

July 9, 2021

Licensee: Yale-New Haven Hospital
License Number: 06-00819-03
Docket Number: 030-01244
Mail Control Number: 617101

TO: U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

RE: Amendment Request

To whom it may concern:

This letter is to request an amendment to our radioactive materials license to include Actinium-225 (Ac-225) for the purposes of medical diagnosis, therapy, and research in humans and research and development as defined in 10 CFR 30.4. There is a growing interest in the research and development of alpha-emitting radionuclides for use in targeted alpha therapy (TAT). Therefore, we are requesting a maximum possession limit of 20 mCi. Prior to the implementation of use, all policies and procedures associated with the safe use of this material shall be reviewed, approved, and ratified by the Radiation Safety Committee.

Ac-225 doses will be received as unit doses prepared at an external radiopharmacy and thus preclude dose manipulation at YNHH at this time. All human use administrations of Ac-225 will be conducted on the 20 York St campus by RSC approved Authorized Users. Each administrations will be documented with a written directive in accordance with 10 CFR 35 Subpart E.

We thank you in advance for your prompt attention to this matter. Should you have any questions or concerns, please contact me at the number listed below.

Sincerely,

Elizabeth Herbert

Elizabeth Herbert

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