

7/14/2023

Jason M. Kelly, MPH
U.S NRC Region III
Materials Licensing Branch
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4352
630-829-9500
Jason.Kelly@nrc.gov

RE: U.S. NRC Materials License #13-32535-02 - Control Number 635546 -Request for Additional Information

Dear Mr. Jason Kelly,

This letter is a response to your July 13, 2023 letter regarding our license amendment for RAML #13-32535-02. The responses are in the order received:

1. We commit to provide training in our procedures to all individuals involved in Y-90 TheraSphere microsphere use, commensurate with the individual's duties to be performed. This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres.

If you have questions or need additional information, please contact me at 765-838-5877 or jnepute@iuhealth.org.

Sincerely,



Joshua Nepute, MD
Radiation Safety Officer
Indiana University Health Arnett Hospital
RAML #13-32535-02

Martha Pavon

From: Jason Kelly
Sent: Monday, July 17, 2023 7:29 AM
To: Martha Pavon
Subject: FW: RE: [External] U.S. NRC Materials License #13-32535-02 -Control Number 635546 Request for Additional Information
Attachments: final amendment request TheraSpheres.pdf

Good morning. Attached is an incoming Response to a Request for Additional Information from Materials License No. 13-32535-02 (Indiana University Health Arnett Hospital), Docket No. 030-37189 in reference to Control No. 635546.

Jason M Kelly, MPH
Health Physicist
U.S. NRC Region III – DRSS MLB
Phone: (630) 829-9737
E-mail: Jason.Kelly@nrc.gov

From: White, Amanda G <awhite56@IUHealth.org>
Sent: Friday, July 14, 2023 3:25 PM
To: Jason Kelly <Jason.Kelly@nrc.gov>
Cc: Owens, Danielle <dowens12@IUHealth.org>
Subject: [External_Sender] RE: [External] U.S. NRC Materials License #13-32535-02 -Control Number 635546 Request for Additional Information

Mr. Kelly,
Please see the attached document for completion of required documents for our amendment request. I appreciate your time and attention to this matter and please let me know if you have any additional requests. Thank you again!

Amanda White CNMT
Supervisor Imaging Services
Nuclear Medicine, PET/CT
Indiana University Health Arnett
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From: Jason Kelly <Jason.Kelly@nrc.gov>
Sent: Thursday, July 13, 2023 9:51 AM
To: White, Amanda G <awhite56@IUHealth.org>
Cc: Nepute, Joshua A <jnepute@IUHealth.org>; Owens, Danielle <dowens12@IUHealth.org>
Subject: [External] U.S. NRC Materials License #13-32535-02 - Request for Additional Information

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Ms. White:

I am finalizing the amendment to your license for review by my mentor, Laura Cender, Health Physicist. In reviewing the entirety of the amendment request, I noted one additional item that was lacking:

Section 5.4, "Team Approach," of the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Rev. 10.2, April 20, 2021, identifies that the applicant shall commit to provide training in the licensee's procedures to all individuals involved in Y-90 microsphere use, commensurate with the individual's duties to be performed. This training must be provided to all individuals preparing, measuring, performing dosimetry calculations, or administering Y-90 microspheres. Here is a link to the referenced guidance: <https://www.nrc.gov/docs/ML2108/ML21089A364.pdf>

While your institution had previously committed to providing this training in correspondence dated October 28, 2016, that commitment was specific to yttrium-90 as SIR-Spheres. Please provide a similar commitment applicable to yttrium-90 as TheraSpheres.

Please respond to this request for additional information in writing within 10 calendar days. Please reference your license number and Control Number 635546 in your signed response letter.

Jason M Kelly, MPH
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