From: Tran, Frank
To: Jim Mikowski
Subject: Request additional information for NRC License No. 13-09649-02
Date: Friday, July 16, 2021 8:49:00 PM

Dear Mr. Mikowski:

This refers to the renewal license application for Terre Haute Regional Hospital, NRC License No. 13-09649-02. We reviewed the application in accordance with NUREG-1556, Volume 9, Revision 3 and Volume 20, Revision 1 and will need the following.

1. The current license (Amendment No. 72) listed two authorized users: David E. Dascal, M.D. for 35.100, 200, 300 (limited to the oral administration of sodium iodide I-131) and Christopher M. Granville, M.D. for 35.100 and 200. However, the application did not provide information about them. If the licensee would like their authorization continue to be listed on the license, please state.

2. In Item 7.4 of the application, the licensee states that the Authorized Medical Physicist (AMP) will be Edward E. Johnston, lll. Based on the scope of the license (licensed material are not authorized under 35.433 or 35.600 or 35.1000 (sealed sources for medical use)), the NRC policy is not to list AMPs in the license. Therefore, we will not list Mr. Johnston as an AMP on this license.

3. Please confirm if the licensee will use PET radionuclides or not. If PET radionuclides will be used, provide a description of the areas (indicate the areas and surroundings with dimensions/scale including the areas above and below and shielding evaluations) where PET radionuclides will be used as discussed in Section 8.9.1, “Facility Diagram” in NUREG-1556, Vol. 9.

4. Please indicate the facility areas where 10 CFR 35.300 and 35.400 licensed material will be used. If those material will be used for in-patients, provide the diagram for in-patient rooms with dimensions/scale and surrounding areas (including the areas above and below) and the shielding calculations as discussed in Section 8.9.1, “Facility Diagram” in NUREG-1556, Vol. 9.

5. In accordance with 10 CFR 35.2 and Item 8.7.2, “Authorized Users” (AU), in NUREG-1556, Vol. 9, please provide the medical license number and issuing entity (e.g., State or territory) for each AU and confirm if it is active.

6. If the proposed RSO, Mr. Edward Johnston, is an outside consultant or contractor, provide additional information as discussed on page 8-25 in Section 8.7.1, “Radiation Safety Officer (RSO) and Associate Radiation Safety Officer (ARSO)”. If not, please state.

7. Section 10.12, "Area Surveys" of the application did not provide information related to the radiation monitoring for the areas where 10 CFR 35.300 and 35.400 material will be administered. Please provide a description for radiation monitoring (surveys) at

those areas.

8. Based on Section 8.9.1, “Facility Diagram” in NUREG-1556, Vol. 9, provide a description of the emergency response equipment for the areas where 10 CFR 35.400 licensed material for manual brachytherapy will be administered.

9. For alpha emitter drugs permitted by 10 CFR 35.300, does the licensee use unit dose or will the dose be calibrated in-house? If the dose will be calibrated in-house, please identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer’s instructions to calibrate the instrument, for measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator.

10. Item 8 in page 16 of 106 pages has several typos in the commitment 5, please resubmit the statement as “We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.”

To continue review of your application, we request that you submit the response with date and authorized signature to this correspondence within 30 calendar days. In your response, please refer the license number, docket number and Mail Control No. 626966.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC’s “Rules of Practice,” a copy of this correspondence will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Best regards,

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