Establishing a Hospital-based I-125 Seed Breast Localization Program

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Need a pic of Grand Dads Bluff looking over La Crosse
Objective

- To provide guidance on implementing a breast localization program using I-125

Disclaimer/Conflict of Interest

- We have just completed our 6th case.
- I have no conflict of interest in any vendor of I-125 seeds or any medical device used for this procedure.
Learning Objectives

- Understand the Radioactive Material (RAM) license requirements and the requirements of Authorized Users.
- Understand the merits of a I-125 seed breast localization or Radioactive Seed Localization (RDL) versus the standard wire localization procedure that is currently being used.
- Understand the necessary equipment needed and the limitations.
Learning Objectives (Cont.)

- Understand the level of RAM safety training needed based on personnel work locations.
- Understand the ramifications of a lost seed.
Topics

- What is it?
- Regulatory requirements
- Potential Hazards
- Equipment
- Seed tracking and handoff
- Training
I-125 Breast Seed Localization

This is a new procedure that involves a radiologist implanting a I-125 radioactive “seed” in a suspected cancer site. Days later the surgeon can use the gamma probe in a similar manner to a breast sentinel lymph node procedure to locate the seed(s).

I-125 (Iodine)
- Low energy (27 keV)
- Half-life 59.4 days
- 1-3 seeds implanted in each patient
I-125 RSL Vs. Wire Localization (WL)

- RSL can be used in conjunction with Sentinel Node procedures that use Tc-99m sulfur colloid with a gamma probe with multiple window settings.

- Some Surgeons report that RSL produces fewer positive margins and reoperation rates than WL.

- Some Surgeons report an improved surgical approach with RSL resulting in better cosmetic outcomes.
Getting Ready for the Implant
Implant Procedure
Verification of Implant
Results of Surgical Procedure
Histology Seed Extraction Procedure
The use of these iodine-125 and palladium-103 seeds for therapy is currently regulated under 10 CFR 35.400: "Use of sources for manual brachytherapy" and the equivalent Agreement State regulations.

In the RSL procedure, the iodine-125 or palladium-103 seeds are implanted for localization by an authorized user and are not intended to deliver a therapeutic dose to tissue. Therefore, this application is not regulated under 10 CFR 35.400 or the equivalent Agreement State regulation.

The use of these seeds for RSL procedures will be regulated under 10 CFR 35.1000: "Other medical uses" and the equivalent Agreement State regulations.
NRC and Agreement States Licensing Guidance (cont.)

If the licensee intends to transfer the radioactive tissue samples, i.e., the tissues will still contain the seed(s), or more than 1 microcurie of iodine-125 or 100 microcuries of palladium-103 contamination from a leaking source, to an outside pathology laboratory, the licensee must ensure before shipment that the samples will be transferred to an NRC or Agreement State licensed laboratory authorized to receive the seeds or radioactive contaminated tissue (10 CFR 30.41). The applicant must also ensure that packages will be properly prepared in accordance with 10 CFR 71.5 or an equivalent Agreement State regulation for shipping.
If the licensee intends to transfer the radioactive tissue samples, i.e., the tissues will still contain the seed(s), or more than 1 microcurie of iodine-125 or 100 microcuries of palladium-103 contamination from a leaking source, to an outside pathology laboratory, the licensee must ensure before shipment that the samples will be transferred to an NRC or Agreement State licensed laboratory authorized to receive the seeds or radioactive contaminated tissue (10 CFR 30.41). The applicant must also ensure that packages will be properly prepared in accordance with 10 CFR 71.5 or an equivalent Agreement State regulation for shipping.
Reporting

If a seed is lost, ruptured or if a patient doesn’t return in a reasonable time one may have to report to the NRC or agreement state.

Talk about Danbury Incident. Express to patient the importance of returning for seed explant.

www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html

For example, if a patient doesn’t return she can receive a dose of 70.2 cGy/MBq or 2.6 cGy/microCurie at 1 cm. Even a seed as small as 100 microCuries can result in 260 cGy from the time it is implanted to decay.
Radiation Safety Committee (RSC)

- If you have a RSC you will most likely need the committee approval in order to submit your amendment to the state.
- Discuss what will happen if a seed is lost. Talk about all the different fingers in the pie
Potential Hazards

- Radiation exposure from seeds

- Handling. Radiation dose to hands can be high if seeds aren’t handled safely. Safe at a distance.

