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

October 30, 2023

Mohammed H. Aljallad, Ph.D, DABR,
Radiation Safety Officer
MedStar Washington Hospital Center
110 Irving Street, N.W.
Room BA94
Washington, D.C. 20010-2975

SUBJECT: MEDSTAR WASHINGTON HOSPITAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637419

Dear Dr. Aljallad:

This is in reference to your letter dated August 22, 2023, requesting to amend NRC License No. 08-03604-03. In order to continue our review, we need the following additional information:

1. Your letter dated August 22, 2023, discussed training for the use of actinium-225 DOTATATE as meeting 10 CFR 35.390 or 10 CFR 35.396, suggesting the connection to administration of unsealed material under 10 CFR Part 35 Subpart E. Please confirm that you will use written directives described by 10 CFR 35.40(b)(2) with written procedures consistent with 10 CFR 35.41 for your use of actinium-225 DOTATATE by treating actinium-225 DOTATATE as a material covered by 10 CFR Part 35 Subpart E.

2. Your letter dated August 22, 2023, did not discuss where the preparation, usage, administration, and storage of actinium-225 DOTATATE will occur. Please confirm either (1) that the preparation, usage, administration, and storage of the actinium will be within areas that have already been approved by the NRC or the MedStar Radiation Safety Committee (RSC), or (2) the preparation, usage, administration, and storage of actinium-225 DOTATATE will be in a new area that has not been previously associated with the preparation, usage, administration, and storage of NRC-licensed radioactive material. If the latter, please describe the new area and confirm that the MedStar RSC has, or will prior to receipt of actinium-225, approved the new area for the preparation, usage, administration, and storage, of actinium-225 and whether this area is within the addresses described in your NRC license, Amendment 65, License Condition 10.

3. Your description of use was adequate. Nonetheless, the NRC attempts to use consistent language to describe the licensee's authorized use of radioactive material. Your use appears to fall within the following language:

   "*For use in medical diagnosis, therapy, and research in humans. Research and development as defined in 10 CFR 30.4, including instrument calibration.*"

   Please confirm the adequacy of this language to your requested use. Many of your other authorizations include language regarding the use of radioactive materials for "student instruction" and "in-vitro studies." While these are not described in your August 22, 2023, letter, please confirm the need for inclusion of this language or its absence from the proposed authorization.

4. Consistent with a telephone conversation with NukeMed, Inc. (dba Spectron Rx), your amendment request's statements regarding the absence of actinium-227 as a long-lived (>120 day half-life) impurity was verified. Please confirm you understand that should the procurement or production source of your actinium-225 change, it may impact the presence of the actinium-227 impurity and that this change may require an amendment to your NRC license to authorize the possession of the impurity isotope and the potential for impact to your need for financial assurance under 10 CFR 30.35.

5. The August 22, 2023, letter included a Pharmacy Manual for Protocol RYZ101-301. Appendix C of this document includes a description of the actinium-225 decay chain. This decay chain does not appear to describe gamma photons related to this decay, in particular two prominent gamma photons associated with francium-225 (218 keV, approximately 11 percent) and bismuth-213 (440 keV, approximately 26 percent). No response is required for this item.

6. During the review of your NRC license for this amendment, it was noted that your present license (Amendment No. 65), License Condition 17 and 19, conflict in part with the authorizations in 10 CFR 35.67 and 10 CFR 35.92. To address this, the NRC will include language clarifying that these license conditions do not apply to licensed radioactive materials authorized by 10 CFR Part 35. No response is required for this item unless the clarification described above is inconsistent with your perspective of the issue.

We will continue our review upon receipt of this information. Please reply to my attention at:

R1DRSSMail.Resource@nrc.gov
Reference – Jason vonEhr
Mail Control No. 637419

In order to continue prompt review of your application, we request that you submit your response to this letter within 15 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. 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.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5256 or via electronic mail at Jason.vonEhr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jason E. VonEhr

Digitally signed by Jason E. VonEhr
Date: 2023.10.30 14:36:30 -04'00'

Jason vonEhr, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 08-03604-03
Docket No. 030-01325
Mail Control No. 637419

cc:

Jean V. Mabout, MBA, Senior Director, Radiology & Radiation Safety
Carlos Garcia, M.D., Chariman, Radiation Safety Committee

MEDSTAR WASHINGTON HOSPITAL CENTER, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637419 DATED OCTOBER 30, 2023

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SUNSI Review Complete: JEV

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