



CONVERSATION RECORD

DATE OF SIGNATURE

06/23/2015

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

Laura T. Smith, M.S., Radiation Safety Officer

DATE OF CONTACT

06/23/2015

TYPE OF CONVERSATION



E-MAIL



TELEPHONE



INCOMING



OUTGOING

E-MAIL ADDRESS

laura.smith2@stjohn.org; lsphysics@att.net

TELEPHONE NUMBER

(586) 808-3058

ORGANIZATION

St. John Hospital and Medical Center; Attn: Nuclear Medicine
22101 Moross Rd., Detroit, MI 48236

DOCKET NUMBER(S)

030-02028

LICENSE NUMBER(S)

21-03210-01

CONTROL NUMBER(S)

586816 re Amendment Request Letter dated 04/05/2015;
received via fax at NRC RIII on 05/14/2015

SUBJECT

We have reviewed the request to add an I-125 seeds for non-palpable lesion localization authorization; see below for additional information needed to complete our review. Please submit requested information on or before close of business on July 10, 2015.

SUMMARY AND ACTION REQUIRED:

Submitted information includes substantive deviations from NRC guidance for requests to use I-125 seeds for palpable lesion localization, which may be found at the website, <http://www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html>.

Please submit a letter enclosing additional items, confirming statements provided in the guidance document, and as noted below. The letter should be dated and signed by you, as the Radiation Safety Officer, or other duly authorized management official. Additional information may be submitted as a pdf file attached to an email message to me at sara.forster@nrc.gov, or via facsimile to (630) 515-1078. Please reference the Control No. 586816, as listed at the top of this memo when addressing the items below:

1. Submit a facility diagram for each area of use where I-125 seeds for localization of palpable breast lesions will be received, used, and stored. Include room numbers, security, storage, refrigerators, freezers, hoods, and radioactive materials work areas in your diagrams. The diagrams also must show the dimensions, street address, and room number(s) for each area of use. Diagrams for each area where seeds will be received, implanted, collected via biopsy, and sent to pathology, and stored as decay-in-storage, at a minimum, must be included with the request. Previously submitted diagrams are unclear as to areas of use for the new modality.
2. Confirm that general surgeons who locate and remove the tissue containing the seed(s) will do so only:
 - (i) while working under the supervision of an Authorized User (AU) approved by the licensee's Radiation Safety Committee (RSC) for the use of I-125 seeds for palpable lesion localization and
 - (ii) after completing radiation safety training - provided by the licensee's RSO or an authorized AU - that includes:
 - Performing the related radiation surveys using appropriate instrumentation;
 - Preparing, implanting, and safely 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.

NAME OF PERSON DOCUMENTING CONVERSATION

Sara A. Forster, M.S., Health Physicist, Materials Licensing, U.S. NRC RIII Office, 2443 Warrenville Rd., Ste. 210, Lisle, IL 60532

SIGNATURE

6/23/2015

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CONVERSATION RECORD (continued)

L. Smith

CN 586816

SUMMARY AND ACTION REQUIRED (Continued):

3. Confirm that Pathology personnel, as applicable, will have received instruction and radiation safety training in the radiation safety aspects of safely handling the seeds, prior to handling specimens containing radioactive material, including the following topics:

- 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 of the seeds post-implantation; and
- Proper disposal of the seeds and/or specimens containing the seed(s).

4. Provide copies of procedures that describe your radiation safety program for all departments involved in the Radioactive Seed Localization (RSL) procedure, including the surgery and the pathology laboratory, including those specified below:

- 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.

5. To supplement the procedures section included with the request, please confirm the statements below, concerning all departments involved in the RSL procedure, including surgery and the pathology lab:

- Emergency response equipment will be available near each surgery suite and pathology laboratory during specimen handling;
- Procedures will be conducted under the supervision of the authorized user, who should consult with the surgeon prior to implanting the sources;
- Procedures will be developed, implemented, and maintained for source accountability from implantation to explantation and final disposal;
- All personnel involved with the RSL procedure, including the Radiation Safety Officer, will be trained on routine monitoring and emergency procedures.

Forster, Sara

From: Forster, Sara
Sent: Tuesday, June 23, 2015 1:05 PM
To: Smith, Laura T. Smith (Laura.Smith2@stjohn.org); lsphysics@att.net
Subject: Additional Information Request for St. John Hospital and Medical Center amendment, NRC Lic. No. 21-03210-01
Attachments: 02240.586816.21-03210-01 telecon signed.pdf

Dear Ms. Smith:

See the attached file for additional information needed to complete the review of the recent amendment request for NRC Lic. No. 21-03210-01. Note that the attached phone conversation record requests additional information on or before close of business on July 10, 2015. Additional guidance may be found in NUREG 1556, Vol. 9, Rev. 2, "Program Program-Specific Guidance About Medical Use Licenses;" or at NRC's licensing guidance webpage for palpable lesion localization authorizations, which may be found, respectively, at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>; or
<http://www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html>.

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have. Please also send a quick email when you receive this message, to confirm receipt.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer
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