- A broken seed can contaminate personnel, equipment, and the immediate area. I-125 can be taken up by thyroid tissue of the patient. Potassium Iodine (KI) (Lugal Solution) may have to be administered to the patient to act as a thyroid blocking agent.

- Lost seed(s) means a lockdown in the area until the seed(s) is found. Must check linen, containers, bottom of personnel shoe, etc. until seed is found. Lockdown means nothing enters or leaves the area until the seed is found.
The use of I-125 for RSL or breast seed localization is governed by what section of NRC or agreement state radioactive material license:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1. Manual Brachytherapy</td>
</tr>
<tr>
<td>20%</td>
<td>2. Other Medical Use</td>
</tr>
<tr>
<td>20%</td>
<td>3. Uptake, Dilution and Excretion</td>
</tr>
<tr>
<td>20%</td>
<td>4. Imaging and Localization</td>
</tr>
<tr>
<td>20%</td>
<td>5. Diagnostic or Radiotherapy</td>
</tr>
</tbody>
</table>
The use of I-125 for RSL or breast seed localization is governed by what section of NRC or agreement state radioactive material license:

- 2. Other Medical Use

The Authorized User of I-125 for RSL or breast seed localization can be a physician performing:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1. Uptake and dilution studies</td>
</tr>
<tr>
<td>20%</td>
<td>2. Imaging &amp; localization studies</td>
</tr>
<tr>
<td>20%</td>
<td>3. High dose brachytherapy via afterloader</td>
</tr>
<tr>
<td>20%</td>
<td>4. Manual brachytherapy</td>
</tr>
<tr>
<td>20%</td>
<td>5. Radioactive drugs for medical use</td>
</tr>
</tbody>
</table>
The Authorized User of I-125 for RSL or breast seed localization can be a physician performing:

- 4 Manual brachytherapy

If your facility is planning on transferring breast specimens containing I-125 radioactive seeds to an outside laboratory then you must follow proper DOT shipping procedures and ensure that the lab:

1. Disposes of the seed right after the seed is removed
2. Is Accredited
3. Has a NRC or Agreement State RAM License
4. Has enough personnel
5. Is located nearby
If your facility is planning on transferring breast specimens containing I-125 radioactive seeds to an outside laboratory then you must follow proper DOT shipping procedures and ensure that the lab:

3. Has a NRC or Agreement State RAM License

Emergency Kit

In all three locations (CBC, Surgery and Pathology) an emergency kit will be present in the room any time a seed is implanted or removed. The kit is there because if a seed is lost or damaged one can’t leave the immediate area. The emergency kit will contain:

1. Survey meter with thin window NaI probe.
2. A shielded container for the seed.
3. Reverse pressure forceps.
Emergency Kit – with Instructions
You may find that your surgery/OR doesn’t want to give up any of the gamma probes that are used for sentinel node procedures. This is a problem since Pathology/Histology will be the ones digging the seed(s) out of the specimen. We found a refurbished gamma probe unit that permanent resides in histology.
# Seed Tracking & Inventory

<table>
<thead>
<tr>
<th>Date Arrived</th>
<th>Number</th>
<th>Activity per seed</th>
<th>Total Activity</th>
<th>Initials</th>
<th>Date Received</th>
<th>Initials</th>
<th>Action</th>
<th>Seeds Received from</th>
<th># Seeds Received</th>
<th># Unused Seeds in CBC</th>
<th># Used Seeds DIS</th>
<th>Total Inventory</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/5/13</td>
<td>5</td>
<td>0.11</td>
<td>0.55</td>
<td>JW</td>
<td>11/5/13</td>
<td>SAS</td>
<td>Locked in cupboard</td>
<td>Rad/Onc</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>11/11/13</td>
<td>SAS</td>
<td>Locked in cupboard</td>
<td>Pathology</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>
## RADIOACTIVE SEED LOCALIZATION (RSL) 
### WRITTEN DIRECTIVE

