



By the 2025 PCS Ad hoc Committee on Sentinel Lymph Node Biopsy

FOREWORD

It is with immense pride and a profound sense of purpose that I, as President of the Philippine College of Surgeons (PCS), present the Philippine Sentinel Lymph Node Biopsy (SLNB)

Philippine College of Surgeons' 2025 Consensus Statement on Safe Incorporation of Sentinel Lymph Node Biopsy for Breast Cancer Into Clinical Practice

Consensus Guidelines. This landmark document represents a significant stride forward in our collective commitment to advancing surgical excellence and patient care in the Philippines.

These guidelines are a testament to the power of collaboration and shared vision within our surgical community. I extend my deepest gratitude to the three distinguished societies whose unwavering dedication and expertise made this consensus possible: the Philippine Society of General Surgeons, the Surgical Oncology Society of the Philippines, and the Philippine Society of Breast Surgeons. Their collaborative spirit in developing a unified approach to Sentinel Lymph Node Biopsy underscores a shared commitment to improving the quality of surgical practice across our nation.

The development of these guidelines reflects a meticulous process of evidence-based review and expert deliberation. They aim to standardize best practices, enhance surgical outcomes, and ultimately, provide Filipino patients with the highest standard of care. By fostering a common understanding and application of SLNB techniques, we empower our surgeons with the knowledge and tools necessary to deliver precise and effective treatment.

As we embark on the implementation of these guidelines, I am confident that they will serve as a cornerstone for continuous improvement in surgical oncology, particularly in the management of breast cancer. The PCS remains steadfast in its mission to promote excellence, uphold ethical standards, and foster unity among all surgical specialties. This consensus is a shining example of what we can achieve when we work together for the betterment of our profession and the health of our countrymen.

Together, we continue to elevate the standard of surgical care in the Philippines.

Sincerely,



Joselito M. Mendoza, MD, FPCS
President, Philippine College of Surgeons 2026



Message From the 2025 PCS President and Convenor of the Ad hoc Committee on SLNB

Quality Surgery for All is what the Philippine College of Surgeons is all about. This has been the guiding mission and vision of the college for the last nine decades and we have been making tangible activities and programs the past several years spanning several presidents of the college.

Last year, we spearheaded the creation of a technical working group led by the Committee on Patient Safety and Quality Assurance, the Committee on Cancer and the society stakeholders - PSGS, SOSP and PSBS. They were tasked to come up with a Consensus Guideline on the Safe Incorporation of Sentinel Lymph Node Biopsy in our Surgical Practice. This is all about quality.

Eventually, the result is a standardized performance of sentinel node biopsy in the country and improved outcome at par with world standards. Last December, during our Annual Clinical Congress, the output was presented in a session which coincidentally coincided with the Manila Declaration on Quality Surgery by the ASEAN Federation of Surgical Colleges. This is a testament to our commitment to assuring that every patient, gets the best and safe surgical procedure at all times.

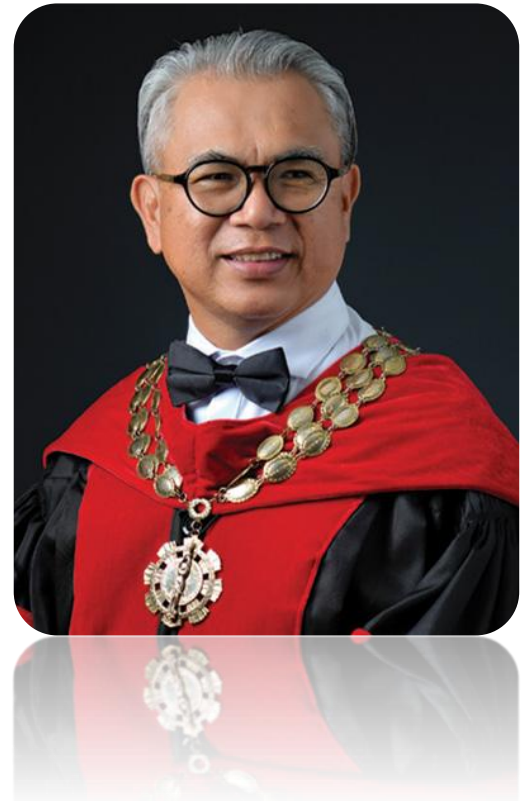
Congratulations to all the men and women behind this consensus guidelines and may this spark more quality focused guidelines across all surgical disciplines and specialties.

