From: Gallaghar, Robert
To: Peter Mas (pmas@snet.net)
Subject: Request for Additional Information - Mail Control No. 592212
Date: Wednesday, December 07, 2016 11:02:00 AM
Attachments: image001.png

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

License No. 06-00253-04
Docket No. 03001239
Control No. 592212

Dear Mr. Mas,

This is in reference to your letter dated October 13, 2016 requesting an amendment to License No. 06-00253-04 to add authorization to perform radioactive seed localization (RSL) and to add an authorized user for 10 CFR 35.100, 35.200, and 35.1000 for RSL. In order for us to continue our review additional information is necessary.

1. Please submit a facility diagram and description of the location(s) where the radioactive sources will be received, used, and stored. If tissues containing the RSL seeds are sent to pathology following surgery, both pathology and the surgical suite must be identified as locations of use.

2. Please submit a copy of the certification from the American Board of Radiology for Diana Jones, M.D., Ph.D. and a copy of a license or permit (NRC or Agreement State) Dr. Jones is listed on. Conversely you may provide documentation that Dr. Jones has completed 80 hours of training and experience, including a minimum of 40 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of sealed sources. The training and experience must include, at a minimum:

   (i) Classroom and laboratory training in the following areas-
   - (A) Radiation physics and instrumentation;
   - (B) Radiation protection;
   - (C) Units of radioactivity and exposure;
   - (D) Radiation biology; and

   (ii) Work experience, under the supervision of an RSL preceptor AU, which includes participation in at least three cases including:
   - (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation protection surveys;
   - (B) Characteristics, preparation, safe handling, precautions, and labeling of radioactive seeds and needles containing radioactive seeds. Proper methods for storage, inventory and disposal of sealed sources including decay in storage program;
   - (C) Using administrative controls to prevent a medical event;
   - (D) Instruction on procedures to safely mitigate contamination from a leaking, damaged or ruptured sealed source;
   - (E) Performing routing monitoring after all uses of the seeds to account for all seeds specified in the prescription and to ensure rapid identification and remediation of a damaged, ruptured, lost/missing or leaking source; and remediation of a damaged, ruptured, lost/missing or leaking source;
   - (F) Proper use and maintenance of appropriate instrumentation (i.e., intraoperative gamma probe) to identify the location of an implanted seed(s) for excision; and
   - (G) Training provided by either an RSL preceptor AU or a 10 CFR 35.290 preceptor AU experience with sentinel node biopsy using photon emitting radiopharmaceuticals (e.g. technecium-99m) to include performing the related radiation surveys using the appropriate instrumentation (i.e., intraoperative gamma probe) to identify the location

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of an implanted seed(s) for excision; and

Provide written attestation, signed by an RSL preceptor authorized user (AU) that Dr. Jones has satisfactorily completed the requirements in this section and is able to independently fulfill the radiation safety-related duties as an AU for RSL use.

3. Please confirm that any authorized user currently approved for any byproduct material permitted by 10 CFR 35.400 will have received and documented training in the use of instrumentation (i.e., intraoperative gamma probe) employed to identify the location of implanted seed(s) for excision. Such training should be provided by either an RSL preceptor AU or a 10 CFR 35.290 preceptor AU experienced with sentinel node biopsy using photon emitting radiopharmaceuticals (e.g. technicium-99m).

4. Please submit documentation of training of Peter Mas, Radiation Safety Officer, in the radiation safety. Regulatory issues, and emergency procedures for RSL procedures. This training requirement may be satisfied by completing training that is supervised by an individual (RSO or AU) that is authorized for RSL procedures.

5. RSL procedures involve an interdisciplinary team. Therefore, such team members must have the appropriate radiation safety training as described in "Low Activity Radioactive Seeds Used for Localization of Non-Palpable Lesions and Lymph Nodes Licensing Guidance, October 7, 2016, Revision 1" (hereafter called The Guidance). Please confirm that all radiologists, surgeons, and pathology personnel meet the training requirements contained in Section 5 of The Guidance. The Guidance may be found at http://www.nrc.gov/docs/ML1619/ML16197A568.pdf.

6. Section C. under "General Information," in Item 2 describes use of a written directive for RSL procedures at Hartford Hospital. The Guidance states that a written directive is not required. Please confirm that you will develop procedures to assess the radiation dose to tissues for seeds remaining in place for an extended period of time as described in Section 6 of The Guidance.

7. Section A.2., entitled "Instructions for Seed Localization," describes the requirements for authorized users to be authorized for RSL at Hartford Hospital. Please confirm that only individuals who meet the requirements of Section 5 of the Guidance, and who have been approved by the NRC as being authorized for iodine-125 and/or palladium-103 for use as temporary implants to localize non-palpable lesions will perform RSL at Hartford Hospital.

8. Please confirm that you will follow the medical event reporting described in Section 7, "Medical Event Reporting [10 CFR 35.3045]" of The Guidance.

9. Please submit the information required by 10 CFR 35.12(d). The guidance contained in Section 8, "Specific Information on Radiation Safety Precautions and Instructions for Radioactive Seed Localization [10CFR 35.12(d)(1)(i)]" of The Guidance may be helpful in preparing your response.

10. Please confirm that all staff involved in the seed localization program will receive training in response to an abnormal situation along with the annual radiation safety instruction and annual refresher training discussed in Section D. "Safety Precautions."

11. Please confirm that all seed localization procedures will be conducted under the supervision of the AU, who should consult with the surgeon prior to implanting the source(s).

12. Please confirm that surveys will be performed and records will be maintained as described in 10 CFR 35.404.

13. Please confirm that procedures will be developed, implemented, and maintained for source accountability from source acquisition, implantation, explantation and final disposal.

14. Please confirm that the names and telephone numbers of the authorized users and the Radiation

Safety Officer to be contacted in the event an abnormal situation occurs are added to the written emergency procedures.

15. Please confirm that you will notify the NRC in the future that you have permitted an AU to work at your facility without need to request an additional license amendment provided the following conditions are met:

    i. The AU satisfies the training and experience criteria listed in NRC's licensing guidance for the RSL program; and
    ii. The AU is currently listed for an RSL program use on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee; and;
    iii. The Hartford Hospital provides to the NRC a copy of the license or permit on which the AU is listed for the RSL program; and
    iv. The Hartford Hospital provides documentation to the NRC for each AU of the above listed conditions no later than 30 days after the date that the Hartford Hospital allows the AU to work as an AU for the RSL program.

We will continue our review upon receipt of the requested information. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment request. Please contact Robert Gallaghar at (610) 337-5182 if you have any questions.

Regards,

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