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**PharmaLogic**
Take The Lead

October 17, 2018

J9

US Nuclear Regulatory Commission, Region 1
Division of Nuclear Materials Safety
Attn: Medical and Licensing Assistance Branch
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406

Subject: RAM License Amendment, License # 030-34289/47-25375-01MD

Dear Sir or Madam,

PharmaLogic, West Virginia is requesting an amendment to the license referenced above to add an authorized user, Reid Gadziala, RPh. Attached to this request is a copy of the RAM license from our Virginia facility listing him as an authorized nuclear pharmacist. If you need any additional information, please do not hesitate to reach out.



Reid Gadziala, PharmD., BCNP
PharmaLogic Holdings Corp.
Director, Quality and Regulatory Affairs
rgadziala@pharmalogic.info

[REDACTED]

PharmaLogic Holdings Corp
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Phone: 561-416-0085 • Website: www.pharmalogic.info

610245

NUCLEAR MATERIALS-001

REC'D IN LAT 10/17/2018



**COMMONWEALTH OF VIRGINIA
DEPARTMENT OF HEALTH**

RADIOACTIVE MATERIALS LICENSE

Under the Code of Virginia Section 32.1-229.3 and 12VAC5-481, Virginia Radiation Protection Regulations, and in reliance on statements and representations made by the licensee, a license is issued authorizing the licensee to receive, acquire, possess and transfer radioactive material designated below; to use the material for the purpose(s) and at the place(s) designated below; and to deliver or transfer the material to persons authorized to receive it in accordance with 12VAC5-481, Virginia Radiation Protection Regulations. This license is subject to all applicable rules and orders of the Virginia Department of Health now or hereafter in effect, and to any conditions specified below.

<p align="center">Licensee Name and Address</p> <p>1. Blue Ridge Isotopes, LLC</p> <p>2. 1630 Midland Road Salem, VA 24153</p>	<p>In accordance with letters dated May 31, 2018</p> <p>3. License Number: 161-449-1 is hereby amended to read as follows.</p> <hr/> <p>4. Amendment No.: 10</p> <hr/> <p>5. Expiration Date: August 31, 2022</p>
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6. Radioactive material	7. Chemical and/or physical form	8. Maximum amount of radioactive materials that the licensee may possess at any one time under this license:	9. Authorized Use:
A. Any radioactive materials with Atomic Numbers 1-83 except those specifically listed below	A. Any	A. 100 millicuries per radionuclide; 1 curie total	A through H: Preparation and distribution of radioactive drugs to authorized recipients in accordance with 12VAC5-481-480 I. Preparation and distribution of radioactive drugs and radiochemicals to authorized recipients for non-medical use.
B. Yttrium-90	B. Any	B. 200 millicuries	
C. Molybdenum-99	C. Any	C. 200 curies	
D. Technetium-99m	D. Any	D. 200 curies	
E. Iodine-131	E. Any	E. 3 curies	
F. Xenon-133	F. Any	F. 2 curies	
G. Samarium-153	G. Any	G. 500 millicuries	
H. Fluorine-18	H. Any	H. 10 curies	

RADIOACTIVE MATERIALS LICENSE

License Number: 161-449-1

Amendment No: 10

I. Any radioactive material approved by 12VAC5-481-2010	I. Sealed source	I. No single source to exceed the maximum amount listed on the Sealed Source and Device Registry (SSD); total not to exceed 1 curie	I. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 12VAC5-481-480 J. Redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.
J. Any radioactive material permitted by 12VAC5-481-430 G	J. Prepackaged units	J. 50 millicuries	J. Redistribution to specific licensees pursuant to 12VAC5-481-430 G provided the packaging and labeling remain unchanged.
K. Any radioactive material permitted by 12VAC5-481-1830	K. Sealed source	K. No single source to exceed the maximum amount listed on the Sealed Source and Device Registry (SSD); total not to exceed 300 millicuries	K. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 12VAC5-481-480 J.
L. Depleted Uranium	L. Metal	L. 999 kilograms	L. Shielding for molybdenum-99/technetium-99m generators.
M. Germanium-68	M. Any	M. 100 millicuries	M. and N. For use of Eckert and Ziegler GalliaPharm generators to prepare Gallium-68 radiopharmaceuticals for imaging and localization studies.
N. Gallium-68	N. Any	N. 100 millicuries	

CONDITIONS

10. Licensed material may only be used or stored at the licensee's facilities located at 1630 Midland Road, Salem, Virginia.
11. **The Radiation Safety Officer for this license is Jessica Comstock, Pharm.D.**

RADIOACTIVE MATERIALS LICENSE

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12. Licensed material shall be used by, or under the supervision of:
- A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 12VAC5-481-480 I 2.
- B. Authorized Nuclear Pharmacists:**
- | | |
|-----------------------------|-------------------------------|
| David Arnold, Pharm.D. | Ware Mitchell, Pharm.D. |
| Jessica Comstock, Pharm.D. | Glen Palmer, R.Ph. |
| Reid Gadziala, R.Ph. | Sarah Skeele, Pharm.D. |
| Bynum Kimmons, R.Ph. | Jeremiah Taylor, Pharm.D. |
| Jon L. McReynolds, Pharm.D. | Anna Wierzbicki, R.Ph. |
13. The licensee is authorized to transport licensed material in accordance with the provisions of Chapter 481, Part XIII, 'Transportation of Radioactive Material.'
14. This license does not authorize commercial distribution of licensed material to persons exempt from licensing pursuant to 12VAC5-481-400.
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
16. Per 12VAC5-481-740, no sealed source shall be stored for a period of more than 5 years without being tested for leakage or contamination
17. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers, limited to radiopharmacy supplied syringes and vials and their contents.
18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 12VAC5-481-450 C for establishing decommissioning financial assurance, except that the licensee is exempt from the requirements of 12VAC5-481-450 C with respect to germanium-68/gallium-68 generators returned to the distributor in accordance with letter dated June 29, 2017.
19. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Surveys the waste at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background.
- B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers that will be managed as biomedical waste after they have been released from the licensee; and

RADIOACTIVE MATERIALS LICENSE

License Number: 161-449-1

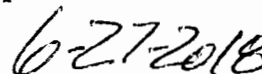
Amendment No: 10

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. Chapter 481 'Virginia Radiation Protection Regulations' shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated June 29, 2017.
B. Letter dated April 11, 2018.
C. **Letter dated May 31, 2018.**

FOR THE VIRGINIA DEPARTMENT OF HEALTH



MICHAEL L. FULLER
DIRECTOR RADIOACTIVE MATERIALS PROGRAM



DATE



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee PharmaLogic WV, Ltd. ATTN: Reid Gadziala, Pharm.D., BCNP, MBA Director, Quality and Regulatory Affairs 9 W. Benedum Industrial Park Drive Bridgeport, WV 26330	Date October 17, 2018
	License Number(s) 47-25375-01MD
	Mail Control Number(s) 610245
	Licensing and/or Technical Reviewer or Branch Tara Weidner

This is to acknowledge receipt of your: Letter and/or Application Dated: 10/17/2018

The initial processing, which included an administrative review, has been performed.
 Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
 Follow the instructions on the form for submission.

The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239