Tomczak, Tammy

From: Tran, Frank
Sent: Wednesday, June 18, 2014 3:06 PM
To: Tomczak, Tammy
Cc: Pelke, Patricia
Subject: FW: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Hi Tammy,

We combined a request (ML14136A461) from 21-03210-01 to CN 583824 assigned to me. However, during the review the licensee could not timely provide additional information that I requested with regard to the CN583824.
In the other hand, they may be able to provide sufficient information to complete the request in ML14136A461. The licensee requested to expedite the request in ML14136A461. Could you please create a new license amendment for the request in ML14136A461 and ask Patty to assign it to me. I will pick it up tomorrow, if possible.

Thank you,

Frank

From: Laura T. Smith- Physics [mailto:lsphysics@att.net]
Sent: Monday, June 09, 2014 7:50 AM
To: Tran, Frank
Subject: Re: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Thanks, because they are in a HUGE hurry. I hope to acquire that shielding, etc information ASAP to speed things up.
=)

Laura Smith
pager 313 609-2038
I prefer email communications

From: "Tran, Frank" <Frank.Tran@nrc.gov>
To: Laura T. Smith- Physics <lsphysics@att.net>
Sent: Monday, June 9, 2014 8:35 AM
Subject: RE: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Yes, we could process them separately.

From: Laura T. Smith- Physics [mailto:lsphysics@att.net]
Sent: Monday, June 09, 2014 7:32 AM
To: Tran, Frank
Subject: Re: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Ok, thanks. But I need the star batt drive approval first, so can you process them separately?

Laura Smith
pager 313 609-2038
I prefer email communications

From: "Tran, Frank" <Frank.Tran@nrc.gov>
To: Laura T. Smith- Physics <lsphysics@att.net>
Cc: "Simmons, Toye" <Toye.Simmons@nrc.gov>
Sent: Monday, June 9, 2014 8:20 AM
Subject: RE: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Dear Ms. Smith:

We did not request information regarding the use of sealed source low dose rate brachytherapy seeds for localization of non-palpable lesions for the facility located at 1901 Star Batt Drive, Rochester, Michigan, nor mentioned this facility in Item 3. The information requested in Item 3 is in response to your request dated April 25, 2014 to use sealed source low dose rate brachytherapy seeds for localization of non-palpable lesions at 22101 and 22151 Moross Road, Detroit, Michigan, and 19229 Mack Avenue, Grosse Pointe Woods, Michigan.

Sincerely,

Frank Tran

From: Laura T. Smith- Physics [mailto:lsphysics@att.net]
Sent: Monday, June 09, 2014 6:59 AM
To: Tran, Frank
Cc: Simmons, Toye
Subject: Re: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Ok, I will acquire all of item #2.
I am not sure I understand at all what #3 has to do with that location, we will NOT be performing any sealed source low dose rate brachytherapy seeds for localization of non-palpable lesions

At this location at all - could you just put in a statement we are not authorized for that use at that specific location?

Laura Smith
pager 313 609-2038
I prefer email communications

From: "Tran, Frank" <Frank.Tran@nrc.gov>
To: "Laura T. Smith- Physics (lsphysics@att.net)" <lsphysics@att.net>
Cc: "Simmons, Toye" <Toye.Simmons@nrc.gov>
Sent: Monday, June 9, 2014 7:34 AM
Subject: Re: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Dear Ms. Smith:

The documentation related to the HDR were submitted and tied down in the license no. 21-13562-01 issued to Crittenton Hospital Medical Center. We cannot remove these documents from its license and place under your license. To add this

location to your license, you should provide sufficient information regarding the location so that this location can stand alone in your license and not to link to license no. 21-13562-01.

Please provide a response for Items 2 and 3 of our request.

Thank you,

Frank Tran

From: Laura T. Smith- Physics [mailto:lsphysics@att.net]
Sent: Friday, June 06, 2014 11:36 AM
To: Tran, Frank
Subject: Re: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Mr. Tran,
I have no idea other than I have been very sick lately how I made that mistake on the letter. It is 1901 Star Batt Drive, Rochester, Michigan
and I have fixed that in the attachment to reflect the correct address.

Why do I have to show calculations for the HDR unit that already exists for years now? It is only a transfer.

The I-125 seed program is a separate amendment, and I need that approved separately, as it is not an expedited request, as this part is - since that program is not even started, and this request not being completed is holding patients.

