

## **Guidance to Implementing Breast Sentinel Lymph Node Biopsy (SLNB) within a Hospital: An Information Package (Tool Kit)**

### **Introduction**

Cancer Care Ontario released the guideline “Sentinel Lymph Node Biopsy (SLNB) in Early-Stage Breast Cancer” which describes:

- Target population
- Intended users of the guideline
- Clinical practice recommendations and evidence
  - The role of SLNB in specific clinical circumstances
  - Factors that affect the success of SLNB
  - Potential harms and benefits
  - Technical aspects SLNB
- Organization of care recommendations

This guideline recommends SLNB as the preferred method of axillary staging for a person with clinical presentation of early-stage cancer in the absence of clinically or pathologically positive lymph nodes.

### **Guideline Link:**

<http://www.cancercare.on.ca/cms/One.aspx?portalId=1377&pageId=10418#>

### **Current State of Sentinel Lymph Node Biopsy in Ontario**

Efforts are being taken by Ontario hospitals performing breast cancer surgery to ensure their patients have access to SLNB. Hospitals can provide their patients with access by:

- a) offering SLNB on site (onsite nuclear medicine department is in place)
- b) offering SLNB on site, but sending patients to another facility for nuclear medicine injections (partnering with another facility for nuclear medicine)
- c) not offering SLNB, but referring patients to a nearby facility where SLNB is available.

### **Purpose**

Provide information on tools to consider to improve the availability of SLNB at your hospital and address common barriers to SLNB.

## Table of Contents

<b>Frequently Asked Questions .....</b>	<b>3</b>
<b><i>General</i>.....</b>	<b>3</b>
<b>1. Why should a hospital offer SLNB? .....</b>	<b>3</b>
<b>2. What is needed to perform SLNB at a hospital? .....</b>	<b>3</b>
<b><i>Surgeon Training</i>.....</b>	<b>3</b>
<b>3. What training opportunities are available for surgeons interested in performing SLNB?.....</b>	<b>3</b>
<b><i>Nuclear Medicine</i> .....</b>	<b>4</b>
<b>4. What type of nuclear medicine license is required to perform SLNB?.....</b>	<b>4</b>
<b>5. What type of access is there to Nuclear Medicine?.....</b>	<b>4</b>
<b>6. What is involved in applying for a Nuclear Medicine License? .....</b>	<b>6</b>
<b>7. What is the cost for applying for a Nuclear Medicine License? .....</b>	<b>6</b>
<b>8. How long does it take to get a Nuclear Medicine License?.....</b>	<b>6</b>
<b><i>Equipment</i>.....</b>	<b>7</b>
<b>9. What type of equipment is needed to perform SLNB? .....</b>	<b>7</b>

## **Frequently Asked Questions**

### ***General***

#### **1. Why should a hospital offer SLNB?**

There are many benefits to offering SLNB:

- Less invasive surgery (outpatient procedure and no need for drains)
- Fewer complications (i.e. infections, sensory changes and lymphedema)

#### **2. What is needed to perform SLNB at a hospital?**

The resources needed to perform SLNB in a hospital setting are:

- Supportive hospital administration (i.e. for observership & staff education)
- Trained surgeons
- Access to a Nuclear Medicine department with established protocols
- Available equipment for surgical and nuclear medicine procedures
- Pathologist to assess the specimens according to a standardized protocol

### ***Surgeon Training***

#### **3. What training opportunities are available for surgeons interested in performing SLNB?**

In order to perform SLNB, the following are required:

- Understanding the concepts of lymphatic mapping, radio guided surgery & SLNB;
- Indications and techniques of SLNB in breast cancer;
- Introduction to radiation safety; and
- Pathological evaluation of sentinel lymph nodes

SLNB should be performed by an experienced team. If your centre is currently not performing SLNB, it would be best to consider training and mentorship of the entire multidisciplinary team. Contact: [SOPinfo@cancercare.on.ca](mailto:SOPinfo@cancercare.on.ca) for more information regarding training opportunities and/or available resources.

## ***Nuclear Medicine***

### **4. What type of nuclear medicine license is required to perform SLNB?**

In Canada, radioisotopes must be used within a licensed nuclear medicine facility. A nuclear medicine license can be acquired through the Canadian Nuclear Safety Commission (CNSC).

A Diagnostic Nuclear Medicine (862) license is required to perform SLNB in a facility. The Diagnostic Nuclear Medicine license allows the administration of unsealed nuclear substances to humans for diagnostic purposes related to their health care (e.g. tests, procedures, imaging); processing of radio pharmaceuticals and laboratory studies which are part of the diagnostic studies.

