



Oakwood®

November 24, 2014

U.S. Nuclear Regulatory Commission, Region III
Attn: Materials Licensing Section
2443 Warrenville Rd.
LISLE, IL 60532-4352

RE: Amendment Request
NRC License #21-04515-01

This is a request to please amend license #21-04515-01 to authorize Dr. **Jessica Kaniowski, MD** for the use of I-125 sealed source(s) for temporary implants to localize non-palpable breast lesions under 10 CFR 35.1000.

Dr. Reed is already an authorized user under 10 CFR 35.100 and 35.200. Under the NRC guidelines for this procedure (use of I-125 temporary implants for localization of non-palpable lesions) user's supervised work experience should include at least 3 cases for this procedure. So far Dr. Reed has performed 3 cases under the supervision of Dr. Choon K. Lee (please see the attached attestation).

Since there is no specific Form 313A for this use I drafted a free format form to supply the necessary information.

If you have any questions, please contact **Taljit Sandhu, Ph.D.** at (313)-593-7564 or sandhut@Oakwood.org. We appreciate your prompt attention to this matter.

Sincerely,

Taljit S. Sandhu, Ph.D.
Brachytherapy RSO
Radiation Oncology Department
Oakwood Hospital and Medical Center
18101 Oakwood Blvd.
Dearborn, MI 48123

PRECEPTOR ATTESTATION

For 10 CFR 35.1000: Iodine -125 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions.

Under the guidelines published on November 10, 2010 by the Nuclear Regulatory Commission (NRC) the Radioactive Seed Localization (RSL) is covered under 10 CFR 35.1000.


There is no specific format for NRC form 313A for this procedure. The following information is submitted in lieu of Form 313A.

As an Authorized User (35.400 and 35.1000 for temporary iodine-125 implants) I attest that **Jessica Kaniowski, MD** _____ has performed 3 cases for Radioactive Seed Localization (RSL) under my supervision with following supervised work experience:

- Ordered, received and unpacked radioactive materials safely.
- Performed radiation surveys as needed using proper instrumentation.
- Implantation and removal of RSL sources safely, including the use of handling tools to manipulate seeds and the proper use of shields.
- Routine monitoring before, during, and after all uses of the seeds.
- Is aware of all the emergency procedures regarding broken or leaking seeds.
- Review and understanding of all the administrative controls in place to prevent a medical event.
- Maintaining running inventories of radioactive material on hand.

This individual is already on our NRC License as an Authorized user for 10 CFR 35.100 and 35.200 and is therefore well experienced in radiation safety. And now has achieved a level of competency sufficient to function independently as an authorized user for RSL procedure covered under 10 CFR 35.1000.

Name: Nitin Vaishampayam, MD (Authorized User 35.400 , 35.600 and 35.1000)

Signature: 

Telephone Number: 313-593-7336

Date: 11/24/14

License # **21-04515-01**

Facility: Oakwood Hospital and Medical Center
18100 Oakwood Blvd.
Dearborn, MI 48123



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TALJIT SANDHU, Ph.D

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forever

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