

**From:** [Nguyen, Janice](#)  
**To:** [Richard Van Sant \(rvansant@pharmalogic.info\)](mailto:rvansant@pharmalogic.info)  
**Subject:** NRC Request for Additional Information for PharmaLogic WV, Ltd. (Mail Control Number 592430)  
**Date:** Friday, January 13, 2017 12:58:00 PM

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Licensee: PharmaLogic WV, Ltd.  
License No.: 47-25375-01MD  
Docket No.: 030-34289  
Control No.: 592430

**PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL**

Dear Mr. Van Sant:

This is in reference to your letter dated November 11, 2016, requesting to amend Nuclear Regulatory Commission License No. 47-25375-01MD. In order to continue our review, we need the following additional information:

1. The letter dated November 11, 2016 was not signed. Either resubmit the letter with management signature, or submit a signed statement that you concur with all information and commitments made in the letter dated November 11, 2016.
2. Please confirm that the maximum possession limit requested is 100 mCi of Ge-68 and 100 mCi of Ga-68. In addition, please confirm the maximum number of Eckert and Ziegler GalliaPharm generators that will be possessed at one time, per location.
3. Please confirm that the authorized use will be "for use of the Eckert and Ziegler GalliaPharm generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies."
4. Please provide a description of where the Eckert and Ziegler GalliaPharm generator(s) will be received and stored.
5. Please confirm that you are not requesting that James Cordonier II, R.Ph., Kevin Hart, R.Ph., and Richard Sucese, R.Ph. be Authorized Nuclear Pharmacists for the Eckert and Ziegler GalliaPharm generator.
6. Please confirm that you are requesting an exemption to 10 CFR 30.35(a)(1), which requires that you have a Decommissioning Funding Plan (DFP) to obtain a license to possess Ge-68/Ga-68 generators. Exemption guidance is found in the July 29, 2016 memorandum (Agencywide Documents Access and Management Accession No. ML16082A415).
7. Please confirm if you wish to be authorized to make minor revisions to your Eckert and Ziegler GalliaPharm generator program, and that you will follow the conditions below. An applicant initially applying for authorization for the use of the Eckert and Ziegler GalliaPharm generator for preparation of Ga-68 radiopharmaceuticals for imaging and localization studies for may request to incorporate into its license a change process similar to 10 CFR 35.26. Such a change process can allow some

future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

- 1) The revision does not require a license amendment under 10 CFR 35.13; and
- 2) the revision is based upon NRC's current guidance for use of the Eckert and Ziegler GalliaPharm generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000 posted on the NRC Medical Uses Licensee Toolkit;
- 3) the revision has been reviewed and approved by the licensee's Radiation Safety Officer and management; and
- 4) the affected individuals are instructed on the revised program before the change is implemented; and
- 5) the licensee will retain a record of each change for five years; and
- 6) the record will include a copy of the current guidance for use of the Eckert and Ziegler GalliaPharm generator to prepare Ga-68 radiopharmaceuticals for imaging and localization studies under 10 CFR 35.1000, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

If approved, these conditions for use of updated guidance will be incorporated as license conditions in the licensee's license.

8. In your application for the Eckert and Ziegler GalliaPharm Germanium-68/Gallium-68 Pharmacy Grade Generator, it appears you will be requesting an exemption from having a Decommissioning Funding Plan (DFP) in accordance with 10 CFR Section 30.35, "Financial Assurance and Recordkeeping for Decommissioning." In a July 29, 2016 memorandum (Agencywide Documents Access and Management Accession No. ML16082A415) the NRC determined that an exemption to the DFP requirement for medical Ge-68/Ga-68 generators may be granted under certain circumstances. Therefore, licensees may request an exemption to providing a decommissioning funding plan and provide a signed agreement with Eckert and Ziegler to return the generators to them. In addition, in accordance with 10 CFR 30.35, licensees must continue to submit Financial Assurance (FA), when warranted. The amount of FA to be submitted would be based on the number of generators possessed. For instance, licensees possessing more than 2 and up to 20 Ge-68 generators (with an estimated activity of >100 to 1000 mCi) would be subject to the requirement in § 30.35(d) for a minimum \$1,125,000 in financial assurance for the decommissioning of site(s). Licensees possessing one or two Ge-68 generators (50 to 100 mCi) would be subject to a \$225,000 FA minimum. Please provide the financial assurance documents required by 10 CFR 30.35. Please refer to NUREG-1757, Volume 3, Section A.4 for guidance. Checklist 1 may be helpful for determining the mechanism that will be used and the supporting documents that require submission. FA must be in place and complete prior to amending the NRC license for possession of this material.

We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 592430. Please submit a reply within 30 days. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits**, see our **toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Thank you in advance for your help!

Sincerely,

*Jan*

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