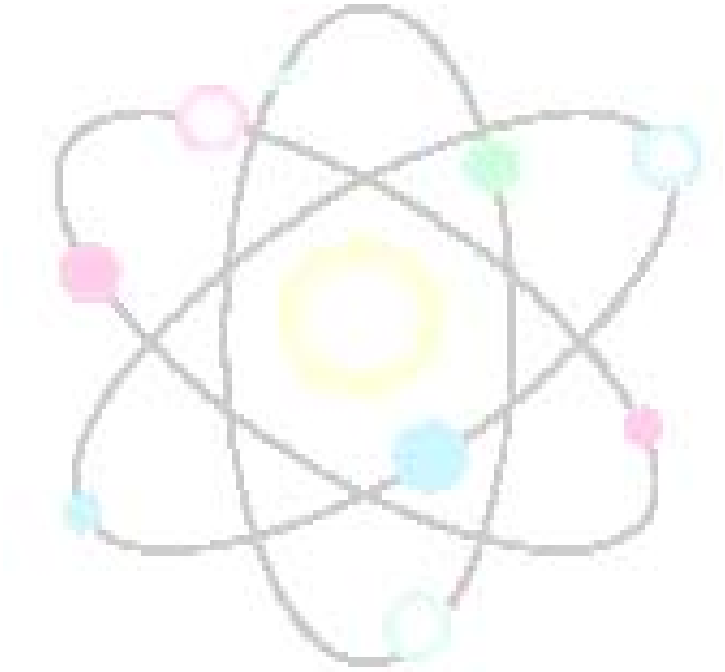
MINNESOTA DEPARTMENT OF HEALTH



LOW DOSE RATE BRACHYTHERAPY SEEDS FOR LOCALIZATION ON NON-PALPABLE LESIONS

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REGULATORY GUIDE FOR IODINE-125 AND PALLADIUM-103 LOW DOSE RATE BRACHYTHERAPY SEEDS FOR LOCALIZATION OF NON-PALPABLE LESIONS

Purpose

The purpose of radioactive seed localization of non-palpable lesions[1] is to localize suspicious tissues for excision with the use of radioactive seeds. Radioactive seed localization differs from current localization procedures, whereby a non-radioactive wire is implanted into the lesion site and excised along with the affected tissue. The radioactive seed localization technique offers advantages over the wire implantation technique for localizing lesions. For example, with the use of radioactive seed localization, the bracketing of lesions and the post-localization of mammograms is not impeded by wires, and radioactive seed localization can be performed up to five days before surgery, minimizing schedule conflicts.

Radioactive seed localization uses radioactive seeds previously approved for the treatment of cancerous tumors. For instance, typically, Iodine-125 and Palladium-103 seeds[2] between 200 – 300 µCi/seed are implanted into a breast lesion using a standard 18-gauge needle. These seeds are normally implanted within mammography or ultrasound suites and removed within surgical suites between 2 and 5 days post implantation. The radioactive seed(s) can be easily located with appropriate instrumentation (using a technique with which surgeons are familiar because of its similarity to sentinel lymph node biopsy and radio-guided parathyroidectomy) and surgically removed with minimal injury to non-affected tissue. The seed(s) may be removed from the tissue specimen in surgery, or the tissue specimen containing the seed(s) can be sent to pathology for removal of the seed and analysis of the tissue. The seed or seeds are then disposed of in accordance with 4731.4429.

Licensing Guidance

In the radioactive seed localization 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 4731.4450. The use of these seeds for radioactive seed localization procedures will be regulated under 4731.4404: "Other medical uses."

[1] An area of suspicious tissue detected by mammography that needs further evaluation.
[2] Multiple seeds may be used to define irregularly shaped lesions.

This guidance is intended to address situations where the physical locations of implant, excision, and recovery of these seed(s) are all authorized by the same radioactive materials license.

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 (4731.3105). The applicant must also ensure that packages will be properly prepared in accordance with 4731.0402.

