



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

August 11, 2022

Daniel Altman, M.D.
Radiation Safety Officer
Clark Memorial Hospital
1220 Missouri Ave.
Jeffersonville, IN 47130

Dear Dr. Altman:

This letter is in reference to your requests dated May 20, 2022 and June 10, 2022, for an amendment to your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-12367-01.

The U.S. NRC's guidance document applicable to your licensed operations, which I refer to throughout this letter as "the guidance", is NUREG-1556, Volume 9, Rev. 3, dated September 2019, "Consolidated Guidance About Materials Licenses: Program – Specific Guidance About Medical Use Licenses." This guidance is available on the NRC Web site at: <https://www.nrc.gov/docs/ML1925/ML19256C219.pdf>

Upon review of your request, I identified the following areas requiring additional or clarifying information:

1. Section 8.7.1, "Radiation Safety Officer," of the guidance identifies that the Radiation Safety Officer (RSO) is responsible for the oversight of licensed operations. The RSO must have sufficient organizational authority and management prerogative to enforce appropriate radiation protection rules, standards, and practices.

Submit a delegation of authority supporting the requested appointment of the proposed RSO. Appendix I, "Radiation Safety Officer Duties, Responsibilities, and Delegation," of the guidance includes an example delegation of authority on page I-4. Note that the delegation of authority should be signed by the RSO and a management representative. Include the printed name, title and date for each individual signing.

2. The Preceptor/Applicant Attestation included a statement from the preceptor physician attesting that the proposed RSO has training in radiation safety, regulatory issues, and emergency procedures for Title 10 of the *Code of Federal Regulations* (10 CFR) §35.100, §35.200, §35.300 (limited to oral administration of sodium iodide I-131).

As your license also authorizes 10 CFR §35.300 for parenteral administration of therapeutic radiopharmaceuticals, please submit documentation on behalf of the proposed RSO identifying applicable training in radiation safety, regulatory issues and emergency procedures for 10 CFR §35.300 for parenteral radiopharmaceuticals.

In addition, please confirm that the proposed RSO is also aware of other authorized licensed materials, including prepackaged kits for *in-vitro* studies and strontium-90 sealed sources authorized for possession only, incident to disposal.

3. 10 CFR §35.59, "Recentness of training," requires that individuals obtain the training and experience specified in 10 CFR Part 35, Subparts B, D, E, F, G, and H, within 7 years preceding the date of application, or the individual must have related continuing education and experience.

Your request referenced a Kentucky Radioactive Material License No. 202-115-26, Amd. No. 73, which was issued on May 29, 2015. The documentation of training and experience preceded the receipt of your application to add these physicians to your license by more than 7 years. Therefore, either provide a copy of a license issued within the last 7 years identifying the requested physicians for the requested licensed materials or provide documentation of related continuing education and experience as required by 10 CFR §35.59.

4. Your request did not provide the applicable medical license number for the requested physicians as required. I searched the Indiana Medical Licensing Board's website and obtained the medical license number for the requested physicians. This included the following physicians:

| <u>Physician Name</u> | <u>License Number</u> | <u>Expiration Date</u> |
|-----------------------|-----------------------|------------------------|
| Frank E. Lee, M.D. | 01053218A | 10/31/2023 |
| Eric A. Jones, M.D. | 01086462A | 10/31/2023 |

Though, I also located additional physicians with a similar name, varying in middle name or middle initial, for the above physicians. Please either confirm that the above physicians are those you are requesting to add to your license or provide the correct Indiana Medical License Number for the physicians you are seeking to add to your license.

5. The preceptor/applicant statements submitted on behalf of the applicant physician, Eric A. Jones, M.D., identifies that applicable training and experience was supervised by Rathana Subramaniam, M.D., Ph.D., M.P.H., under Texas Radioactive Materials License No. L00384 (University of Texas Southwestern Medical Center).

Please provide a copy of the referenced license and/or other documentation identifying the preceptor physician as an Authorized User of materials described in 10 CFR §35.100, §35.200 and §35.300 [equivalent to Title 25 Texas Administrative Code §289.256(ff), §289.256(hh) and §289.256(kk) respectively].

In accordance with 10 CFR §2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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>.

To continue review of your application, please submit your response to this letter within 15 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if no response is received 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, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-01658
License No.: 13-12367-01
Control No.: 631414