From: Frank Tran
To: David.Cragg@beaumont.edu
Subject: Request additional information for NRC Materials License No. 21-26392-01
Date: Tuesday, September 27, 2022 11:37:00 AM

Dear Dr. Cragg:

This refers to the license renewal application for Beaumont Michigan Heart Group, NRC Materials License No. 21-26392-01. We reviewed the application in accordance with the NRC regulations and licensing guidance; specifically, NUREG-1556, Volume 9, Revision 3 and Volume 20, Revision 1. Based on the review, we will need the following information.

1. Regarding training for individuals working in or frequenting the restricted areas, provide the following statement: “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.”

2. Provide the facility dimensions or scale for the facility diagram(s). In addition, please indicate the direction of north in the diagram(s).

3. Please indicate if Positron Emission Tomography (PET) isotopes will be used at your facilities. If PET isotopes permitted by 10 CFR 35.200 will be used, please provide the radiation shielding evaluation for the facility (including information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used; the calculations should include the workload assumptions used).

4. With regard to the calibration of radiation monitoring instruments, it is not clear if the “qualified persons” will be authorized to calibrate the instruments under a current license issued by the NRC or an Agreement State. Therefore, based on the licensing guidance in NUREG-1556, Volume 9, Revision 3, provide the following statement: “Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations.”

5. It is not clear in the application if the licensee will keep the radiation dose assessment record or not. Therefore, based on the licensing guidance in NUREG-1556, Volume 9, Revision 3, provide the following statement: “ We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502.”

6. The NRC requires the licensee to be accountable for its licensed material and to provide security for licensed material. Based on the licensing guidance in NUREG-1556, Volume 9, Revision 3, please provide the following statement: “We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: license possession limits are not exceeded;

licensed material in storage is secured from unauthorized access or removal; licensed material not in storage is maintained under constant surveillance and control; and records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

7. If testing of leakage for sealed sources will be performed by an external vendor, provide the following statement: "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit." Alternatively, you could provide a response as discussed in Section 8.10.11, "Leak Tests", in NUREG-1556, Volume 9, Revision 3.

8. Regarding the contamination survey for areas of use, provide the following statement: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

9. The section related to the safe use of unsealed licensed material cited an incorrect regulation. Provide the following statement: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

To continue the review of your application, we request that you submit your response under a dated and signed cover by October 25, 2022. In the cover letter, please reference Mail Control No. 632328. We will assume that you do not wish to further pursue this licensing action if we do not receive a reply within the specified timeframe noted above.

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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References:

NRC Regulations: https://www.nrc.gov/reading-rm/doc-collections/cfr/index.html
NUREG-1556 Series: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html
NUREG-1757: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/index.html