UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 7, 2024

William S. Gooch
Radiation Safety Officer
Medical Outsourcing Solutions
1735 DeKalb Ave.
Sycamore, IL 60178

Dear Mr. Gooch:

This letter is regarding your request received May 22, 2024, for an amendment to U.S. Nuclear Regulatory Commission (NRC) Materials License No. 12-35254-01.

The U.S. NRC's guidance document for your type of license, which I refer to below 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 U.S. NRC website at: https://www.nrc.gov/docs/ML1925/ML19256C219.pdf

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

1. Title 10 of the *Code of Federal Regulations* (10 CFR) 35.80(a)(1) specifies that you obtain a letter signed by management of each client for which services are rendered that permits the use of byproduct material at the client's facility and clearly delineates the authority and responsibility of the licensee and the client.

   Your request included a letter from your client, Cardiac Care Consultants, PC, authorizing your company to provide Nuclear Medicine Services at their facility in Munster, Indiana Though, the letter did not include sufficient detail to describe and delineate your authority and responsibility and the client.

   Therefore, please resubmit your request providing a mobile medical service agreement signed by both a management representative of your client and your company. For additional information, please refer to the sample mobile medical service agreement in Appendix V, "Radioactive Materials Guidance for Mobile Medical Services," of the guidance.

2. In accordance with 10 CFR §30.33 and 10 CFR §35.12, submit a complete facility diagram and description of the proposed base location and associated safety equipment.

   The description and diagram of the proposed base location should demonstrate that the building is of adequate construction and design, ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with 10 CFR §20.1301 {e.g., shielding and roping off of areas greater than 0.02 mSv [2 mrem] in any one hour}.

Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For additional information, refer to Appendix V, "Radioactive Materials Guidance for Mobile Medical Services," of the guidance.

3. Section 8.7.1, "Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)," of the guidance identifies that the Radiation Safety Officer, with written agreement from licensee management, may assign duties and tasks to the Associate Radiation Safety Officer (ARSO) that are limited to the types of use for which the ARSO is listed on the license.

   Submit documentation of the appointment of the ARSO. Appendix I, "Radiation Safety Officer Duties, Responsibilities, and Delegation," of the guidance, includes a Model Appointment of ARSO on page I-5. Note that the appointment documentation should be signed by the RSO and a management representative. Include the printed name, title and date for each individual signing.

   Please also include applicable contact information for the appointed ARSO, which may include office phone number, mobile phone number, fax number and e-mail address.

4. Your request included apparent updates to the following procedures and commitments:

   - Radioactive Materials and Purpose(s) for Which Licensed Material Will be Used
   - Financial Assurance and Recordkeeping for Decommissioning
   - Training for Individuals Working in or Frequenting Restricted Areas
   - Radiation Safety Program
   - Waste Disposal Procedures

   Your company had previously provided applicable commitments and procedures addressing these areas in accordance with the U.S. Nuclear Regulatory Commission's NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses."

   Clarify if you are seeking to update and revise your existing commitments and procedures. If so, additional time will be required to review your request to ensure that your proposed procedures are equivalent and include the minimum requirements specified in regulation. Otherwise, please affirm that you would like to rescind and void the submitted procedures.

5. Your request included an apparent addition for the list of Authorized Users in your license, including a reference to Anuradha Divakaruni, M.D., and Rami M. Doukky, M.D.

   Clarify if you are seeking to add Anuradha Divakaruni, M.D., and Rami M. Doukky, M.D., as Authorized Users to the license. If applicable, include documentation of the requested physicians' training and experience and evidence of current licensure by the Indiana Medical Licensing Board.

   For additional information, please refer to Section 8.7.2, "Authorized Users (AUs)," from the guidance.

6. Section 8.13, “Item 13: Certification,” specifies that a representative of the legal entity filing the application must sign and date the NRC Form 313, “Application for Materials License.” The representative signing the application must be authorized to make binding commitments and to sign official documents on behalf of the applicant (i.e., a certifying official).

   You signed the submitted application for a license amendment. Though, your title is not recognized as that of a certifying official (i.e., President, Director or Manager).

   Therefore, please revise and submit the application bearing the signature of a certifying official. For additional information, you may refer to Chapter 3, “Management Responsibility,” of the guidance.

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 request, 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 I 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, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by JASON KELLY
Date: 2024.06.07 15:17:19 -05'00'
Adobe Acrobat version: 2024.002.20759

Jason M. Kelly, MPH, CPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-38851
License No.: 12-35254-01
Control No.: 640996