UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

January 27, 2017

Jason J. Wilson, R.Ph.
Radiation Safety Officer
Radiopharmacy Incorprated
1409 E. Virginia St.
Evansville, IN 47711

Dear Mr. Wilson:

In the letter dated December 7, 2016, Richard L. VanSant, Pharm.D., Director of Regulatory Affairs, PharmaLogic Holdings Corp., requested to add an authorization for the possession and use of germanium-68/gallium-68 (Ge-68/Ga-68) generators to your NRC License No. 13-26246-01MD. In that letter, Mr. VanSant provided supporting documentation including commitments and a generic "Return Agreement for GalliaParm™ $^{68}Ge/Ga^{68}$ Generators," signed by Glen Palmer, Chief Operating Officer, PharmaLogic and a General Manager (name undecipherable) for Eckert & Ziegler RadioPharma GmbH (E&Z). We have reviewed submitted information, including the absence of financial assurance required for the possession of the types and quantities of material requested. Please note that we cannot add an authorization for possession and use of germanium-68, absent additional information, including required financial assurance and a legally binding agreement for the return and acceptance of returned generators between Radiopharmacy Incorporated, NRC License No. 13-26246-01MD and the generator manufacturer, E&Z.

Concerning the request to add the referenced authorization, additional information is needed to complete our review as follows:

1. The above-referenced letter provided radionuclide, form, possession limit (PL), and authorized use (use) information for a combined authorization for Ge-68/Ga-68. However, 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, specific to commercial nuclear pharmacy.

   Accordingly, please update the requested radionuclide, form, PL, and use information to specify specific information for each radionuclide. Your response should indicate the total number of generators requested, include confirmation that the requested use authorization is specific to the E&Z GalliaPharm™ generator, and that use is limited to the preparation of Ga-68 radiopharmaceuticals for imaging and localization studies, or otherwise explain why the guidance document cannot be followed.

2. The above-referenced letter included a facility diagram. However, that diagram was unclear as to scale, omitted any description of where the E&Z GalliaPharm generator(s) would be received and stored, and was silent as to areas adjacent to – including above and below – the indicated use area.

Accordingly, please resubmit the facility diagram, including a description of where the generator(s) will be received, used, and stored. The diagram should be drawn to scale and indicate a brief description (i.e. cafeteria, offices, restrooms, inaccessible roof, etc.) of uses above, below, and adjacent to the Ge-68/Ga-68 use area.

3. In the above-referenced letter, Mr. VanSant stated that the licensee would develop procedures to determine breakthrough of 5 microcuries Ge-68 per 50 millicuries of Ga-68. However, the above-referenced NRC licensing guidance document includes an update to the breakthrough limit due to a conversion error made in the September 28, 2016 version of that document.

   Accordingly, please confirm that the licensee will develop and implement written procedures for the determination of breakthrough that will detect whether the eluate exceeds the manufacturer's 0.001 percent breakthrough limit, i.e., the presence of Ge-68 in excess of a ratio of 0.01 µCi Ge-68 per mCi Ga-68.

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 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.

5. Under 10 CFR 30.35(a)(1), an applicant for a license to use and possess Ge-68/Ga-68 generators must submit a Decommissioning Funding Plan (DFP) together with financial assurance determined from the DFP. The above-referenced letter contained no such DFP.

   If you are not requesting an exemption to the regulatory requirement to submit a DFP to the NRC, please submit a DFP in support of your application.

6. 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:

   (i) Explicitly requesting an exemption from the 10 CFR 30.35 DFP requirement;

   (ii) Demonstrating that a legally binding agreement is in place for the licensee to return the generators to the manufacturer or distributor when the generators expire and are no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals; that legally binding agreement between the licensee and generator manufacturer or distributor must highlight licensee commitments to return expired generators back to the manufacturer or distributor and also must include a manufacturer or distributor commitment to take expired generators back; and

(iii) Including Financial Assurance (FA) certification based on possession limit –

a. For up to two generators and up to 100 millicuries total, FA amount is $225,000; or

b. For three to twenty generators and up to 1 curie total, FA amount is $1,125,000.

Our review of the above-referenced letter indicated the following:

(i) Although it contained a copy of a generic (non-licensee specific) agreement between Pharmalogic and E&Z, it was silent as to any request for an exemption from NRC's regulatory DFP requirement.

Accordingly, please confirm that you are requesting an exemption from the 10 CFR 30.35(a)(1) requirement to have and submit a DFP to the NRC.

(ii) Although it contained a copy of a generic return agreement between Pharmalogic and E&Z, that agreement was unclear as to the legally binding effect on E&Z and the licensee, with respect to the above-referenced license.

Accordingly, please submit a legally binding agreement between the manufacturer and the licensee. At a minimum, in addition to information already contained in the submitted generic agreement, the document should:

a. Include the licensee's name and license number;

b. Be signed and dated by either you or other duly authorized representative of Radiopharmacy Incorporated, including an organizational chart or description explaining that individual's authority to sign on behalf of the licensee;

c. Be co-signed and dated by a duly-authorized E&Z representative, including a legibly printed or typed name and title;

d. Be notarized or otherwise authenticated as a legally binding document;

e. Include a manufacturer or distributor commitment to accept expired generators from the licensee, regardless of the licensee's financial status or shipping specifications, etc. (any "return guidelines" that are required as part of the agreement should be included with the agreement for NRC review); and

f. Include any additional requirements specified in NRC's July 29, 2016 exemption memo and enclosure.

(iii) To date, no FA has been submitted on behalf of Radiopharmacy, Inc., 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 FA documents 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." FA must be in place and complete prior to amending the NRC license for possession of this material.

Please provide a written response to this letter by February 10, 2017. Your response should be dated and signed by authorized personnel. You may submit your response via facsimile to my attention at (630) 515-1078. Include the reference control number 592549 with your response. We will resume our review once we receive your response. If you have any questions, or if you need additional time to submit requested information, please do not hesitate to contact me at 630-829-9892 or sara.forster@nrc.gov.

Sincerely,

Sara A. Forster

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch

License No. 13-26246-01MD
Docket No. 030-31910

Forster, Sara

From: Forster, Sara
Sent: Friday, January 27, 2017 2:28 PM
To: 'rvansant@pharmalogic.info'; 'jwilson@radiopharmacy.com'
Subject: Additional Information Request for Radiopharmacy Incorporated, NRC Lic. No. 13-26246-01MD, CN592549
Attachments: 02500 592549 13-26246-01MD Radiopharmacy Incorporated RFAI telecon.docx

Dear Mr. Van Sant and Mr. Wilson:

Please see the attached file for additional information needed to complete the review of one recent amendment request for NRC Lic. No. 13-26246-01MD. I spoke with Mr. Van Sant this afternoon regarding the December 7, 2016, letter requesting to add an authorization for receipt, use and possession of Ge-68/Ga-68 generators, as Mr. Van Sant is listed as the designated contact person on that request. Note that the attached conversation record requests additional information on or before the close of business on February 10, 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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United States Nuclear Regulatory Commission
Protecting People and the Environment