From: Lanzisera, Penny
To: Peggy Pust
Subject: Request for Additional Information for Amendment Request
Date: Thursday, June 29, 2017 5:13:00 PM

Licensee: Monongalia General Hospital
License No. 47-16259-01
Docket No. 030-10683
Mail Control No. 599829

Good afternoon Ms. Pust, I am providing the request to your attention as I do not have the email address for Mr. Murray. Please forward this request to Mr. Murray for his review.

Please provide the additional information to support the addition of a therapy device to your license:

1. In your letter date May 18, 2017 you requested the addition of Dr. Paul Saconn for uses described in 10 CFR 35.400.
    a. To support this request, please provide a copy of the license/permit listing the preceptor, Dr. McMullen, for this use and any other uses preceptoring.
    b. It appears that you may also be requesting to add Dr. Saconn for uses described in 10 CFR 35.394. If so, please provide documentation of a third, recent case, using greater than 33 mCi of I-131 under an authorized user's supervision and a copy of the license/permit listing the supervisor for this use. In addition, please provide a copy of the license/permit listing the preceptor, Dr. Mintz, for this use.
    c. It appears that you may also be requesting the use of the HDR device by Dr. Saconn. If so, please provide documentation of the vendor training received by Dr. Saconn and indicate the type of unit used. If the type of unit is different from your requested unit, provide documentation of the vendor training provided to Dr. Saconn for your proposed unit.
    d. Please provide a revised preceptor attestation for Dr. Saconn that indicates the he "has achieved a level of competency sufficient to function independently as an authorized user for a remote afterloader unit."

2. Provide documentation of the vendor training provided to Mr. Murray, Ms. Pervola, and Mr. Perna. In addition, please describe the refresher training provided to Dr. Hunjan on the use of the unit.

3. Provide the serial number of the unit to be provided.

4. Describe the types of "other disease" to be treated with the unit. Please note that the sealed source and device registry and the FDA's 510k approval describes the types of uses authorized.

5. 10 CFR 35.12(b)(2) requires that licensees submit procedures required by 10 CFR 35.610 and 35.643. Please provide the step-by-step spot-check procedures and acceptance criteria for the items listed in 10 CFR 35.643 (e.g., electrical interlocks) for your remote afterloader. Additionally, please provide your emergency procedures. Finally, please confirm that if spot-checks indicate the malfunction of

any system, that the control console will be locked in the off position pursuant to 10 CFR 35.643(e).

6. Please identify the activities conducted in all contiguous areas surrounding the area of use. Location, room numbers, and principle use of each adjacent room should be provided, including areas above, beside, and below, and an indication of whether the room is a restricted area as defined in 10 CFR 20.1003.

7. Provide the type, thickness, and density of the shielded door. In addition, confirm that all walls, the ceiling, and the floor include at least 42 inches of concrete as noted in the shielding plan.

8. Describe the method for securing the unit when in the treatment room and any other storage area (e.g., locks on the doors).

9. 10 CFR 35.610 requires, in part, that all device operators, authorized medical physicists, authorized users, and the Radiation Safety Officer participate in drills of the emergency procedures, initially and at least annually. Please confirm that emergency drills will be done as part of the initial and annual training and specify who will participate in them.

10. Item F in the Attachment indicates that 2 Ludlum 14C and 1 Fluke 451P will be possessed. However, Item J indicates that a Ludlum 3 with a 44-38 probe will be possessed. Please clarify and indicate who will calibrate the instrument(s).

11. Confirm that training records of initial and refresher training will include the date of the instruction.

12. Please indicate if extremity dosimeters will provided to all staff tasked with responding to an emergency involving the unit.

You may fax the above information to my attention to 610-337-5269 or send a pdf letter signed by management via email. Please reference Mail Control No. 599829 in your response. If we do not receive a response within 30 days, we will consider that you no longer require the addition and void your request. Please contact me via email with any questions. Sincerely,

Penny Lanzisera
Senior Health Physicist
U.S. NRC, Region I