

From: [Nathan Bryant](#)
To: alanj@rad.hfh.edu
Subject: CN 647760 Request for Additional Information
Date: Friday, November 21, 2025 2:56:00 PM
Attachments: image001.jpg

Good afternoon, Mr. Jackson,

This email is in response to the renewal application dated July 10, 2025, to renew U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-04109-16. Upon reviewing your request, the following areas were identified and require additional information:

1. Germanium-68/Gallium-68 Pharmaceutical Grade Generators Licensing Guide, July 2019, Section 4.3 identifies an address of use and facility diagram with description of the location where the generator will be received, used, and stored, should be submitted.

Please confirm where the generators will be used and stored. Please include which location and room numbers.

2. Please provide the following statement regarding Material Receipt and Accountability:

“We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

license possession limits are not exceeded

licensed material in storage is secured from unauthorized access or removal

licensed material not in storage is maintained under constant surveillance and control

records of receipt (either from the licensee’s own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.”

3. Please provide the following statement regarding Safe use of Unsealed Licensed Material:

“We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201.”

4. In your renewal application you provided a link to the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance document. Please refer to the attached Y-90 commitments and submit in writing the listed commitments.

5. In your renewal application you provided a link to the Licensing Guidance for Best Vascular, Inc., Beta-Cath IVB System and three of the required commitments. Please reference the attached Beta-Cath commitments and submit in writing the listed commitments in addition to those already submitted.
6. In your renewal application, I identified the facility diagrams where you will perform therapies. Please provide a statement confirming that all patients will be releasable per 10 CFR 35.75 or provide facility diagrams and description of the inpatient areas where patients will be placed until releasable.
7. Pharmaceutical grade generators contain Germanium-68 in quantities that per the requirements described in 10 CFR 30.35 would require submittal of a Decommissioning Funding Plan. The 35.1000 Germanium-68/Gallium-68 Pharmaceutical Grade Generators Licensing Guidance outlines in Section 7.4 specific requirements for which an exemption to the Decommissioning Funding Plan requirement may be granted. This exemption still requires that financial assurance be provided in the amount of \$225,000 when the license authorizes less than 100 mCi of Ge-68 or \$1,125,000 when greater than 100 mCi of Ge-68 will is authorized. This prescribed amount of financial assurance is additive to the financial assurance that is already in place. To facilitate the addition of Germanium-68/Gallium-68 generators to the license please provide the following:
 - a. The quantity of Germanium-68 and Gallium-68 that should be listed as individual line items on the license for use in Germanium-68/Gallium-68 generators.
 - b. A legally binding agreement for the return of the generators to the manufacturer or distributor that meets the following requirements as described in Section 7.4 of the 35.1000 licensing guidance:
 - i. a commitment that the generator recipient shall return the generator to the manufacturer or distributor;
 - ii. commitment that the generator manufacturer or distributor shall accept receipt of the returned generator;
 - iii. that conditions for the manufacturer or distributor's receipt of the generator are reasonable and facilitate the return of the generator;
 - iv. that the manufacturer or distributor is authorized to possess the radioactive material;
 - v. that the parties to the agreement are the recipient(s) of the generators and the manufacturer or distributor(s) of the generators;
 - vi. that the agreement is signed by persons authorized to enter into

legally binding agreements on behalf of the recipient(s) and manufacturer or distributor(s); and
vii. that the agreement is dated.

- c. An updated Financial Assurance Letter of Credit and accompanying Standby Trust Agreement reflecting the appropriate increase to the current \$225,000 of financial assurance that is currently in place.

Please submit your signed response letter by December 21, 2025. If you need more time or have any questions, please don't hesitate to contact me. As you will not receive a hard copy of this request for additional information, please confirm that you have received this email.

Thank you,

Nathan Bryant
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