



November 21, 2025

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

Subject: License Amendment Request (NRC license #13-32637-01MD)

Dear Sir/ Madam:

On behalf of Guardian Pharmacy of Indianapolis Nuclear LLC (d/b/a Radiopharmacy of Indianapolis) "ROI", I am writing to request following amendment to its radioactive materials license (NRC license #13-32637-01MD) to include the following items (2) in order to accommodate increased demand for emerging radiopharmaceuticals desired by our customers:

1. Please add a new line item for the following request (additions of various isotopes to our license)

Byproduct, Source and/or special nuclear material.	Chemical and/or physical form	Maximum amount that the licensee may possess at any one time under this license	Authorized use
Lutetium-177	Any	1600 millicuries	For preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients

All radioactive material will be used and stored within the clean room or other storage areas in the restricted area as required.

All isotopes listed above ROI will receive and prepare the dose specific amount requested by Physician/ authorized agent and/or in accordance with the drug package insert. ROI will redistribute to authorized recipient(s) only. A small residual amount of waste will be processed through the existing decay in the storage program in compliance with applicable State regulations and 10 CFR 35.92. ROI is aware of possible long-lived contaminants depending on the method of production. If contaminants are detected, ROI will process the waste as Low Level Radioactive Waste and handle/manage accordingly.

If contaminants are detected by our appropriate survey meters, ROI will develop a safe handling and disposal of low-level radioactive waste in accordance with applicable State regulations and 10 CFR Part 20 Subpart K and G.

2. ROI requests an increase in current Maximum Possession Limit for the previously approved isotopes listed below to our radioactive materials license (NRC license #13-32637-01 MD) for the purpose of increased capacity for the preparation Ga-68 radiopharmaceuticals for imaging and localization studies.

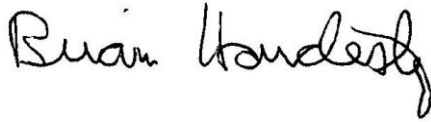
Radionuclides: Germanium 68 (Ge-68) and Gallium 68 (Ga-68)

Chemical and/or physical form: Any

Maximum Requested Possession Limit: 400 millicuries of Ge-68 and 300 millicuries of Ga-68.

Thank you for your attention to these timely matters and positioning ROI to help provide patients with access to new treatments and imaging procedures to improve patient care and outcomes.

Sincerely,

A handwritten signature in black ink that reads "Brian Hardesty". The signature is written in a cursive, flowing style.

Brian Hardesty
Guardian Pharmacy of Indianapolis, Nuclear LLC (d.b.a. Radiopharmacy of Indianapolis)
President and Radiation Safety Officer

Cc: File

Martha Pavon

From: Tammy Tomczak
Sent: Monday, November 24, 2025 8:09 AM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: Guardian Pharmacy of Indianapolis Nuclear LLC (13-32637-01MD) - Amendment Request (Increase current Ga-68/Ge-68 and Lu-177 Maximum Possession Limits)
Attachments: NRC Amendment 11-2024 (isotopes).pdf

Good morning, Martha,

Can you please add the attached to ADAMS?

Thank you!
Tammy

From: Brian Hardesty <Brian.Hardesty@rpofindy.com>
Sent: Friday, November 21, 2025 7:15 AM
To: R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>
Cc: Tammy Tomczak <Tammy.Tomczak@nrc.gov>
Subject: [External_Sender] Guardian Pharmacy of Indianapolis Nuclear LLC (13-32637-01MD) - Amendment Request (Increase current Ga-68/Ge-68 and Lu-177 Maximum Possession Limits)

To Whom it May Concern,

Attached is an amendment request to allow us to provide additional services to the patients we serve. If possible, I would appreciate expedited consideration as our demand for Ga-68-based radiopharmaceuticals will increase significantly in early 2026.

Thanks in advance for your consideration and I look forward to further communications.

If the submission email address has been updated, please let me know and I will update my records.

Regards.

Brian Hardesty, RPh, MBA
Radiopharmacy of Indianapolis

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