Mabuhay ang maninistis na Pilipino. Mabuhay and PCS!

#qualitysurgeryforall #pcsbeyondsurgery #onepcs



Jose Rhoel C. De Leon, MD, FPCS
President, Philippine College of Surgeons 2025



I. INTRODUCTION

Sentinel Lymph Node Biopsy (SLNB) is a cornerstone in the staging and treatment of early breast cancer, allowing for accurate axillary staging while reducing the morbidity associated with a full axillary lymph node dissection (ALND). SLNB is the standard of care procedure for surgical axillary staging for patients with early, clinically node negative breast cancer. As such it is essential that Filipino surgeons adopt and refine this technique with the highest quality standards to ensure optimal patient outcomes.

This Philippine College of Surgeons' 2025 Consensus Statement on Safe Incorporation of Sentinel Lymph Node Biopsy for Breast Cancer Into Clinical Practice summarizes the current indications for SLNB as well as recommendations for safe incorporation into clinical practice with emphasis on key quality indicators for validation and assurance of proper technique. This reflects the consensus of a panel comprised of members of the PCS Committee on Cancer, Committee on Patient Safety and Quality Assurance, Subcommittee on Quality Surgical Improvement Program, Committee on Hospital Standardization and Accreditation, as well as representatives from the Surgical Oncology Society of the Philippines, Philippine Society of Breast Surgeons and the Philippine Society of General Surgeons.

This Consensus statement reflects what the PCS considers to be optimal practice to ensure safe implementation of SLNB.

II. INDICATIONS AND CONTRAINDICATIONS FOR SLNB

SLNB is well established as standard care for surgical axillary lymph node staging in most patients with cN0 breast cancer. Oncologic outcomes of ALND and SLNB that include axillary recurrence, disease-free survival and overall survival are comparable with the benefit of less morbidity with SLNB.

INDICATIONS FOR SLNB

Current indications for SLNB are as follows:

1. cT1-2 invasive breast cancer with a clinically negative axilla
 2. DCIS with suspected/proven microinvasion
 3. DCIS sufficient to require mastectomy
 4. DCIS for lumpectomy in an anatomic location that may compromise performance of a future SLNB or where oncoplastic procedures are necessary for complete resection.
- SLNB may be suitable for select patients with **multicentric** cancers and **T3** disease, however the **evidence is limited** and should only be considered in the context of a multidisciplinary discussion.

CONTRAINDICATIONS FOR SLNB

SLNB should not be offered to **pregnant** patients less than 30 weeks age of gestation. Beyond this, SLNB using technetium 99m sulfur colloid may be safely done. Use of methylene or isosulfan blue dye is contraindicated in pregnancy.

SLNB is contraindicated in patients with clinically palpable nodes as well as patients with inflammatory breast cancer.

III. PRINCIPLES OF SLNB TECHNIQUE

SLNB involves the identification and biopsy of the sentinel lymph node, which is the first node to drain lymph from the primary tumor site. The following steps are critical:

1. **Pre-operative Localization:** A radiotracer (usually technetium-99m sulfur colloid) may be injected on the morning of or the day prior to surgery. Lymphoscintigram may be taken to identify the sentinel nodes; however, this is not a prerequisite to performing SLNB.
2. **Intra-operative Mapping:** The surgeon identifies the sentinel node(s) using the gamma probe (if radioisotope is used) and/or visual inspection for the blue node/s and/or lymphatic tract (if blue dye or methylene blue is used). The surgeon should aim to harvest the node/s that fit the criteria of a sentinel node. The sentinel node(s) may include the hot node, blue node, node at the end of the blue lymphatic channel and any suspicious palpable nodes. These are carefully excised and sent for pathological evaluation. Typically, 1-4 nodes are submitted as sentinel nodes. If no sentinel lymph node is identified intraoperatively, then axillary lymph node dissection should be done.
3. **Pathologic Evaluation:** Sentinel nodes should undergo careful pathological examination, including both hematoxylin and eosin (H&E) staining and additional techniques such as immunohistochemistry if necessary.
 - Intraoperative evaluation with frozen section and imprint cytology may or may not be done. However, findings on frozen section may alter the axillary management of the patient and may spare the patient of an additional surgery or need for radiotherapy.
 - It is important to ensure that the sentinel node(s) are marked properly for evaluation and that proper technique is followed to avoid missed or false-negative results.

