PharmaLogic
Take The Lead

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January 26, 2017

Regional Administrator
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406-1415

Subject: NRC RAM License Amendment, License # 44-30124-01MD 03033449

Dear Sir:

PharmaLogic Ltd is requesting an amendment to the Nuclear Regulatory Commission RAM License # 44-30124-01MD to add Steve Green, PharmD as Authorized Nuclear Pharmacist (ANP).

Steve Green is recognized as an ANP on NRC RAM 47-25375-01MD and is a licensed VT pharmacist with license number 033.0122929. I have enclosed both for your reference.

Regards,

Richard L. Van Sant, PharmD
Director Regulatory Affairs
PharmaLogic

592895

PharmaLogic Holdings Corp
1 South Ocean Blvd, Suite 206 • Boca Raton, FL 33432
Phone: 561-416-0085 • Website: www.pharmalogic.info

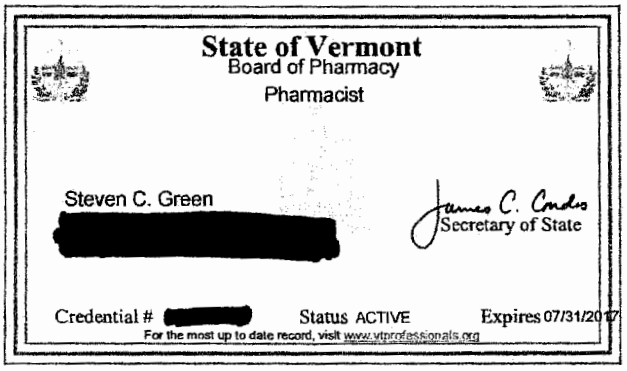
State of Vermont
Board of Pharmacy
Pharmacist

Credential #: [redacted]
Status: ACTIVE
Effective: 01/26/2017
Expires: 07/31/2017

Steven C. Green
[redacted]

James C. Condos
Secretary of State

For the most accurate and up to date record of licensure, please visit www.vtprofessionals.org



PERSONAL INFORMATION WAS REMOVED
[illegible] COPY OF THIS INFORMATION
[illegible] RETAINED BY THE NRC.

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 23

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated July 17, 2013,
1. PharmaLogic WV, Ltd.	3. License No. 47-25375-01MD is amended in its entirety to read as follows:
2. 9 W. Benedum Industrial Park Bridgeport, West Virginia 26330	4. Expiration Date: October 31, 2022
	5. Docket No. 030-34289

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 1 through 83, except strontium-89, yttrium-90, molybdenum-99, technetium-99m, iodine-131, xenon-133, and samarium-153	A. Any	A. 200 millicuries per radionuclide and 2 curies total
B. Fluorine 18	B. Any	B. 1 curie
C. Gallium 67	C. Any	C. 500 millicuries
D. Strontium 89	D. Any	D. 80 millicuries
E. Yttrium 90	E. Any	E. 1 curie
F. Molybdenum 99	F. Any	F. 200 curies
G. Technetium 99m	G. Any	G. 200 curies
H. Indium 111	H. Any	H. 300 millicuries
I. Iodine 123	I. Any	I. 50 millicuries
J. Iodine 131	J. Any	J. 5 curies
K. Xenon 133	K. Any	K. 3 curies
L. Samarium 153	L. Any	L. 1.5 curies
M. Thallium 201	M. Any	M. 1 curies

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 47-25375-01MD

Docket No. 030-34289

Amendment No. 23

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
N. Any byproduct material permitted by 10 CFR 35.400	N. Sealed sources (Bard Brachytherapy Inc. Model STM 1251; IsoAid L.L.C. Model IAI-125A; North American Scientific Model MED 3631, or MED 3633; Theragenics Model 200; Best Medical Models 2301-2308, 2309-2316, or 2331-2335)	N. 0.5 curies
O. Any byproduct material permitted by 10 CFR 31.11	O. Prepackaged units for *in vitro* diagnostic tests	O. 100 millicuries
P. Any byproduct material permitted by 10 CFR 35.65(a)	P. Sealed sources (International Isotopes Idaho Inc. Model BM06E series, BM06S series, BM03-XXA and BM03-XXL series; North American Scientific Inc. Model Med 3503, MED 3550, MED 3400 or MED 3402; Isotopes Product Laboratories Model RV-XXX series, EG-XXX series, and GF Type R Series)	P. 100 millicuries
Q. Depleted Uranium	Q. Metal	Q. 400 kilograms

9. Authorized use:

A. - M. Preparation and distribution of radioactive drugs, production of technetium 99m pertechnetate, compounding of iodine 131 and distribution of unused and used molybdenum 99/technetium 99m generators to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.

N. Redistribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

O. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.

P. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.

Q. Shielding for molybdenum-99/technetium-99m generators.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 47-25375-01MD

Docket No. 030-34289

Amendment No. 23

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 5842B Davis Creek Road, Barboursville, West Virginia and 9 W. Benedum Industrial Park Road, Bridgeport, West Virginia.

11. 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 10 CFR 32.72(b)(2)(i) or (4).

    B. Authorized nuclear pharmacists: James Cordonier II, R.Ph., David Ellis, R.Ph., William Gillette, R.Ph., Steven C. Green, R.Ph., Shelby Griffith, R.Ph., Renae Hamilton, R.Ph., Kevin Hart, R.Ph., Matthew W. Hinton, R.Ph., Garth Kistner, R.Ph., Peteris Kruze, R.Ph., Joseph Lofaro, R.Ph., Shawn Lorrain, R.Ph., Glen Palmer, R.Ph., Laurie Stallings, R.Ph., BCNP, Gerald Strugala, R.Ph., BCNP, Richard Sucese, R.Ph., Timothy Summers, R.Ph., Dana Suttle, R.Ph., Teresa Tribe, R.Ph., Tamiko Ushio, R.Ph., and Zonker White, R.Ph.

12. The Radiation Safety Officer (RSO) for this license is Timothy Summers, R.Ph.

13. 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 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. This license does not authorize commercial distribution of licensed material to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.

15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 47-25375-01MD

Docket No. 030-34289

Amendment No. 23

D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U. S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for five years.

16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U. S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for five years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

18. The licensee is authorized to hold byproduct 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. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 47-25375-01MD

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Amendment No. 23

C. Maintains records of the disposal of licensed materials for three years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. 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.

20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

21. 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. The U. S. Nuclear Regulatory Commission's 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 April 26, 2012 [ML12122A214]
B. Letter dated June 19, 2012 [ML12178A539]
C. Letter dated September 6, 2012 [ML12263A215]
D. Application dated November 16, 2012 [ML1234A305]
E. Letter dated January 10, 2013 [ML13029A564]
F. Letter dated January 23, 2013 [ML13024A257]

For the U. S. Nuclear Regulatory Commission

Original signed by Dennis R. Lawyer

Date August 2, 2013 By _____

Dennis R. Lawyer
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

PharmaLogic Ltd.
ATTN: Richard L. Van Sant, R.Ph., Manager
1191 S. Brownell Road, Suite 40
Williston, VT 05495

Date
February 1, 2017

License Number(s)
44-30124-01MD

Mail Control Number(s)
582895

Licensing and/or Technical Reviewer or Branch
Medical Branch (Branch 1)

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 01/26/2017

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