Information on licensed nuclear medicine facilities can be obtained from CNSC. To determine which facilities are licensed in diagnostic nuclear medicine, visit: <http://www.nuclearsafety.gc.ca/eng/readingroom/licensesearch/index.cfm>

Enter in the following information:

**Country:** Canada

**Province:** ON

**City:** \_\_\_\_\_

**Licensed Purpose (Usetype):**

**Enter:** 862 (Diagnostic Nuclear Medicine)

### **5. What type of access is there to Nuclear Medicine?**

Access to nuclear medicine resources can be challenging for hospitals that do not have an established nuclear medicine department or are located in remote rural areas, not within driving distance of a nuclear medicine facility. There are different models of nuclear medicine access that can be considered by hospitals so that a full breast program and SLNB can be offered to their patient population.

**Model 1:** Hospital has a nuclear medicine department. The patient receives the radioisotope injection and SLNB at the hospital.

**Model 2:** Hospital does not have a nuclear medicine department and is not within driving distance of a nuclear medicine facility. The hospital has a license for radioisotope use only. The patient receives the radioisotope injection and SLNB at the hospital.

**Model 3:** Local hospital does not have a nuclear medicine department, but is within driving distance of a nuclear medicine facility. The patient receives the radioisotope injection at the partnering nuclear medicine facility. SLNB is performed at the local hospital.

See the table below for a more in depth explanation of the nuclear medicine access models.

### Nuclear Medicine Access: Models for Offering Sentinel Lymph Node Biopsy

Models	Description	Patient Details	License	Example
Model 1	<ul style="list-style-type: none"> <li>Hospital has a nuclear medicine facility</li> </ul>	<ul style="list-style-type: none"> <li>Patient receives radioisotope injection and SLNB on site</li> </ul>	<ul style="list-style-type: none"> <li>Complete application for diagnostic nuclear medicine license (862) as per CNSC</li> </ul>	<ul style="list-style-type: none"> <li>Regional Cancer Centre</li> </ul>
Model 2	<ul style="list-style-type: none"> <li>Hospital is not within driving distance of a nuclear medicine department</li> <li>Has a license for handling radioisotopes without having an onsite nuclear medicine department</li> </ul>	<ul style="list-style-type: none"> <li>Patient receives radioisotope injection and SLNB on site</li> </ul>	<ul style="list-style-type: none"> <li>Complete application for diagnostic nuclear medicine license (862) as per CNSC</li> <li>Apply for use of radioisotope injection for SLNB only</li> <li>License application may be less involved; components of entire application process may not be relevant</li> </ul>	<p><u>Hinton Health Care Alberta</u></p> <ul style="list-style-type: none"> <li>No nuclear medicine department or nearby facility</li> <li>Hired Alara Consultants to assist with license application</li> <li>License allows the centre to acquire, transport and utilize radioisotopes for SLNB surgery</li> <li>Assistance from radiation safety consultant with application, training and equipment for the safe handling/ use of substances</li> <li>Process took one year from inception until a license was granted and an on site nuclear medicine supervisor was appointed</li> <li>Radioisotopes acquired from a pharmaceutical facility and pre-filled syringes are transported in lead-lined boxes by courier to local hospital</li> </ul>
Model 3	<ul style="list-style-type: none"> <li>Local hospital partners with a nuclear medicine department housed in a nearby facility</li> </ul>	<ul style="list-style-type: none"> <li>Patient travels to the nuclear medicine department housed in a nearby facility to receive radioisotope injection</li> <li>Timing and dosage of the radioisotope injection adjusted to allow patient to be injected the day before surgery</li> <li>Patient travels back to local hospital for SLNB</li> </ul>	<ul style="list-style-type: none"> <li>Local hospital does not apply for nuclear medicine license</li> <li>Diagnostic nuclear medicine license (862) of partnering facility would be amended to stipulate that radioisotope injections are provided for patients of the local hospital</li> <li>Letter of agreement should exist between the partners indicating: <ul style="list-style-type: none"> <li>Local hospital is taking universal precautions</li> <li>Surgery is conducted in a proper OR setting</li> <li>Appointed, trained individual on site to confirm safety standards are followed</li> </ul> </li> </ul>	<p><u>Winchester District Memorial Hospital</u></p> <ul style="list-style-type: none"> <li>No nuclear medicine department</li> <li>Radioisotope injections occur at Ottawa Hospital, which has an established protocol</li> <li>Requisition sent to nuclear medicine services two weeks prior to surgery</li> <li>Scheduling logistics managed by hospital administration</li> <li>One day prior to surgery, patient travels to Ottawa Hospital for injection with Tc99-Sulfur Colloid Unfiltered which has a slower travel rate to the axilla, allowing the patient to return to Winchester for surgery the following day. In the event of a cancelled surgery, the injection would take place a second time.</li> </ul>

**\*\*Note:** A Diagnostic Nuclear Medicine license (862) is required to perform SLNB. To obtain a license, please contact the CNSC. The CNSC grants licenses on a case by case basis. Granting of a license is not guaranteed.