IV. IMPACT OF INTRAOPERATIVE PATHOLOGIC EVALUATION

Management of the axilla after a positive SLNB is evolving and depends on the number of positive sentinel nodes and the type of breast surgery done as well as receipt of neoadjuvant treatment. This is beyond the scope of this Consensus Statement and should follow the current international and/or local guidelines such as NCCN, ASCO, DOH and institutional CPG's as deemed appropriate.

V. PREREQUISITES PRIOR TO EXECUTION

Successful implementation of SLNB depends on the collaborative effort of a variety of specialties including the surgeon, pathologist, and nuclear medicine physician in institutions with nuclear medicine facilities and a gamma probe.

For an institution that is just about to credential for this procedure, both the surgeon and the pathologist must undergo validation to ensure that quality standards are met.

A. QUALIFICATIONS FOR THE MEDICAL INSTITUTION

To successfully initiate a Sentinel Lymph Node Biopsy program, a medical institution must meet the following essential requirements in infrastructure, equipment, and trained medical personnel.

1. Operating Room Equipment

- Operating room equipped for Major General Anesthesia cases with standard breast surgery instruments and set up.
- Must have trained staff aware of potential allergic reactions to the different tracers and emergency management.

2. Blue Dye

- Supply of medical grade 1% methylene blue, isosulfan blue, or patent blue V.

3. Pathology Laboratory

PATHOLOGIST

- Trained in the evaluation of sentinel lymph nodes
- Trained in identifying micrometastases, ITCs (isolated tumor cells) and interpreting immunohistochemistry
- Must undergo validation if he/she has not undergone specific training for SLNB and has no experience in SLNB
- If the institution is to offer frozen section analysis, the pathologist must validate for such until acceptable false negative rates are met.

The laboratory must have:

- The ability to perform frozen section (optional)
- The ability to perform hematoxylin and eosin (H&E) staining
- Access to immunohistochemistry for cytokeratin (for micrometastases, if needed)

4. Nuclear Medicine Facilities (if available)

NUCLEAR MEDICINE PHYSICIAN

- To perform radiotracer injection, provide imaging (if lymphoscintigraphy is used), and guide localization
- Should have training and/or experience in lymphoscintigraphy

Gamma Probe System

- A handheld gamma detection probe to identify radiotracer-labeled sentinel lymph nodes intraoperatively.
- Should include a sterile probe cover and regular calibration capabilities

Radiotracer Supply & Handling

- Access to Technetium-99m (Tc-99m) sulfur colloid or equivalent.
- Compliance with radiation safety protocols and local regulatory requirements

B. SURGEON QUALIFICATIONS

Adequate training and skills development is warranted. As with any other procedure, performance of SLNB is associated with a learning curve. Early studies on the training and implementation of SLNB mostly used dual tracers however, it is recognized that this is not readily available in the local setting. As such, a **strict method of validation** is recommended in order to establish surgeons' proficiency in the performance of SLNB.

The use of dual tracers during SLNB improve the identification and false negative rates. However, for surgeons who are still undergoing the validation process, we recommend the use of blue dye alone to ensure proficiency.

SLNB is not just a novel surgical technique but is an **important diagnostic modality** with major implications on decisions for adjuvant therapy including recommendations for adjuvant systemic therapy and radiation therapy and ultimately impacts the long-term outcomes of breast cancer patients. It is imperative for surgeons who are planning to validate to have a thorough understanding of the procedure.

Participation in workshops and/or learning modules for Sentinel Lymph Node Biopsy is a **MUST** prior to embarking on validation.

For surgeons who are still undergoing validation, we recommend adherence to specific patient selection criteria to optimize identification rates and minimize false negative rates:

1. Established diagnosis of unifocal, cT1-2, cN0 undergoing total or partial mastectomy
2. DCIS who will undergo mastectomy for cases that will be mentored only. We do not recommend this to be done for self-validation since the patient will require back-up ALND.
3. No prior breast surgery/excision in the periareolar or upper outer quadrant of the breast or any previous incision that may obstruct the lymphatic flow to the axilla
4. Did not receive preoperative systemic therapy

For tumors in the upper outer quadrant, identification rate may be compromised so it is recommended to avoid including these patients during validation.

Before a surgeon is to abandon routine ALND, the Committee recommends two modes of training/validation which is adapted from earlier studies done in the United States and United

Kingdom which established the minimum number of cases needed for a surgeon to meet the required identification and false negative rates. See Appendix A.

