From: Hann, Patrick-John
To: Whiteside, Neil
Subject: Request for Additional Information- License No. 06-00819-03 MC 627431
Date: Tuesday, August 31, 2021 9:54:00 AM

License No. 06-00819-03
Docket No. 03001244
Control No. 627431

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL. ADDITIONALLY, PLEASE BE SURE TO SEND YOUR RESPONSE TO THIS REQUEST FOR ADDITIONAL INFORMATION IN A LETTER SIGNED BY YOUR MANAGEMENT REPRESENTATIVE AND REFERENCE MAIL CONTROL NO. 627431

Mr. Whiteside,

This is in regards to your request to amend License No. 06-00819-03. In order for us to continue our review please submit the following additional information:

1. Please identify the instrumentation that will be used for surveys to evaluate concentrations or quantities of residual radioactivity and the methodology for calibration of the instrumentation, with respect to the use of Ac-225.

2. Please identify whether the patients receiving Ac-225 targeted alpha therapy (TAT) will be on an inpatient or outpatient basis. If they will be on an outpatient basis, please identify the methodology that will be used to determine releases are in accordance with 10 CFR 35.75. Alternatively, if they will be inpatients, please provide a diagram of the facilities in which they will be kept.

3. Please identify the activity to be administered per patient.

4. Please identify the methodology that will be used to calibrate the dose calibrator that will be used to determine the patient dosage for the use of Ac-225, if applicable.

5. Please confirm that your written procedures for area surveys, in accordance with 10 CFR 20.1101, that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70, are inclusive for the use of alpha emitters.

6. Please confirm that the instruction of workers is commensurate with potential radiological health protection problems present in the work place, in respect to the use of Ac-225.

7. Please describe your bioassay program as it pertains to the use of unsealed Ac-225.

8. Please describe the process to evaluate your policies and procedures when new radioactive materials(FDA-approved, clinical trial, or research) will be used.

Patrick-John E. Hann, MHP
Health Physicist