

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 475 ALLENDALE ROAD – SUITE 102 KING OF PRUSSIA, PA 19406-1415

April 4, 2024

Lori Vinci, Chief Operating Officer Starling Physicians, PLLC 2110 Silas Deane Highway Rocky Hill, CT 06067

SUBJECT: STARLING PHYSICIANS, PLLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639862

Dear Lori Vinci:

This is in reference to your letter dated February 9, 2024, requesting to amend NRC License No. 06-14854-01. The specific requests and suggested format for responses to these items may be found in NUREG–1556, Vol. 9, Rev. 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. In order to continue our review, we need the following additional information:

- 1. Our records indicate a change in the license management representative. If you approve of this change and would like to update the licensee management representative, please provide contact information, including a business phone number and business email address, for Sarit Patel as well as their title/position.
- 2. Item 9, *Facility Diagram* Please provide the following:
 - a. Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information – Withhold Under 10 CFR 2.390." For future submittals, please include the security banner when appropriate. No response is required for this item.
 - b. Please describe the location of Room 26, as indicated, relative to the facility/building including which floor it is located on and the associated room number, if applicable.
 - c. It should be specified on the diagram which doors are access controlled (i.e., locked). Specifically, please describe how security is maintained of any areas where material is used, prepared, or stored. Also indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. We were not able to identify an area on your diagram for radioactive waste. Please indicate the waste storage location radioactive waste including PET radionuclide waste and describe how access control is maintained.
 - d. Describe the principal use of the proposed injection room, specifically if it will be utilized for administration of PET radionuclides (i.e. Fluorine-18) or as a PET quiet room. If you will be utilizing the room for PET radionuclide use, please also

indicate the principal use of the area adjacent to Room 26 to the north, as shown, as well as areas above and below the proposed injection room.

- e. Please note that the medical use of Fluorine-18 is not approved at this time. If you are ready to begin using Fluorine-18, please provide an updated facility diagram with PET quiet rooms. If you will be utilizing the Room 26 for PET radionuclide use, also provide shielding calculations for North, West and East walls of the room as well as above and below. The facility diagrams should be to scale and should include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations. The calculations should include the workload assumptions used.
- f. Your current calculations indicate 3/64" lead or equivalent in the wall between the PET/CT scanner and Room 26 (previously Admin Office). Please confirm if this is still adequate in accordance with the principal use of the proposed area of use.
- 3. Item 9, *Other Equipment and Facilities* If the proposed injection room will be utilized for PET radionuclide use, specifically for Fluorine-18, describe additional remote equipment for these uses, as applicable, such as lead-lined syringe carrier, tongs and specialized syringe shields that are specific to 511 keV. Specifically, describe how the radiopharmaceutical will be transported between the hotlab and Room 26.

We will continue our review upon receipt of this information. Please reply to my attention at <u>hiba.ahmed@nrc.gov</u> referencing *Mail Control No.* 639862.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: <u>www.nrc.gov</u>. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <u>http://www.nrc.gov/materials/miau/med-use-toolkit.html</u>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html. Please be aware that you may request that certain portions of your submittal to NRC be withheld form public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

Thank you for your cooperation.

Sincerely,

Hiba Ahmed, Health Physicist Medical and Licensing Assistance Branch Division of Radiological Safety and Security Region I

License No. 06-14854-01 Docket No. 030-08163 Mail Control No. 639862

cc: Richard R. Miguel M.S., DABR, Radiation Safety Officer

610-337-5283 or via electronic mail at hiba.ahmed@nrc.gov.

STARLING PHYSICIANS, PLLC, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639862 DATED APRIL 4, 2024

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