



**RADIOPHARMACY  
OF INDIANAPOLIS**

September 27, 2017

US Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

Dear Ms. Forster:

Per your communication ("letter") dated September 14, 2017 requesting additional information for a recent amendment request for NRC Material License No. 13-32637-01MD (Control No. 600076), below are the response to the action items:

1. The above-referenced letter requested an authorized use that omitted explicit reference to the Eckert and Ziegler GalliaPharm™ germanium-68/gallium-68 generator. Please note that the U.S. Nuclear Regulatory Commission (NRC) licensing guidance document, "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator," dated October 17, 2016 (ML16287A403), outlines expectations for materials and use authorizations, limited to use of the Eckert and Ziegler GalliaPharm™ germanium-68/Gallium-68 generator.

**Accordingly, please confirm that the requested use authorization is specific to the E&Z GalliaPharm™ generator.**

**RESPONSE: I confirm that the requested use authorization is specific to the E&Z GalliaPharm™ generator.**

2. The above-referenced letter indicated that the Radiation Safety Officer (RSO) and Authorized Nuclear Pharmacists (ANPs) would be trained in the safe use, regulatory requirements, and hazards with use of germanium-68 and gallium-68. However, the application was unclear as to which ANPs would be authorized for germanium-68/gallium-68 generator use, and that such training would be received prior to receiving a gallium-68/germanium-68 generator at your facility. Finally, the letter was unclear as to whether the RSO or other individual ANPs listed on your license have already received training.

**Accordingly, please confirm that all ANPs and the RSO currently listed on the license should be authorized for use of the germanium-68/gallium-68 generators and will receive training prior to use.**

**RESPONSE:** To date, we have not received formal training for the product. Furthermore, I confirm all ANPs and the RSO currently listed on the license should be authorized for use of the germanium-68/gallium-68 generators and will receive training prior to use of the E&Z GalliaPharm™ generator.

3. The licensing guidance document referenced above outlines explicit licensee commitments that the NRC may accept in approving the licensee for germanium-68/gallium-68 generator use. Such commitments were excluded from the request.

**Please provide commitments in accordance with pages 5-7 of the guidance document. For your convenience, copies of these pages are attached to this message. In the alternative, for each omitted or revised commitment, please explain why the guidance document was not used and justify any alternative response.**

**RESPONSE:** The RSO and management commits to follow and incorporate Section 5. License Commitments in accordance with pages 5-7 of the guidance document included in the Letter. These commitments will be formally introduced into the licensee's Radiation Safety Program (ALARA Procedures).

4. The licensing guidance document for Ge-68/Ga-68 generators includes an option for licensees and applicant the authority to update Radiation Protection Programs – without a license amendment – provided that such authority is requested and a confirmation that certain conditions will be met is included with the request. We have noted that the above referenced letter was silent as to intentions to make changes to the Radiation Protection Program.

**Accordingly, please confirm that no such authorization is requested. In the alternative, please refer to the guidance document, pages 7-8, and include a request for flexibility to update the program with your response. A confirmation that conditions will be met as specified in the guidance should also be included with any such request.**

**RESPONSE:** I request the authority and submit the corresponding confirmation to update our Radiation Protection Program (ALARA Procedures) prior to the first receipt of an E&Z GalliaPharm™ generator. The update will be in accordance with Section 6. Radiation Protection Program Changes referenced in the Letter.

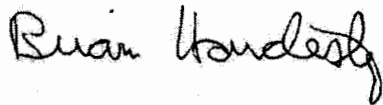
5. Via memo dated July 29, 2016 (ML16082A415), NRC's Office of Nuclear Material Safety and Safeguards (NMSS) authorized the NRC Region III Office to grant specific exemptions from the 10 CFR 30.35(a)(1) DFP requirement noted above. As noted in the memo, our office may grant such an exemption provided that the application provides documentation, including Financial Assurance (FA) certification based on possession limit. Note that, for up to two generators and up to 100 millicuries total, FA amount is \$225,000. To date, although a surety bond has been required, no standby trust agreement nor certification have been submitted on behalf of Guardian, on behalf of the licensee's request to receive, use, and possess Ge-68/Ga-68 generators. The NRC Region III office cannot issue a Ge-68/Ga-68 generators authorization prior to receipt and review of FA documents, as required by 10 CFR 30.35.