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
<td>_________________________</td>
</tr>
<tr>
<td>Clinic ID:</td>
<td>_________________________</td>
</tr>
<tr>
<td>Diagnosis:</td>
<td>_________________________</td>
</tr>
<tr>
<td>Date Scheduled for Implant:</td>
<td>________________</td>
</tr>
<tr>
<td>Date Scheduled for Explant:</td>
<td>________________</td>
</tr>
</tbody>
</table>

### Center for Breast Care

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Implant:</td>
<td>________________</td>
</tr>
<tr>
<td>Radioisotope:</td>
<td>Iodine-125</td>
</tr>
<tr>
<td>Treatment site:</td>
<td>_________________________</td>
</tr>
<tr>
<td>Number of seeds implanted:</td>
<td>________________</td>
</tr>
<tr>
<td>Additional treatment site (if needed):</td>
<td>_________________________</td>
</tr>
<tr>
<td>Number of seeds implanted:</td>
<td>________________</td>
</tr>
<tr>
<td>Seed activity:</td>
<td>_________________________ milliCurie</td>
</tr>
<tr>
<td>Total source strength (total number of seeds x seed activity):</td>
<td>_________________________ milliCurie</td>
</tr>
</tbody>
</table>

**Authorized User’s signature:** _________________________ **Date:** ________________

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin site/s marked “SEED”:</td>
<td>Y  N</td>
</tr>
<tr>
<td>Seed armband placed on patient:</td>
<td>Y  N</td>
</tr>
<tr>
<td>Radiation survey of procedure room:</td>
<td>____________ mR/hr (must be &lt;0.04 mR/hr)</td>
</tr>
</tbody>
</table>
Seed Tracking & Inventory (cont.)

<table>
<thead>
<tr>
<th><strong>Surgery/OR</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of explant:</strong></td>
<td>___________________</td>
</tr>
<tr>
<td>Surgeon/Surgical Resident confirm “SEED” marking and wristband:</td>
<td>Y</td>
</tr>
<tr>
<td>Surgeon reviews Written Directive prior to explant:</td>
<td>Y</td>
</tr>
<tr>
<td>Number of Seeds removed:</td>
<td>_________</td>
</tr>
<tr>
<td>Number of seeds on specimen image matches number of seeds implanted:</td>
<td>Y</td>
</tr>
</tbody>
</table>

**Surgeon’s signature:** ____________________________ **Date:** ________________

Specimen delivered to Pathology/Lab by ______________________ (name) at __________ (time)
Specimen delivered to: ________________________________ (name)

**Pathology**
Specimens entered in log book by:__________________________ (name) on ___________ (date)
Date Seeds Removed from specimen: ____________
Name of Pathologist/Pathology Assistant removing seeds: ________________________________
Number of Seeds removed: _________
Number of Seeds removed matches number of seeds from radiologist/surgeon: | Y | N |
Seeds placed in vial and vial labeled with patient ID: | Y | N |
CBC notified by ______________________ (name) at _______________ (time) that seeds are ready for pickup
## Center for Breast Care

Seeds retrieved from Pathology by: ______________________(name) on __________(date)

Number of seeds retrieved: ________________  

Number of Seeds removed matches number of seeds from radiologist/surgeon  

Seeds logged into storage in CBC  

<table>
<thead>
<tr>
<th></th>
<th>Y</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>N</td>
<td></td>
</tr>
</tbody>
</table>

## Diagnostic Physics

Date of disposal: __________________

Disposed by: ______________________(name)

Disposal method: __________________

Number of seeds disposed: ________________  

Number of seeds disposed matches number of seeds from radiologist/surgeon  

Survey meter ID: ____________________ Background: __________________mR/hr  

Measured exposure rate: ________________mR/hr
The best equipment to assist in locating a lost I-125 seed is:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>1. Ionization Chamber</td>
</tr>
<tr>
<td>20%</td>
<td>2. GM survey meter with Beta probe</td>
</tr>
<tr>
<td>20%</td>
<td>3. GM survey meter with NaI probe</td>
</tr>
<tr>
<td>20%</td>
<td>4. Equipment used to test x-ray devices</td>
</tr>
<tr>
<td>20%</td>
<td>5. Photometer</td>
</tr>
</tbody>
</table>
The best equipment to assist in locating a lost I-125 seed is:

- 3 GM survey meter with NaI probe

Training Staff

- Breast Radiologists and Mammographers
- Breast Surgeons and OR Staff
- Pathology or Histology
ALARA and Radioactive Seeds

Use Distance! Step back when possible.

