From: Tran, Frank
To: aborrok@radiopharmacy.com
Subject: Request for additional information for NRC License Nos. 24-32762-01MD and 24-32762-02
Date: Friday, December 03, 2021 5:14:00 PM

Dear Mr. Borrok:

We have reviewed the license renewal applications for NRC License Nos. 24-32762-01MD and 24-32762-02 for Essential Isotopes in accordance with the licensing guidance in NUREG-1556, Volume 13, Revision 2 and Volume 21, Revision 1. Electronic copies of those guidance can be downloaded from the NRC's website at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/index.html. We will need the following.

1. A description of radiation shielding for the cyclotron vault, the hot cell, the mini cells, and the delivery lines (such as shielding material including surrounding, above and below and thickness, any portable shielding, shielding for waste storage) and the maximum dose rate outside those areas.

2. In the first diagram "Facility Floor Diagram", it appears there is three mini cells. However, there is only two mini cells in the subsequent diagrams. Please provide an explanation for the discrepancy.

3. In Item 10, "Radiation Program – Surveys and Leak Tests", Essential Isotopes commits to survey its facility in accordance with Appendix J of NUREG-1556, Volume 21. Based on Appendix J, please provide a confirmation that the effluent monitoring system has been designed and will be operated in accordance with ANSI N13.1 (2011), "Sampling And Monitoring Releases Of Airborne Radioactive Substances From The Stacks And Ducts Of Nuclear Facilities," and ANSI N42.18 (2004), "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactivity in Effluents."

4. The standard operating procedure (SOP), Radiation Protection Training (RC-3), section "Re-training and Schedules" states that re-training may be provided by the RSO or CRSO or RCD staff. Please describe what the RCD stands for and who are the RCD staff and their qualification to be the instructor in radiation safety. Additionally, section "New Employees" states that the training program will include instructions on the PETNET SOPs. Please help us understand why not Essential Isotopes SOPs, but PETNET SOPs.

5. Regarding the radiation training program, please provide the method the licensee will use to assess the training (e.g., passing the written exam with 80% correct).

6. Please note that, the facility for this license and your other license (24-32762-01MD) is the same; therefore, we will continue to list the sealed sources for calibration/reference in the other license only.

To continue review of your application, we request that you submit the response under a dated and signed cover letter by January 3, 2022. In the cover letter, please refer the license numbers, docket numbers and Mail Control Nos. 628306 and 628308. 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 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.

Sincerely,

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