From: Lanzisera, Penny
To: peter.mas@hhchealth.org
Cc: Seeley, Shawn
Subject: Hartford Hospital Renewal and RSL Addition
Date: Thursday, June 04, 2015 5:28:00 PM

Licensee: Hartford Hospital
License No. 06-00253-04
Docket No. 03001239
Mail Control No. 585984

Dear Mr. Mas:

This is in reference to the application dated January 28, 2015, requesting to renew Nuclear Regulatory Commission License No. 06-00253-04 and your letter dated February 23, 2015, requesting to perform radioactive seed localization under your license. In order to continue our review, we need the following additional information:

1. Please confirm the authorized use for the strontium-90 sealed sources and provide the name of an authorized user who will this use.

2. Please confirm the authorized use for the yttrium-90 microspheres. In addition, please submit your microsphere program in accordance with the revised guidance dated June 2012 found on our website at http://pbadupws.nrc.gov/docs/ML1217/ML12179A353.pdf.

3. Please confirm you wish to remove the following authorized users:

   M. Reza Monsoor, M.D.; Edward B. Cronin, M.D.; John Opalacz, M.D.; Judith Buckley, M.D.; John J. Coen, M.D.; and Jinnah Phillips, M.D.

4. Please confirm you wish to remove the following authorized medical physicists:

   Alicia Harris, M.S., and Kevin J. Dwyer, M.S.

5. Please confirm the middle initials for Monica C. Rossi, M.S, and Robert F. Hoffman, M.S. Please confirm if you wish the notation of Ph.D. for Dr. Farquhar in addition to M.D.

6. Please confirm that spot checks will be performed after each source installation.

7. Please describe the methods utilized to ensure the console keys will be inaccessible to unauthorized persons whenever the device is not in use or unattended.

8. Please confirm the acceptance criteria utilized when determining the following HDR checks: timer accuracy (i.e., 1 sec), decayed source activity (i.e., 1%), and the date/time of the unit's computer (i.e,. 1 hour).

9. Please confirm that you reserve the right to upgrade your survey instruments as necessary, as long as they are adequate to measure the type and level of radiation

for which they are used.

10. Please confirm where the HDR unit will be used. If the unit is used in a location with another radiation producing device, please describe your procedures to ensure that only one unit can be operated at a time.

11. Please confirm that you do NOT perform source installations or maintenance on the HDR unit.

12. Please submit updated diagrams of your facilities to include:

a. All storage and use areas including a description of areas above, below, and adjacent;
b. Description of shielding for the HDR treatment room, the HDR storage room, the PET facility, therapy patient rooms, waste storage areas, and the brachytherapy source storage area; and
c. Location of the fume hood for any volatile materials that are used.

13. For your HDR treatment room, please describe:

a. Warning systems and restricted area controls (locks, signs, warning lights & alarms, interlock systems);
b. Area radiation monitoring equipment and its location within the treatment room;
c. Audio visual equipment and its location within the treatment room;
d. Emergency response equipment and its location within the treatment room; and
e. Shielding calculations to show how public dose limits in 10 CFR 20.1301 are met.

14. Please confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving the HDR unit.

15. For PET areas, please describe any additional safety equipment utilized.

16. Please confirm that for alpha doses, the dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric and mathematical calculation. Alternatively, you may provide a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures.

17. Please confirm whether you would like to continue the use limitations for those facilities as indicated in license condition 10.B. through 10.G. on license number 06-00253-04, amendment No. 115 (e.g. diagnostic use only at outpatient clinics). In addition, please confirm that the location at Memorial Drive is still in Building C.

18. You are currently licensed for use of nuclear medicine at six facilities with only two dose calibrators listed. Please clarify.

19. Please note that HDR full calibration procedures are not required to be submitted to allow flexibility and were not reviewed.