This guidance represents an acceptable means of complying with regulations for radioactive seed localization and is not intended to be the only means of satisfying requirements for a license. Therefore, to meet the requirements of 4731.3070 and 4731.4403, the applicant must provide the information requested below or may submit alternative commitments for review by the MDH to determine whether they meet regulatory requirements. In addition, the commitments contained therein will be reviewed during routine inspections.

Applicants are reminded that licenses issued pursuant to 4731.4404 or the equivalent Agreement State regulation, must still meet the general requirements in 4731.4400 through 4731.4527. For example, 4731.4424 contains requirements for leak testing sealed sources, 4731.4427 contains provisions for release of patients containing implants, and 4731.4525 contains requirements for reporting medical events.

General

Radionuclides, Form, Possession Limits, and Purpose of Use:
Identify the radionuclides, chemical/physical form, maximum possession limit, and purpose of use that will be authorized on the radioactive materials license. For example, the following provides the format for an acceptable request:

> **Radionuclides, Form, Possession Limits (Items 6 through 8 on the license)**
> Item 6: Iodine-125 or Palladium-103
> Item 7: Sealed sources (manufacturer and model number)
> Item 8: 1.5 millicuries maximum per treatment and 15 millicuries total;
>
> **Purpose of Use**
> Item 9: For use as temporary implants to localize non-palpable lesions.

Facility Address and Description
Provide an address of use and submit a facility diagram and description of the location where the radioactive sources will be received, used, and stored.

If the tissues sent to pathology 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, the licensee should be aware that pathology is a location where radioactive sources will be received, used, and stored and therefore must be identified as a location of use in the application.

Authorized Users
Identify each authorized user performing seed implants and explants and provide documentation of their training and experience in the use of the Iodine-125 or Palladium-103 seeds for the radioactive seed localization procedure. MDH Form 313L, “Training and Experience and Preceptor Attestation for Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions,” or other formats may be used to document this training and experience. The authorized user should be considered qualified for

implementation, localization and removal of the seeds if the individual is listed on an MDH license (or an NRC or Agreement State license) and meets the criteria in 4731.4436 or 4731.4458, including supervised work experience under the supervision of a 4731.4458 authorized user and preceptor. Training and supervised work experience should include the following:

- Work experience which includes at least three cases, wherein the authorized user ordered, received, and unpacked radioactive materials safely;
- Work experience that includes performing the related radiation surveys using the appropriate instrumentation;
- Work experience that includes preparing, implanting, and removing radioactive seed localization sources safely, to include the use of remote handling tools to manipulate seeds and the proper use of shields;
- Work experience that includes routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source;
- Work experience that includes using emergency procedures, such as procedures regarding broken or leaking seeds;
- Work experience that includes reviewing and understanding the administrative controls in place to prevent a medical event; and
- Work experience in maintaining running inventories of radioactive material on hand.

Authorized users should ensure that personnel who locate, remove or handle specimens containing seeds are adequately supervised to protect health and safety. Radiation safety training should include:

General surgeons, working under the supervision of an authorized user described above, who locate and remove the tissue containing the seed(s) complete radiation safety training that includes:

- Performing the related radiation surveys using appropriate instrumentation;
- Preparing, implanting, and safety removing brachytherapy sources;
- Performing routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source; and
- Emergency procedures, including how to respond to a leaking source.

This training should be provided by the authorized user described above or the Radiation Safety Officer, as applicable.

Pathology personnel handling specimens containing radioactive material should be instructed in the radiation safety aspects of safely handling the seeds. Radiation safety training should include:

- Minimizing time handling the specimen;
- Using an appropriate survey instrument to perform surveys of hands and work areas following handling of the specimen;
- Routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source.
- Emergency procedures to be followed in the event contamination is identified;
- Accountability, security or the seeds post-implantation; and
- Proper disposal of the seeds and/or specimens containing the seed(s).