Laura Smith
pager 313 609-2038
I prefer email communications

From: "Tran, Frank" <Frank.Tran@nrc.gov>
To: Laura T. Smith- Physics <lsphysics@att.net>
Cc: "Simmons, Toye" <Toye.Simmons@nrc.gov>
Sent: Thursday, June 5, 2014 3:32 PM
Subject: Request for additional information for St. John Hospital & Medical Center (NRC License No. 21-03210-01)

Dear Ms. Smith:

We have reviewed your license amendment requests received May 5, 2014 and May 16, 2014. In order to continue our review please provide a response to the followings:

1) You request to add a location located at 1101 W. University Drive, Rochester, Michigan to your license; however, the HDR's facility is located at 1901 Star Batt Drive, Rochester, Michigan. Please explain.

2) If you would like to add the HDR's facility located at 1901 Star Batt Drive, Rochester, Michigan, to your license, please provide the followings::

a) a readable facility diagram with scale or dimensions

b) a copy of shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations (distances from the exposed source to a target in the adjacent areas (above, below, and surrounding areas) occupational factors, etc.), including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe).

c) a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for the HDR's room;
- Area radiation monitoring equipment;
- Viewing and intercom systems;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and
- Emergency response equipment.

3) You requests an authorization of sealed source low dose rate brachytherapy seeds for localization of non-palpable lesions. In accordance with the Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions licensing guidance, please provide the following commitments:

a) Written waste disposal procedures will be developed, implemented, and maintained for licensed material in accordance with 10 CFR 20.1101, or the equivalent Agreement State regulation, that meet the requirements of the applicable section of Subpart K to 10 CFR 20 and 10 CFR 35.92, or the equivalent Agreement State regulations;

b) Patients will be instructed in writing before implantation and agree in writing to return for removal of the radioactive seeds;

c) Training will be provided at least annually and covering the topics described in 10 CFR 35.410 and records described in 10 CFR 35.410 or equivalent Agreement State requirements will be maintained;

d) All personnel involved with the Radioactive Seed Localization (RSL) procedure, including the Radiation Safety Officer, will be trained on routine monitoring and emergency procedures.

e) We will meet the requirements for temporary implants and develop, implement, and maintain the appropriate procedures in the following regulations: 10 CFR 35.40(a),(b)(6), (c), and (d), 35.41, 35.67, 35.75, 35.310, 35.404, 35.406, 35.410, 35.432, or the equivalent Agreement State regulations.

f) We will m 10 CFR 35.2075 Records of the release of individuals containing unsealed byproduct materials or implants containing byproduct material;

g) We will maintain records for seed localization in accordance with the requirements for temporary implants to include the following 10 CFR 35.2310,"Records of safety instruction"; 10 CFR 35.2404, "Records of surveys after source implant and removal"; 10 CFR 35.2406, "Records of brachytherapy source accountability"; and 10 CFR 35.2432, "Records of calibration measurements of brachytherapy sources."

h) Based on the sealed source models you provided, iodine I-125 is authorized for these models based on the Sealed Sources and Devices Registry registries; however, you requests for Palladium Pd-103 to use in these models. Please explain.

Please provide a response in writing with an authorized signature by July 3, 2014 (in response to CN 583824). If you have any questions regarding the request above, please contact me at 630-829-9623 or reply to this email.

Sincerely,

Frank Tran

From: Laura T. Smith- Physics [mailto:lsphysics@att.net]
Sent: Tuesday, June 03, 2014 3:05 PM
To: Tran, Frank
Subject: Hello

Hello Mr. Tran,

We have purchased a location – 1101 W. University drive, Rochester, Michigan from Crittenton Hospital #21-13562-01, they have put in a license request to delete this location from their license, and we wish to add this location to our license 21-03210-01.

I am checking because I would like to expedite if it is not done or very close (this week done), we cannot perform any patient treatments until this is approved, and their patient list is growing.

Thank you for your help with this.

Laura Smith
pager 313 609-2038
I prefer email communications

ST JOHN PROVIDENCE HEALTH SYSTEM
ST. JOHN HOSPITAL & MEDICAL CENTER

22101 Moross Road
Detroit, MI 48236-2172

April 25, 2014

United States Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road, Ste 210
Lisle, IL 60532-4352

RE: Control Number 582388 NRC #21-03210-01

This is additional information for the continued review of our Breast seed implant program request. If you need any further clarification I am difficult to track down sometimes, so it is best to email directly at lsphysics@att.net (home) and laura.smith7@stjohn.org (work).