**6. What is involved in applying for a Nuclear Medicine License?**

The Canadian Nuclear Safety Commission (CNSC) has a regulatory guide entitled “C-292, Applying for a License – Diagnostic Nuclear Medicine, Therapeutic Nuclear Medicine, Human Research Studies” that is available to facilitate the license application process.

The guide provides information on regulatory framework, regulatory process and pertinent legislation, as well as a license application form and instructions on how to prepare and submit the license application.

The guide can be downloaded from the following link:

[http://www.nuclearsafety.gc.ca/pubs\\_catalogue/uploads/C-292\\_E.pdf](http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/C-292_E.pdf)

Applications for a nuclear medicine license can be submitted through the **Canadian Nuclear Safety Commission**.

<b><i>The Canadian Nuclear Safety Commission Contact Information</i></b>	
<b>Website:</b> <a href="http://www.nuclearsafety.gc.ca/eng/">http://www.nuclearsafety.gc.ca/eng/</a>	<b>Fax:</b> 613-995-5086
<b>Telephone:</b> 1-800-668-5284 (in Canada) or 613-995-5894 (outside Canada)	<b>E-mail:</b> <a href="mailto:info@cnsccsn.gc.ca">info@cnsccsn.gc.ca</a>

Visit the following links for nuclear medicine license assistance:

<http://www.nuclearsafety.gc.ca/eng/licenseesapplicants/substancesdevices/substancesdevices/>

<http://www.nuclearsafety.gc.ca/eng/licenseesapplicants/licensingprocess/index.cfm>

**7. What is the cost for applying for a Nuclear Medicine License?**

Educational institutions and not-for-profit health-care institutions that receive funds from federal, provincial or municipal governments are exempt from paying a licensing fee. Private clinics that wish to apply for a nuclear medicine license are not exempt from paying a licensing fee.

The license is renewed every 5 years. A renewal fee is applied to those institutions that are not exempt from paying a licensing fee.

**8. How long does it take to get a Nuclear Medicine License?**

Once an application has been submitted to the CNSC, it passes through a series of stages that includes review by a licensing division specialist and evaluation based on assessment criteria. The minimum amount of time to process the application is approximately 8 weeks. Application processing may be impacted by the adequacy and correctness of submitted documentation.

There are consultants available to assist with processes such as the license application, safety training and equipment purchases. Hospitals should consider contacting a radiation safety consultant.

### ***Equipment***

#### **9. What type of equipment is needed to perform SLNB?**

Conducting SLNB involves using a combination of surgical and nuclear medicine equipment. Depending on the type of nuclear medicine access model the hospital considers, the equipment required to offer SLNB will vary. The table below lists essential equipment for conducting SLNB and estimated costs.

<b>Equipment Type</b>	<b>Equipment</b>	<b>Estimated Cost/Item*</b>
<i>Surgical</i>	<ul style="list-style-type: none"> <li>• Gamma Probe</li> </ul>	<ul style="list-style-type: none"> <li>• \$ 26,500.00</li> </ul>
<i>Nuclear Medicine</i>	<ul style="list-style-type: none"> <li>• TYPE A Transport container</li> <li>• Stationary lead syringe shield</li> <li>• Table top shield</li> <li>• C vial Pb pig with viewing lead glass</li> <li>• Lead syringe shield (size of shield varies)</li> <li>• Lead apron (size and style of apron varies)</li> <li>• Spare Dose calibrator syringe dipper</li> <li>• Dose calibrator</li> <li>• Cs-137 QA standard for calibrator</li> <li>• Lead biohazard container</li> <li>• Lead garbage container</li> <li>• Radiation contamination survey meter</li> <li>• Radiation survey meter</li> <li>• Miscellaneous radiation safety supplies</li> </ul>	<ul style="list-style-type: none"> <li>• \$ 1,300.00</li> <li>• \$ 100.00</li> <li>• \$ 2,300.00</li> <li>• \$ 400.00</li> <li>• \$ 265.00 - \$ 550.00</li> <li>• \$ 350.00 - \$ 500.00</li> <li>• \$ 130.00</li> <li>• \$ 8,700.00</li> <li>• \$ 600.00</li> <li>• \$ 1,300.00</li> <li>• \$ 875.00</li> <li>• \$ 8,000.00</li> <li>• \$ 1,000.00</li> <li>• \$ 1,000.00 (approx.)</li> </ul>
	<b>ESTIMATED TOTAL</b>	<b>\$ 53,255.00</b>
<p>* <b>Note:</b> Costs for equipment may vary.  <b>Reference:</b> The information in this table was provided by Alara Consultants:  (<a href="http://alaraconsultants.com/index.php?option=com_frontpage&amp;Itemid=1">http://alaraconsultants.com/index.php?option=com_frontpage&amp;Itemid=1</a>)</p>		