



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

August 7, 2018

Reid Gadziala, Pharm.D., BCNP, MBA
Director, Quality and Regulatory Affairs
PharmaLogic Ltd.
1191 S. Brownell Road, Suite 40
Williston, VT 05495

**SUBJECT: PHARMALOGIC LTD., LICENSE AMENDMENT AND ACCEPTANCE OF
FINANCIAL ASSURANCE, MAIL CONTROL NOS. 609115 AND 609189**

Dear Dr. Gadziala:

This refers to your license amendment request dated June 14, 2018. Please find enclosed Amendment No. 35 authorizing the Eckert and Ziegler GalliaPharm™ Ge-68/Ga-68 generator.

Please note that since there are no additional training requirements required by the NRC for the Authorized Nuclear Pharmacists, it is at the licensee's discretion to limit users to those trained by the licensee and/or manufacturer.

We have reviewed your documents dated June 12, 2018, your document received June 20, 2018, and your letter dated July 9, 2018, with attachments, and found them to meet the financial assurance requirements for your license. We have no further questions at this time.

It was noted that on your Standby Trust Agreement (STA), Schedule A, you indicated that the cost estimates listed here were last adjusted and approved by NRC on June 12, 2018. Since you have a legally binding agreement in place with the manufacturer for the return of the Germanium-68/Gallium-68 generators, and have financial assurance (FA) in place using certification amounts prescribed by the table in 10 CFR 30.35, you are not required to have a Decommissioning Funding Plan in accordance with the Memorandum, "Revision of Technical Basis for Granting Specific Exemption from Decommissioning Funding Plan Requirement for Germanium-68/Gallium-68 Generators," dated July 13, 2017 [ML17075A487]. Therefore, this statement was not required. You may remove this statement when the STA is amended.

The following documents currently provide your financial assurance:

Standby Trust Agreement dated June 12, 2018 [ML18180A324 and ML18205A352]
Letter of Credit dated June 12, 2018 [ML18176A292]
Certification of Financial Assurance received June 20, 2018 [ML18180A324]

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at (610) 337-5006 or via electronic mail at janice.nguyen@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at:

<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,



Janice Nguyen, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

License No. 44-30124-01MD
Docket No. 030-33449
Mail Control Nos. 609115 and 609189

Enclosure:
Amendment No. 35

cc: Robert S. Hickman, Pharm.D.
Radiation Safety Officer

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Thank you for your cooperation.

Sincerely,

Janice Nguyen, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
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cc: Robert S. Hickman, Pharm.D.
Radiation Safety Officer

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