Accordingly, please submit additional FA documents (Standby Trust Agreement (STA) and Certification) in the amount of \$225,000 (for a PL of up to two generators and 100 millicuries total, as indicated in the initial application), as required by 10 CFR 30.35. For additional guidance, please refer to Appendix A, "Standard Format and Content of Financial Assurance Mechanisms for Decommissioning" of NUREG-1757, Volume 3, revision 1, "Financial Assurance, Recordkeeping, and Timeliness." For your convenience, key relevant checklists and guidance are attached to this letter. FA must be in place and review complete prior to amending the NRC license for possession of this material.

**RESPONSE:** Licensee is addressing these FA requirements specifically through correspondence related to Mail Control Number 600624.

Please let me know if you have any questions or require additional information.

Sincerely,

A handwritten signature in cursive script that reads "Brian Hardesty".

Brian Hardesty, RPh.  
Guardian Pharmacy of Indianapolis Nuclear LLC (dba Radiopharmacy of Indianapolis)  
Vice President and Radiation Safety Officer

CC: file

## Song, Taehoon

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**From:** Forster, Sara  
**Sent:** Thursday, September 28, 2017 7:19 AM  
**To:** Pavon, Sandy; Sandrik, Lauren; Song, Taehoon  
**Subject:** FW: RE: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN600076  
**Attachments:** USNRC Response (control 60076) (ROI 09282017).pdf; Standby Trust (Copy 09282017).pdf

Please scan in and return to me. Thank you!

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**From:** Brian Hardesty [mailto:bhardesty@rpofindy.com]  
**Sent:** Thursday, September 28, 2017 7:13 AM  
**To:** Forster, Sara <Sara.Forster@nrc.gov>  
**Subject:** [External\_Sender] RE: Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN600076

Ms. Forster,

Attached is my response to the items listed in your letter dated September 14, 2017. I have also attached a copy of the Standby Trust Agreement (item 5) to which the originals will be sent to Ms. Bishop's office tomorrow..

I will be in the office until 3:00pm EST time today if you have any questions or you can always reach me on my mobile (317-522-3855).

Regards,

Brian Hardesty, RPh, MBA  
Radiopharmacy of Indianapolis  
6538 Corporate Drive  
Indianapolis, IN 46278  
P: 317-347-0102  
F: 317-347-0802

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**From:** Forster, Sara [mailto:Sara.Forster@nrc.gov]  
**Sent:** Thursday, September 14, 2017 11:07 AM  
**To:** Brian Hardesty <bhardesty@rpofindy.com>  
**Subject:** Additional Information Request for Guardian Pharmacy of Indianapolis Nuclear, L.L.C., Lic. 13-32637-01MD, CN600076

Dear Mr. Hardesty:

Please see the attached file for additional information needed to complete the review of your recent amendment request for NRC Lic. No. 13-32637-01MD. Note that the attached conversation record requests additional information on or before the close of business on September 28, 2017. Additional guidance may be found in NUREG 1556, Vol. 13, rev. 1, "Program-Specific Guidance About Medical Use Licenses;" NUREG-

1757, Volume 3, Revision 1, "Consolidated NMSS Decommissioning Guidance - Financial Assurance, Recordkeeping, and Timeliness;" Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance" (ML16287A403); and "Memo – Authorization for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators" (ML16082A415); which may, respectively, be found at:

<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/>;

<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/>;

<https://www.nrc.gov/docs/ML1628/ML16287A403.pdf>; and

<https://www.nrc.gov/docs/ML1608/ML16082A415.pdf>.

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Do not hesitate to call me with any questions you may have, or if additional time is needed to complete this request.

Sincerely,

**Sara A. Forster, Health Physicist Licensing Reviewer**

U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

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