



October 29, 2015

Vered Shaffer, Ph.D.
Materials Licensing Branch
US Nuclear Regulatory Agency – Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Doctor Shaffer,

Materials License 21-08317-01

Here is the additional information you requested in an e-mail dated October 16, 2015.

1. **Add** material and use 35.1000 to Authorized Users:
 - a. Robert M. Prust, M.D.
 - b. David K. Heimburger, M.D.
 - c. Doug Brown, M.D.

Regarding RSL:

Authorization 6: Iodine-125

Authorization 7: Sealed sources (IsoAid, LLC Model IAI125A (Advantage I-125)

Authorization 8: 1.5 millicuries maximum per treatment and 15 millicuries total

Authorization 9: For use as temporary implants to localize non-palpable lesions.

Authorized Users: We have three individuals authorized to use these sources under 35.400. One or more of them will preceptor the new 35.1000 AUs.

The licensee commits to the following:

- Surveys will be performed and records will be maintained as described in 10 CFR 35.404 or equivalent Agreement State requirements;
- All sources will be accounted for and all records maintain as described in 10 CFR 35.406 or equivalent Agreement State requirements;

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Please see EMERGENCY PROCEDURE FOR A LEAKING OR BROKEN I-125 SEED for more information.

Thank you.

Sincerely,

Dennis J. Aurand

Dennis Aurand, MS, DABR[®]

Diagnostic Medical Physicist

Radiation Safety Officer

daurand@mhc.net

phone: 231.392.8612

fax: 231.935.3204

EMERGENCY PROCEDURE FOR A LEAKING OR BROKEN I-125 SEED

1. After seed implantation, perform a radiation exposure survey of the placement needle and patient to confirm transfer.
2. After explantation, perform a radiation exposure survey of the patient.
3. If the survey identifies radiation exposure (above background), assume the radioactive seed was damaged.
 - a. Confirm location of seed fragment(s) visually, by gamma probe, or radiograph.
 - b. Remove seed fragment(s) from the patient and/or tissue.
 - c. Place seed fragment(s) in an appropriate shielded container for transfer to the Hot Lab.
 - d. Perform a radiation exposure survey of the area.
 - e. Isolate contaminated areas.
 - f. All personnel will remain in the room until monitored for radioactive contamination.
 - g. Contact a Nuclear Medicine Technologist to assist in the decontamination process.
 - h. Follow the procedure for Decontamination of a Radioactive Spill to identify areas of contamination and perform decontamination.
 - i. Restrict room access until Nuclear Medicine personnel, under the direction of the RSO, have released the room.
 - j. Transport tissue to laboratory and inform pathology personnel of contamination status.
4. Because of the low dose of the source, patient decontamination after seed removal may not be necessary. If deemed appropriate, the authorized user may prescribe the patient stable iodine to block the I-125 from entering the thyroid. Consult the FDA guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" for guidance and dosage information.
5. Pathology laboratory personnel are equipped to handle radioactive samples.
 - a. For leaking or broken seeds discovered in the lab, follow above procedure starting at 3.a.

Key Contacts:

Nuclear Medicine -57229

Radiation Safety Officer - Dennis Aurand, 28612

Authorized User - Dr. Heimbürger, 57100

Shaffer, Vered

From: Aurand, Dennis <daurand@mhc.net>
Sent: Thursday, October 29, 2015 12:58 PM
To: Shaffer, Vered
Subject: [External_Sender] RE: Amendment to NRC License for Munson Medical Center
Attachments: NRC amendment add 1000 additional information needed October 29 2015.pdf

Please see attached.

Dennis Aurand, MS, DABR®
RSO, Diagnostic Medical Physicist
Munson Medical Center
Traverse City, MI
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From: Shaffer, Vered [mailto:Vered.Shaffer@nrc.gov]
Sent: Friday, October 16, 2015 4:07 PM
To: Aurand, Dennis
Subject: Amendment to NRC License for Munson Medical Center

Hi Dennis,

Thanks for speaking with me regarding your amendment request for Munson Medical Center, License 21-08317-01. In order for me to continue with my review for the amendment request, I am going to need the following additional information:

- 1). Please provide the name(s) of the 35.400 authorized user(s) on your license that you would like to add the 35.1000 authorization limited to iodine-125 seeds for localization of non-palpable lesions.
- 2). Please provide the maximum amount of activity that will be possessed for these treatments (ex. 1.5 millicuries maximum per treatment and 15 millicuries total).
- 3). Please state the following two commitments in your cover letter:
 - Surveys will be performed and records will be maintained as described in 10 CFR 35.404 or equivalent Agreement State requirements;
 - All sources will be accounted for and all records maintain as described in 10 CFR 35.406 or equivalent Agreement State requirements;
- 4). Please provide the written procedures for the following:

Provide the following written procedures that describe your radiation safety program for all departments involved in the RSL 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: (i) 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; (ii) instructions to pathology personnel for responding to a leaking/cut source and decontamination of personnel and area; (iii) 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; (iv) patient follow-up should they not return for explantation, including a commitment to make multiple attempts at contacting the patient and to perform a dose assessment; and (v) names and telephone numbers of the authorized users and the Radiation Safety Officer to be contacted;

Please provide me this additional information in a signed and dated cover letter by November 6th. If you have any questions please don't hesitate to get in touch with me.

Thanks!
Vered

Vered Anzenberg Shaffer, Ph.D.
Health Physicist

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