Written Directives

The sources used for this procedure are brachytherapy sources that can deliver a therapeutic dose; therefore, a written directive is required. The written directive must meet the requirements in 4731.4408, Subpart 1 and Subpart 2.F. The exposure from a 300 µCi source is as follows:

Distance	Exposure	
	10 Seconds	One Minute
1 cm	135 mrem	810 mrem
15 cm	0.6 mrem	3.6 mrem
30 cm	0.15 mrem	0.9 mrem

Safety Precautions and Instructions for Seed Localization
Provide the following written procedures that describe your radiation safety program for all departments involved in the radioactive seed localization procedure, including the surgery and the pathology laboratory:

- Written procedures for routine monitoring before, during, and after all uses of the seeds to ensure rapid identification and remediation of a broken or leaking source; and
- Written emergency procedures for responding to an abnormal situation to include:
    - instructions for responding to a source rupture (e.g. cut by a scalpel) during surgical removal to include procedures for retrieval of leaking/cut sources, contamination control, decontamination of the patient and area from a ruptured source and saturation of the patient's thyroid with stable iodine in the case of an I-125 source rupture;
    - instructions to pathology personnel for responding to a leaking/cut source and decontamination of personnel and area;
    - the process for restricting access to and posting of the implantation/explantation/pathology area in the event of an unaccounted for or ruptured source to minimize the risk of inadvertent exposure from seeds;
    - patient follow-up if they do not return for seed removal (including a commitment to make multiple attempts at contacting the patient and to perform a dose assessment); and
    - names and telephone numbers of the authorized users and the Radiation Safety Officer to be contacted.

Licensees must commit to the following actions for all departments involved in the radioactive seed localization procedure, including the surgery and the pathology laboratory:

- Emergency response equipment will be available near each surgery suite and pathology laboratory during specimen handling;
- The activity of sealed sources will be verified prior to each patient implant using an instrument calibrated in accordance with nationally recognized standards or the manufacturer's instructions and retain a record that includes:
    - the radioisotope;
    - the patient's name or identification number;
    - the measured activity; and
    - the name of the individual who measured the activity;
- Procedures will be conducted under the supervision of the authorized user, who should consult with the surgeon prior to implanting the sources;
- Surveys will be performed and records will be maintained as described in 4731.4451 or equivalent Agreement State requirements;
- All sources will be accounted for and all records maintain as described in 4731.4452 or equivalent Agreement State requirements;
- Procedures will be developed, implemented, and maintained for source accountability from implantation to explantation and final disposal;

- Written waste disposal procedures will be developed, implemented, and maintained for licensed material in accordance with 4731.2010, that meet the requirements of the applicable section of 4731.2400 to 4731.2460 and 4731.4429;
- Patients will be instructed in writing before implantation and agree in writing to return for removal of the radioactive seeds;
- Training will be provided at least annually and covering the topics described in 4731.4453 and records described in 4731.4453 will be maintained; and
- All personnel involved with the radioactive seed localization procedure, including the Radiation Safety Officer, will be trained on routine monitoring and emergency procedures.

Survey Instrumentation
Licensees must have adequate equipment and provide information on equipment calibration. The licensee should possess and use a properly calibrated radiation survey instrument. The survey instrument should be a portable survey instrument which is equipped with a thin crystal sodium iodide (NaI) probe when performing surveys for radioactive seed localization procedures involving Iodine-125 and Palladium-103. A NaI probe is the most appropriate instrumentation because they are both very low energy gamma emitters and thus are very difficult to detect using a conventional survey instrument. Applicants must submit a description of the survey instrumentation and calibration for the instruments they will use.

Emergency Response Equipment
Licensees must submit information showing it has equipment adequate to protect public health and safety and minimize danger. In order to demonstrate this, licensees should submit a description of the equipment to be used in the case of an emergency such as loss or rupture of a seed. This equipment should include gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument, and caution radioactive materials labels.

