



Oakwood®

July 5, 2011

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. Sophia Roumanis, M.D. for the use of I-125 sealed source(s) for temporary implants to localize non-palpable breast lesions under 10 CFR 35.1000.

Dr. Roumanis is already an authorized user under 10 CFR 35.100, 35.200 and 35.300. 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 she has performed 4 cases under the supervision of Drs Chang and Vaishampayan (please see the attached attestations).

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

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## PRECEPTOR ATTESTATION

**For 10 CFR 35.1000:** Iodine -125 and Palladium -103 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.

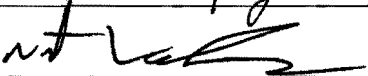
There is no specific format for NRC form 313A for this procedure. The following information is submitted in lieu of Form 313A.

I attest that SOPHIA ROUMANIS M.D. has performed 2 cases for Radioactive Seed Localization (RSL) under my supervision as an authorized user and performed the following:

- Ordered, received and unpacked radioactive materials safely.
- Performed radiation surveys as needed.
- Implanted the radioactive seed(s) safely.
- Is aware of all the emergency procedures regarding broken or leaking seeds.
- Aware of all the procedures and understands 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, 35.200 and 35.300 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 Vaishampayan, M.D.

Signature: 

Telephone Number: 313-593-7336

Date: 7/9/12

License # 21-04515-01

Facility: Oakwood Hospital and Medical Center  
18101 Oakwood Blvd.  
Dearborn, MI 48123-2500

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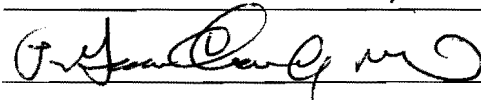
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- Performed radiation surveys as needed.
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Name: JUNG H. CHANG, M.D.

Signature: 

Telephone Number: 313-593-7336

Date: 1/5/2012

License # 21-04515-01

Facility: Oakwood Hospital and Medical Center  
18101 Oakwood Blvd.  
Dearborn, MI 48123-2500



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TALJIT SANDHU, Ph.D.

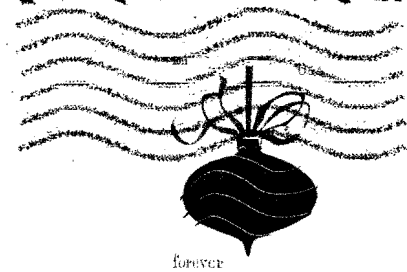
Oakwood Hospital  
& Medical Center

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