

From: [Forster, Sara](#)
To: [Edward Wroblewski](#)
Subject: Additional Information Request re Ascension St. Vincent Hospital Amendment request, NRC Lic. No. 13-00133-02, CN630436
Date: Wednesday, April 27, 2022 11:13:00 AM

Good morning, Mr. Wroblewski:

The U.S. NRC Region III office is in receipt of your March 14, 2022 amendment request letter. We have reviewed your request, and additional information is needed, as we discussed via phone earlier this month.

REQUEST FOR A TITLE 10 OF THE CODE OF FEDERAL REGULATIONS (CFR) SECTION 35.1000 THERASPHERES AUTHORIZATION:

1. No Facility diagram was included in the request for the new Theraspheres area of use.
Please include a Facility diagram for the 3700 Washington Ave., Evansville, IN area of use. If multiple areas may be used, please provide a sample diagram for the area where procedures may be performed.
2. A possession limit of 2 curies was requested for the additional Theraspheres area of use. Please note that Theraspheres are already authorized on the license, with an existing possession limit of 2 curies.
Please confirm that you wish to increase your 10 CFR 35.1000 yttrium-90 as TheraSpheres possession limit from 2 curies to 4 curies.

REQUEST TO ADD LEONID DROZHININ, M.D. AS A 10 CFR 35.1000 THERASPHERES AUTHORIZED USER:

3. For a 10 CFR 35.1000 authorized user for yttrium-90 SIR-spheres microspheres seeking to expand the authorization to include TheraSphere microspheres, the current yttrium-90 microspheres guidance document expects that the physician needs (1) work experience under a supervising AU for Therasphere microspheres; and (2) completing training in at least three hands-on patient cases for TheraSpheres, conducted in the physical presence of the AU. Although the documentation of the Dr. Drozhinin's work experience was included in the submission, no record of three patient cases was included.
To have Dr. Drozhinin listed on the license as authorized for TheraSphere use, without qualification, please submit documentation of Dr. Drozhinin's first three patient cases involving TheraSphere administrations. For each of the submitted cases, please include the name & license number of the licensee where administrations were conducted, the name of the supervising authorized user and the date on which the TheraSpheres were administered.
4. If the proposed AU has not completed the three hands-on patient TheraSphere cases prior to authorization, the licensee may request conditional approval of the AU, pending completion of the 3 cases. Such a request should include: (1) the request for conditional approval; (2) documentation of at least three mock simulated cases; (3) a commitment that the requested individual will complete at least 3 supervised hands-on patient TheraSphere administrations within 1 year of the license amendment authorizing the

conditional approval; and (4) a commitment that the licensee will submit documentation of the individual's completion of the first 3 patient cases within 30 days of the 3rd case being completed.

If a conditional approval is being sought, at this time, please (1) request conditional approval; (2) provide documentation of at least 3 simulated mock cases; (3) provide commitment that 3 actual patient cases will be completed within 1 year of the amendment; and (4) provide commitment that documentation of 3 actual patient cases will be submitted to NRC within 30 days of the amendment adding the authorizations.

REMOVAL OF THE 2020 MERIDIAN ST., ANDERSON, INDIANA 10 CFR 35.600 HIGH DOSE RATE REMOTE AFTERLOADER AUTHORIZATION:

5. The request indicated that the 10 CFR 35.600 Nucletron Model 105.002 authorization should be removed from the license, due to the close-out of the referenced Anderson, Indiana location of use. Please note, however, as discussed, that the referenced materials authorization also applies to an Indianapolis, Indiana location of use, as listed in Subitem No. 10.A. of your license. Per our discussion, we have noted that the number of sources and possession limits for the referenced authorization should be reduced, it should not be eliminated.

Please confirm that the licensee is requesting that the 10 CFR 35.600 HDR authorization listed in Subitem No. 6.K. should be reduced to a possession limit in Subitem No. 8.K. of two sources; not to exceed 13 curies each and 20 curies total.

UPDATED FACILITY DIAGRAMS FOR THE 8333 NAAB RD., INDIANAPOLIS, INDIANA & 3699 EPWORTH RD., NEWBURGH, INDIANA LOCATIONS OF USE:

6. The request included updated facility diagrams for the referenced locations. However, the diagrams were unclear as to what addresses each applied to, the dimensions or scale of each diagram, and locations of key features within each area of use (locked doors, waste, sinks, work areas, etc.).

Please provide revised diagrams of the two new areas of use, including the street address, dimensions or scale, and locations of key features within each area. Please note that, upon final demolition and close-out of radioactive materials use areas at the Newburgh, Indiana location of use, final close-out surveys and decommissioning surveys must be submitted to the NRC. The license will be amended with the updated area of use information accordingly.

Please provide a response via a signed and dated letter within 14 days (on or prior to May 11, 2022). For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me via email or phone.

Thank you in advance for your prompt attention to this request,

Sara A. Forster, Health Physicist Licensing Reviewer
U.S. Nuclear Regulatory Commission - Region III