Although the exposure rate to personnel from unshielded radioactive seeds is very high at their surface, it drops to background level at 1 meter.

Once the seeds are implanted the exposure rate drops to background level at 18-24 inches (due to shielding from tissue).
ALARA and Radioactive Seeds

Use Shielding! Keep seeds in a shielded container except when being used. When seeds are in incised tissue then the tissue sample should be placed in a shielded container.

If you have to pick up a loose seed, use the reverse pressure forceps from the seed tray and put the seed in a shielded container.
Pre & Post-Procedure

All seeds must be accounted for in CBC when the seed(s) are implanted, when the incised tissue is removed in surgery and when the seeds are removed from the tissue in Lab.

In CBC, a mammogram will be done to ensure all seed implanted are physically located in the tissue.

In surgery a specimen radiograph will be made to verify the correct number of seeds are in the excised tissue and the remaining tissue will be surveyed to ensure no seed ruptured or was severed in two during the procedure. Depending on the view of the radiography it can be difficult to see a complete seed.
Pre & Post-Procedure (Cont.)

In the pathology lab, a physical count will be made and compared to the surgery/radiologists notes for the correct number of seeds.

At no time are scissors to be used to remove the seed from tissue. Scalpels and tweezers/reverse pressure forceps are the only items to be used.
Pre & Post-Procedure (Cont.)

In all three locations (CBC, Surgery and Pathology) when the # of seed(s) is/are verified one must still use the radiation survey meter in the area to verify that no seeds are present. Lab personnel will contact CBC personnel to pick up seeds.

To ensure that no seeds are lost, all waste material, waste containers, instrument trays, and linens must be surveyed with a radiation survey meter after the procedure and documented.
Source Security

- State law requires radioactive material to be under the licensee’s control at all times.

- All radioactive seeds must be with an authorized individual or in a locked location at all times.
Source Security - Sterilization

- Seeds are obtained in pre-loaded, sterilized needles.
Why does one have to use a radiation survey meter or gamma probe to ensure all seeds have been removed if the seed can be seen in a breast specimen radiograph:

<table>
<thead>
<tr>
<th>20%</th>
<th>1. The seed is not radiographic</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>2. The seed could have multiplied</td>
</tr>
<tr>
<td>20%</td>
<td>3. The seed could have become more radioactive</td>
</tr>
<tr>
<td>20%</td>
<td>4. The seed could have been transected</td>
</tr>
<tr>
<td>20%</td>
<td>5. The seed could have moved</td>
</tr>
</tbody>
</table>
Why does one have to use a radiation survey meter or gamma probe to ensure all seeds have been removed if the seed can be seen in a breast specimen radiograph:

- **4. The seed could have been transected**

- Radioactive Seed Localization with I-125 Non-Palpable Lesion Prior to Breast Lumpectomy and/or Excisional Biopsy: Methodology, Safety, and Experience of Initial Year, Dauer et al., Health Physics 105(4):356-365; 2013
Dosimetry Badges

- At this time we are not planning on monitoring radioactive seed implant staff at GL for occupational radiation dose. We may monitor pathology.
References


- www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html

- “Radioactive Seed Localization with I-125 Non-Palpable Lesion Prior to Breast Lumpectomy and/or Excisional Biopsy: Methodology, Safety, and Experience of Initial Year, Dauer et al., Health Physics 105(4):356-365; 2013
Acknowledgements

- Mary Ellen Jafari – Colleague for pictures and writing the RAM amendment
- Breast Radiologists at Gundersen Health System
Questions?