Procedures
The following rules summarize the requirements for iodine and palladium seeds that are temporarily implanted that should be used to develop, implement, and maintain the appropriate procedures:

4731.4408	WRITTEN DIRECTIVES
4731.4409	PROCEDURES FOR ADMINISTRATIONS REQUIRING WRITTEN DIRECTIVES
4731.4424	POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES; REQUIREMENTS
4731.4427	RELEASE OF INDIVIDUALS CONTAINING UNSEALED RADIOACTIVE MATERIAL OR IMPLANTS
4731.4441	SAFETY INSTRUCTION
4731.4451	SURVEYS AFTER SOURCE IMPLANT AND REMOVAL
4731.4452	BRACHYTHERAPY SOURCE ACCOUNTABILITY
4731.4453	BRACHYTHERAPY; SAFETY INSTRUCTIONS
4731.4455	BRACHYTHERAPY; CALIBRATION MEASUREMENTS

Records
Because the iodine and palladium seeds are temporarily implanted, the applicant should maintain records for seed localization in accordance with the requirements for temporary implants to include the following:

4731.4500	RADIATION PROTECTION PROGRAM RECORDS
4731.4501	WRITTEN DIRECTIVE RECORDS
4731.4502	INSTRUMENT CALIBRATION RECORDS
4731.4504	LEAK TEST AND INVENTORY RECORDS

4731.4506	RELEASE RECORDS; INDIVIDUALS CONTAINING UNSEALED RADIOACTIVE MATERIAL OR IMPLANTS
4731.4510	SAFETY INSTRUCTION RECORDS
4731.4511	SURVEY RECORDS; SOURCE IMPLANT AND REMOVAL
4731.4512	BRACHYTHERAPY SOURCE ACCOUNTABILITY RECORDS
4731.4513	BRACHYTHERAPY SOURCE CALIBRATION RECORDS

Reports

The licensee must report any medical event, except for those that result from patient intervention, to include:

4731.4525	MEDICAL EVENT; REPORT AND NOTIFICATION
4731.4526	DOSE TO AN EMBRYO/FETUS OR CHILD; REPORT AND NOTIFICATION
4731.4527	REPORT OF A LEAKING SOURCE.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION
03/10/2010	Authorized Users	Changed text to reference the Training and Experience and Preceptor Form and appended Preceptor Form (313L).
7/19/10	313L Form	Correct Rule reference on page 1

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AUTHORIZED USER
TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION FOR
LOW DOSE RATE BRACHYTHERAPY SEEDS FOR LOCALIZATION OF NON-PALPABLE LESIONS

Name of Proposed Authorized User	State or Territory Where Licensed

PART I – TRAINING AND EXPERIENCE

(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within seven years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed.

☐ **1. Not currently an Authorized User for 4731.4432 and 4731.4434:**

a. Attach a completed MDH Form 313D (or equivalent).

b. Indicate the training provider and dates of training for Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions in the following Table.

c. Complete Part II Preceptor Attestation

☐ **2. Currently an Authorized User for 4731.4432 and 4731.4434:**

a. Provide a copy of the Radioactive Materials License or Permit that authorizes that use.

b. Indicate the training provider and dates of training for Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions in the following Table.

c. Complete Part II Preceptor Attestation

Description of Training	Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions	
	Training Provider	Dates
Safety procedures		
Clinical use of the seeds		
Supervising Individual If training provided by supervising individual. *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*		License or Permit Number (that lists the supervising individual as an Authorized User of Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions or Manual Brachytherapy)

AUTHORIZED USER
TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION *(continued)*

☐ I meet the NRC or Agreement State requirements as an Authorized User for Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions.

☐ I meet the NRC or Agreement State requirements as an Authorized User for Manual Brachytherapy.

PART II - PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies the training and experience required. If more than one supervising individual is necessary to document supervised work experience, provide a separate preceptor statement from each.

☐ I attest that _____ has received the training required for safety procedures and clinical use for Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions.

AND

☐ I attest that _____ has achieved a level of competency sufficient
Name of Proposed Authorized User

to function independently as an Authorized User for Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions.

Complete the following for preceptor attestation and signature:

☐ I meet the NRC or Agreement State requirements as an Authorized User for Low Dose Rate Brachytherapy Seeds for Localization of Non-Palpable Lesions.

☐ I meet the NRC or Agreement State requirements as an Authorized User for Manual Brachytherapy.

Name of Preceptor:	Signature:	Date:

Telephone Number:	License or Permit Number:	Facility Name:
	☐ NRC ☐ Agreement State *(Specify):*	

MDH Form 313L