From: Jason Kelly
To: paul.morozov@gmail.com
Subject: U.S. NRC Materials License #13-00142-02 - Request for Additional Information
Date: Friday, June 2, 2023 3:58:00 PM

Dr. Morozov:

I have reviewed the letter dated May 31, 2023, signed by Susan Brumley, Vice President, Ancillary Services, regarding the request for authorization to use yttirium-90 TheraSpheres.

The U.S. Nuclear Regulatory Commission's (NRC's) guidance document applicable to the request, which I refer to below as "the guidance," is Y-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, Rev. 10.2. This guidance is available on the U.S. NRC website at: https://www.nrc.gov/docs/ML2108/ML21089A364.pdf

Upon review of the letter, I identified the following areas in which additional or clarifying information is needed:

1. The request identified a commitment to establishing a change process similar to Title 10 of the Code of Federal Regulations (10 CFR) §35.26. In accordance with Section 6.9, "Radiation Protection Program Changes,' of the guidance please confirm that the following conditions will be met for revisions to your radiation safety program:

a. the revision is in compliance with the regulations;

b. the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC's Medical Uses Licensee Toolkit Web site;

c. the revision has been reviewed and approved by the licensee's RSO and licensee's management;

d. the affected individuals are instructed on the revised program before the change is implemented;

e. the licensee will retain a record of each change for five years; and

f. the record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

2. The request identified a commitment to medical event reporting in accordance with the criteria specified in Section 6.3, "Medical Event Reporting," of the guidance. Please confirm that your institution will also comply with the medical event reporting and notification requirements described in 10 CFR §35.3045(b)-(g).

Please respond to this request for additional information in writing within 10 calendar days. Please

reference your license number and Control Number 634902 in your signed response letter.

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