- As noted under your last request The possession limit under subitem #8C is now addressed within this request. Specifically we request to change our current "As needed (not to exceed 2 curies of Iodine-131) to:
  - 2.5 Curies total for all therapy doses, with the specific of 2 Curies of Iodine-131.
- Please add the 10 CFR 35.1000 approval category to our RAM license 21-03210-01.
- The Radiation Safety Committee will use the licensing guidance for I-125 seeds for the localization of non-palpable lesions, a use permitted by 10 CFR 35.1000, when evaluating proposed authorized users for this modality.
- The manufacturers name and model number for the sealed sources for this 35.1000 program is Vendor/Model: IAI-125A Model number for the Isoaid Advantage I-125 seed. BEST Iodine Seed, Model #2301
- **Radionuclides, Form, Possession Limits:** Authorization: 6: Idoine-125 or Palladium-103 Authorization 7: Sealed sources Authorization 8: 1.5 millicuries maximum per treatment and 20 millicuries total (for this specific Breast treatment); our maximum for the facility remains at 300millicuries.
  Purpose of Use: Authorization 9: For use as temporary implants to localize non-palpable lesions.
  Facility Address and Description: The same as noted on our current license, we will use the material at: 22101 and 22151 Moross Road, Detroit, Mi as well as at our facility at Van Elslander Cancer Center, 19229 Mack Ave, Grosse Pointe Woods, MI. To be clear all for these facilities are all located on the same hospital campus, and are already approved RAM use locations.
- **Authorized Users:** At our facility we approved our own Authorized Users. The Radiation Safety Committee will use the licensing guidance for I-125 seeds for the localization of non-palpable lesions, a use permitted by 10 CFR 35.1000, when evaluating proposed authorized users for this modality. Including Identify each authorized user performing seed implants and explants and provide documention of their training and experience in the use of the Iodine-125 or palladium-103 seeds for the RSL procedure. NRC Form 313A, "Medical Use Training and Experience and Preceptor Attestation," 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 a license (NRC or Agreement State) and meets the criteria in:

10 CFR 35.490 or the equivalent Agreement State regulations; or
10 CFR 35.290 , including supervised work experience under the supervision of a 10 CFR 35.490 authorized user and preceptor. Training and supervised work experience should include the following:

- Work experience which includes at least 3 cases, wherein the authorized user ordered, received, and unpacked radioactive material safely;
- Work experience that includes performing the related radiation surveys using the appropriate instrumentation;
- Work experience that includes preparing, implanting, and removing RSL 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.

- General surgeons, working under the supervision of an authorized user described above, who locate and remove the tissue containing the seed(s) should complete radiation safety training that includes: General surgeons, working under the supervision of an authorized user described above, who locate and remove the tissue containing the seed(s) should 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 will be provided by the authorized user described above or the Radiation Safety Officer, as applicable prior to starting the first procedure.

- 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).

This training will be provided by the authorized user described above or the Radiation Safety Officer, as applicable prior to starting the first procedure.

Written Directives:

The written directive will meet the requirements in 10 CFR 35.40 (a) and (b)(6) where the licensee may specify exposure time for the temporary implant.

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We will provide the following written procedures that describe our radiation safety program for all departments involved in the Radioactive seed localization (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; and

We commit to the following actions for all departments involved in the RSL 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: (i) the radioisotope; (ii) the patient's name or identification number; (iii) the measured activity; and (iv) 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 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;
- 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 10 CFR 20.1101, or the equivalent Agreement State

Survey Instrumentation

We have adequate equipment and will calibrate our equipment as required at an approved calibration service, most probably Radiological Physics Service, Plymouth, MI. We possess and know how to use a properly calibrated radiation survey instrument. The survey instrument is a portable survey instrument which is equipped with a thin crystal sodium iodide (NaI) probe when performing surveys for RSL 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

We have equipment adequate to protect public health and safety and minimize danger. Our equipment includes gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument, and caution radioactive materials (CRAM) labels.

We will not transfer the radioactive tissue sample to an outside laboratory, we are using our own on site internal laboratory.

Procedures

We will be the requirements for temporary implants and develop, implement and maintain the appropriate procedures in the following regulations: 10 CFR 35.40(a),(b)(6), (c), and (d), 35.41, 35.67, 35.75, 35.310, 35.404, 35.406, 35.410, 35.432, or the equivalent Agreement State regulations.

Records

We confirm we will maintain records for seed localization in accordance with the requirements for temporary implants to include the following, or the equivalent Agreement State regulations:

10 CFR 35.2024	Records of authority and responsibilities for radiation protection programs;
10 CFR 35.2026	Records of radiation protection program changes;
10 CFR 35.2041	Records for procedures for administrations requiring a written directive;
10 CFR 35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials;
10 CFR 35.2067	Records of leak tests and inventory of sealed sources and brachytherapy sources;

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facsimile transmittal

To:	NRC	**Fax:**	1 630 515 1078
From:	Laura T. Smith	**DATE:**	January 13, 2014
Re:	License Amendments	**Pages:**	7 including this cover
CC:			

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Please email me to confirm you have received this request, at lsphysics@att.net

Laura Smith, MS, DABR