From: Elliott, Robin
To: msellards@st-marys.org
Cc: Norweck, Jim; Lanzisera, Penny
Subject: Renewal of License No. 47-09576-01
Date: Thursday, April 25, 2013 8:52:00 AM

License No. 47-09576-01
Docket No. 030-03388
Control No. 579896

Dear Mr. Sellards:

Please acknowledge receipt of this email. This is in reference to your application dated January 23, 2013 requesting to renew Nuclear Regulatory Commission License No. 47-09576-01. In order to continue our review, we need the following additional information:

1. Please confirm that Drs. McWhorter and Cansino should be removed as Authorized Users and Mr. Allan should be removed as an Authorized Medical Physicist.

2. Please submit facility diagrams for inpatient I-131 therapy rooms and manual brachytherapy rooms. Include location, room numbers, and principle use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms. Indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003. Follow the guidance in Section 5.2 of NUREG 1556 Vol. 9 Rev 2 to determine if the response includes security–related sensitive information and needs to be marked accordingly.

3. You have stated that if I-131 liquid is used, it will be used, stored, handled, and administered under the fume hood located in the Nuclear Medicine Department, whenever possible. Please explain how your current procedures will assure that the fume hood is operational at the time the I-131 is used and how you will verify compliance with the dose limits of 10 CFR 20.1301.

4. In Item 2 of the "HDR Program: Primary Continuous Viewing and Communication System" description on Page 18, you state, "Further treatments will be suspended if both viewing systems or the audio communication system fails." Please confirm that it should read "either" the viewing or audio communication system fails.

5. In the "HDR Program: Emergency Equipment" section on Page 19, please confirm that the emergency equipment must always be kept with the HDR unit when it is being used for a treatment.

6. You have provided your HDR Daily QA on Page 41. Please provide the following information regarding these checks:
    a. Who will perform the checks?
    b. Confirm that if the spot-check results indicate the malfunction of any system, you will

lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. Please confirm that the category of "indicator lamps and other status/operational displays" includes: timer accuracy, clock (date and time) in the unit's computer, and decayed source activity in the unit's computer.
d. Please confirm that your "source status indicators" includes those on the remote afterloader unit, on control console and in the facility.
e. Verify that your safety check includes the presence of the emergency equipment referred to in Item 5 above.
f. The procedure on Page 22 and on Page 41 references that treatments can be performed with the authorized user and the medical physicist (or the Radiation Safety Officer) physically present. 10 CFR 35.615(f)(2) does not allow for the Radiation Safety Officer to serve in this capacity. Please confirm that you will have an authorized user and the authorized medical physicist physically present as described in 10 CFR 35.615 (f) (2).
g. For all periodic spot-checks defined in 10 CFR 35.643, provide step-by-step procedures for performing the checks and the associated acceptance criteria.

7. Please note that you were not required to submit your full calibration procedures and these procedures were not reviewed in detail. However, the following items were noted and should be corrected:
   a. Timer accuracy and linearity must be performed over the typical range of use.
   b. Length of applicators must be measured.

8. In reference to your SIR-spheres Program, please provide the following:
   a. Confirm that the treatment site will be specified in the pre-implantation written directive.
   b. Confirm that your training program will include those individuals who will be responsible for disposal of the SIR-spheres and the training will include a review of IN 2007-10 which can be found at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2007/in200710.pdf
   c. Confirm that if the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the AU will document such changes in the written directive within 24 hours after the completion or termination or the administration. The modification to the written directive must include the reason for not administering the intended dose/activity, the date, and the signature of an AU for Y-90 microspheres.

9. Please confirm the model number for the Sr-90 ophthalmic applicator in storage and describe your plans and timeline for disposal.

10. Please confirm that you do not order, receive, or store PET radiopharmaceuticals. Describe your current arrangement for mobile PET services and include whether any St. Mary's facilities or personnel are utilized.

11. For the Radioactive Waste Decay-In-Storage Room, Page 11, please confirm the following:
    a. The door to outer area is key locked.
    b. The door to the waste storage room within the outer area is also key locked with a different key that is controlled by authorized Nuclear Medicine personnel.
    c. The walls and door are not shielded other than the heavy gauge steel door and concrete cinder block construction.
    d. The area above is the radiology department corridor/patient holding with at least 4" of concrete in the floor and ceiling.
12. Describe any additional shielding for the brachytherapy storage room in Oncology. Page 13. For instance, are lead bricks used for additional shielding or are the walls/ceiling 12" concrete blocks?
13. You have requested that James Norweck be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:

    a. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

    b. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

    c. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

    d. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

14. Confirm that all conduits in the HDR treatment room were installed at an angle.

15. Please provide any program changes based on your plan to upgrade to the Nucletron Digital HDR afterloader. With regards to the new model, confirm that the unit will not be used in pulsed mode. Alternatively, you may submit procedures for how personnel and public exposures will be controlled when used in this mode.

16. Please indicate what instrumentation you have to survey for seeds following I-125 seed implants, such as NaI scintillation detectors.

17. In order to facilitate future communications, please provide your business facsimile number.

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office by signed letter or fax and refer to Mail Control No. 579896. Security-related sensitive information in your application or any subsequent responses must be marked as specified in Regulatory Issue Summary 2005-31, available at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf If you have any questions regarding the above items, please contact me at (610) 337-5076.

If we do not receive a reply from you within 30 calendar days from the date of this email, we will assume that you do not wish to pursue your application.

Regards,

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