1. **Mentored/Proctored** – This method may apply to institutions with high volume of cases and the availability of validated surgeons who already perform SLNB
 - Initially, assists in 5 cases of SLNB then:
 - 20 cases performed under the direct supervision of a surgeon who is trained and validated to do SLNB
2. **Self-Validation** – This method may apply to institutions where there are no validated surgeons who perform SLNB or who failed to complete 20 mentored cases during training:
 - Initially, assists in 5 cases or directly supervised in first 5 cases then:
 - 20 cases of SLNB with back up ALND with an acceptable identification rate of $\geq 95\%$ and a False negative rate of $\leq 10\%$
3. **Combination of Mentored and Self-validation**
 - Initially, assists in 5 cases of SLNB then:
 - 20 cases of combination of mentored by a validated surgeon and with back-up ALND without a mentor
 - Identification rate $\geq 95\%$ and a false negative rate of $\leq 10\%$ for cases with back-up ALND
 - Trainees who have been mentored but have not yet met the required numbers for validation/credentialing during their residency training period may continue to validate beyond their residency training using this method until they have met the prescribed number of cases and/or acceptable identification and false negative rates.

VI. QUALITY STANDARDS

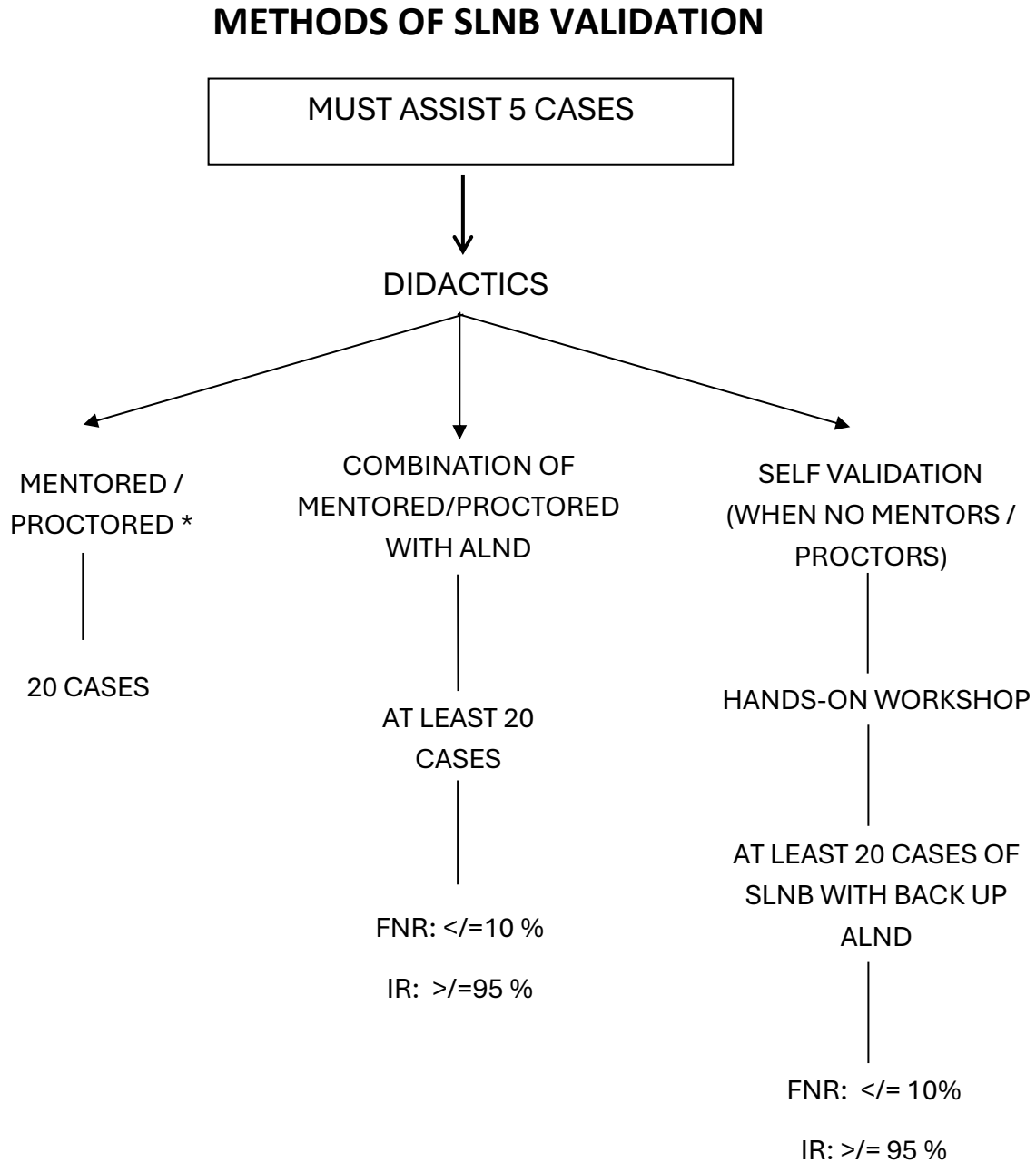
A standardized documentation must be established for monitoring and quality improvement.

