
3) The document office
4) Storage area for block and slides.

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

Supplement requirements for medical laboratory compliance with ISO 15189 (N 07 15 001) applies.

**6.4 Pre-examination processes**

Supplement requirements for medical laboratory compliance with ISO 15189 (N 07 15 001) applies.

**6.5 Examination processes**

To perform gross specimen of surgical pathology, for Medical Residency and other officers can examine under the supervise of pathologist. The examination of microscopic pathology must perform by pathologist.

**6.6 Ensuring quality of examination results**

1) A quality slide evaluation system.

2) The comparison record between the diagnosis from frozen section and results from Paraffin section

3) Participate in proficiency test with organization that are recognized nationally, internationally or recognized by the Royal College of pathologist of Thailand. In case of no organization that provides proficiency test, laboratory has conducted inter laboratory

comparison between laboratories through quality evaluation of surgical pathology from the Royal College pathologist of Thailand.

4) If unable operate in accordance with article 6.6 (3), the laboratory has to review the diagnosis or some part of pathology diagnosis regularly and record the performance review. When conflicting opinions must have the correct procedure and record.

**6.7 Post-examination processes**

6.7.1 The evidence and document storage system should be organize in timing as following,

1) Specimen log book and report at least 3 year.

2) Gross specimen, collection bags or containers with no specimen at least 2 week after diagnosis.

3) Paraffin block at least 5 years.

4) Slide at least 5 years.

5) Duplicate copies of report and the request from at least 10 years.

6.7.2. Paraffin block should keep in an appropriate area which not affect the quality of paraffin block and ready to retrievable.

**6.8 Reporting of results**

In a report should including at least gross examination, paraffin block information (the number and location). The diagnostic pathology results shall be reviewed, approved, and signed by pathologist.

## ☞ 7. Data record and used document

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## ☞ 8. History of change

| Revision | Document Changes | Prepared / Revised by |
|---|---|---|
| 00 | Initial document | - |
| 01 | - | Surasak Muenphon |
| 02 | Change detail in Supplement requirement | Surasak Muenphon |
| 03 | - Change format and detail in Procedures (clause 6)<br>- Add clause 7 and 8 | Nattakarn Laieddee |

## Appendix 1

### Controlled copy list

| | | |
|---|---|---|
| 1. | Director of Bureau of Laboratory Quality Standards | Code No. 07 00 |
| 2. | Head of Laboratory Accreditation Section 1 | Code No. 07 03 |
| 3. | Head of Laboratory Accreditation Section 2 | Code No. 07 04 |
| 4. | Quality Manager | Code No. QCC |
| 5. | Ms. Nattakarn Laieddee | |