20. In accordance with the guidance for radioactive seed localization found at http://www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html please submit the following:

a. Identify the radionuclides, chemical/physical form, maximum possession limit, and purpose of use. For example, the following provides the format for an acceptable request:

Authorization 6: Iodine-125 or Palladium-103
Authorization 7: Sealed sources (manufacturer and model number). List all manufacturers and model numbers requested.
Authorization 8: 1.5 millicuries maximum per treatment and 15 millicuries total;
Authorization 9: For use as temporary implants to localize non-palpable lesions.

b. Submit a facility diagram and description of the locations where the radioactive sources will be received, used, and stored, including areas in nuclear medicine, radiation oncology, and surgery. Since the tissues that are sent to pathology will still contain the seed(s), then pathology is a location where radioactive sources will be received, used, and stored and therefore must be identified as a location of use in the application. In addition, please indicated where retrieved sources will be held for decay-in-storage.

c. The authorized user shall be consider qualified for this use if the individual is **currently listed on a license** for 10 CFR 35.490 or 10 CFR 35.290, and for 35.290 physicians, have completed and submitted to the NRC for approval additional training and supervised work experience as follows:

- 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.

It appears that Drs. James, Sheikh, and Sobolewski are not currently listed on

a license for 10 CFR 35.290 and have not documented completion of all components of work experience. Therefore, these physicians cannot be added to your license for this use at this time. Other authorized users on your license may be listed for this use immediately if desired. For instance, any physician currently authorized on your license for 35.400 may be immediately listed on your license for this use. Please advise. In addition, please note that this use does not fall under either 35.400 or 35.200 and each authorized user approved for this use will include "radioactive seed localization" in their authorization.

d. 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 should be provided by the authorized user described above or the Radiation Safety Officer, as applicable. Please describe training provided to general surgeons.

e. 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).

Please describe training provided to pathology personnel.

f. Please confirm that exposure time is documented in the written directive in accordance with 10 CFR 35.40 (e.g., 5 days for a 0.3 millicurie iodine-125 seed) and that for cases exceeding 20% of this time, the case will be evaluated in accordance with the medical event reporting requirements in 10 CFR 35.3045 and reported, as indicated. In addition, please confirm that the exposure to patients not returning for seed removal will be reported to the NRC as a medical event in accordance with 10 CFR 35.3045, as required.

g. Confirm that written emergency instructions provided to all departments involved in the program, including surgery and pathology, will 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; and (ii) 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.

h. Confirm the following actions for all departments involved in the 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 and a record will be retained 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;
- If the source activity reported by the manufacturer will be used, confirmation that the manufacturer measures each source using an instrument calibrated in accordance with nationally recognized standards will be done;
- 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 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;
- Patients will be instructed in writing before implantation and agree in writing to return for removal of the radioactive seeds; and
- 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.

i. You indicated that you will use a thin window GM or a low energy gamma probe for surveys conducted during the implant, during explant, and during pathology. A NaI probe is the most appropriate instrumentation because of the low energy gamma emitter that is difficult to detect using a conventional survey instrument. Please confirm the type of instrument used and provide your rationale if not using a NaI probe.

j. Please confirm that you will 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, and 35.432.

k. Please confirm that you will maintain the following records for seed localization:

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;
10 CFR 35.2075 Records of the release of individuals containing unsealed byproduct materials or implants containing byproduct material;
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;
10 CFR 35.2432 Records of calibration measurements of brachytherapy sources.

l. Please confirm that you will report any medical event, except for those that result from patient intervention, in accordance with 10 CFR 35, Subpart M, or the equivalent Agreement State regulation, to include:

10 CFR 35.3045 Report and notification of a medical event;
10 CFR 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child;
10 CFR 35.3067 Report of a leaking source.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

We will continue our review upon receipt of this information. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5102. You may scan and e-mail your reply to shawn.seeley@nrc.gov or fax your response to 610-337-5269. Please reference Mail Control No. 585984 in your response.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

As a reminder, please have a member of management approve and sign any submittal to this office.

Please send a return e-mail to confirm that you received this message.

Thank you for your assistance.

Shawn Seeley, Health Physicist
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