In order to safely offer SLNB to patients, the following key quality indicators should be achieved: (See appendix B for the formulas for computation)

- **High Detection Rate:** The identification rate of the sentinel node should be at least 95%.
- **Low False-Negative Rate:** A false-negative rate of less than or equal to 10% is a marker of quality practice. This is achievable with careful technique and proper patient selection.
- **Proper Handling of Sentinel Nodes:** Sentinel nodes must be appropriately labeled, preserved, and sent for both gross and microscopic examination by a pathologist experienced in breast cancer staging.
- **Multidisciplinary Collaboration:** The involvement of radiologists, pathologists, and oncologists is essential for optimal outcomes.

APPENDIX

APPENDIX A: Methods of SLNB Validation recommended by the PCS Ad Hoc Committee on SLNB



*MENTORED/PROCTORED- Under the direct supervision of a trained AND validated surgeon

** FNR- false negative rate; IR – identification rate

APPENDIX B: Formulas for computation of Identification and False Negative Rates

IDENTIFICATION RATE

$$\text{IDENTIFICATION RATE} = \frac{\text{\# of cases of successful SLN identification}}{\text{Total \# of SLNB cases}} \times 100$$

VALIDATION FOR SURGEONS:

1. For surgeon's validation of sentinel lymph node biopsy (SLNB), rates are calculated by comparing the results of permanent section (H&E) of both the sentinel lymph nodes (SLNs) and the presence of any additional lymph nodes harvested during axillary lymph node dissection (ALND)
2. *Only the results from the **permanent section (H&E)** will be considered in calculating the False Negative Rate for Surgeon's Validation.*

FALSE NEGATIVE RATE

Surgeon Validation

Only the results from the permanent section (H&E) will be considered in calculating the False Negative Rate for Surgeon Validation.

$$\text{FALSE NEGATIVE RATE (Surgeon Validation without FS)} = \frac{\text{False Negative}}{\text{Actual Positive}} = \frac{\text{False Negative (c)}}{\text{True Positive (a) + False Negative (c)}} \times 100$$

TRUE POSITIVE (a)

- If SLN is positive on final histopathology with no additional positive nodes in ALND
- If SLN is positive on final histopathology with additional positive nodes in ALND

FALSE NEGATIVE (c)

- If SLN is negative on final histopathology BUT with positive nodes in ALND

TRUE NEGATIVE (d)

- If SLN is negative on final histopathology with no additional positive nodes in ALND

VALIDATION FOR PATHOLOGISTS:

1. For pathologist's validation of sentinel lymph node biopsy (SLNB) **Frozen Section**, False Negative Rates are calculated by comparing the results of intraoperative frozen section (FS) with the more definitive results of permanent sections (H&E).
2. Data from ALND will be excluded from the computation of Pathologist's Validation.

FALSE NEGATIVE RATE

Pathologist validation for Frozen Section

- Frozen section results will be used exclusively to calculate the False Negative Rate for Pathologist Validation.
- Data from ALND will be excluded from the computation of Pathologist Validation.

$$\text{FALSE NEGATIVE RATE (Pathologist Validation)} = \frac{\text{False Negative}}{\text{Actual Positive}} = \frac{\text{False Negative (c)}}{\text{True Positive (a) + False Negative (c)}} \times 100$$

TRUE POSITIVE (a)

- If SLN is positive on FS and positive on final histopathology

FALSE NEGATIVE (c)

- If SLN is negative on FS, positive on final histopathology

TRUE NEGATIVE (d)

- If SLN is negative on FS and final histopathology

SLNB FS	SLNB Paraffin H&E	
	POSITIVE	NEGATIVE
POSITIVE	TP (a)	FP (b)
NEGATIVE	FN (c)	TN (d)

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