PHARMA-LOGIC
THE LOGICAL CHOICE

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December 8, 2011

Regional Administrator
U.S. Nuclear Regulatory Commission
Region I
Commercial and R&D Branch
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

03033449

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

Dear Sir:

PharmaLogic Ltd is requesting an amendment to the Nuclear Regulatory Commission RAM License # 44-30124-01MD to change the Radiation Safety Officer to **Richard Sucese, RPh.**

PharmaLogic Ltd is also requesting to add **Matthew W. Hinton, RPh** as an authorized user, please reference (attached) NRC RAM License # 47-25375-01MD for credentials.

PharmaLogic Ltd is also requesting to add **Zonker White, RPh** as an authorized user, please reference (attached) PA DEP License # PA-0730.

Thank you,

R. Sucese

Richard Sucese, PharmD, RPh
Facility Manager

PharmaLogic Ltd
9 Krupp Drive ♦ P.O. Box 786 ♦ Williston, VT 05495
802-862-9944 ♦ Fax: 802-863-1633

574519

NMSS/RGN1 MATERIALS-002

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 17

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, December 10, 2010,
1. PharmaLogic WV, Ltd.	3. License No. 47-25375-01MD is amended in its entirety to read as follows:
2. 109 Platinum Drive Suite A Bridgeport, West Virginia 26330-2007	4. Expiration Date: May 31, 2012
	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. Flourine 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
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

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 47-25375-01MD

Docket No. 030-34289

Amendment No. 17

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
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)	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.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 109 Platinum Drive, Suite A, Bridgeport, West Virginia; and 5842B Davis Creek Road, Barboursville, West Virginia.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 47-25375-01MD

Docket No. 030-34289

Amendment No. 17

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: Glen Palmer, R.Ph., William M. Chatoff, R.Ph., Thomas Defranco, R.Ph., Shawn P. Lorrain, R.Ph., Gerald Strugala, R.Ph., Timothy Summers, R.Ph., Matthew W. Hinton, Pharm D., and Garth Kistner, R.Ph.

12. The Radiation Safety Officer (RSO) for this license is Glen Palmer, 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.

    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.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No. 47-25375-01MD

Docket No. 030-34289

Amendment No. 17

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

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."

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MATERIALS LICENSE SUPPLEMENTARY SHEET	License No. 47-25375-01MD
	Docket No. 030-34289
	Amendment No. 17

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 July 1, 1996
B. Letter dated August 12, 1996
C. Letter dated October 14, 1996
D. Letter dated November 14, 1996
E. Letter dated February 11, 1997 [ML030770843]
F. Letter dated February 24, 1997 [ML030770839]
G. Letter dated March 4, 1997 [ML030770828]
H. Letter dated March 6, 1997 [ML030770834]
I. Letter dated June 15, 1998 [ML030770817]
J. Letter dated March 21, 2000 [ML003694946]
K. Letter dated January 30, 2001 [ML010390311]
L. Letter dated May 4, 2001 [ML011290352]
M. Letter dated June 4, 2001 [ML011570496]
N. Letter dated August 28, 2001 [ML012500043]
O. Application dated December 5, 2001 [ML013410308]
P. Letter dated December 18, 2002 [ML023570443]
Q. Letter dated January 24, 2006 [ML060240178]
R. Letter dated September 21, 2007 [ML072700136]
S. Letter dated December 10, 2007 [ML073480318]
T. Letter dated January 3, 2008 [ML080040109]
U. Letter dated June 2, 2009 [ML091530323]

For the U. S. Nuclear Regulatory Commission

Date December 15, 2010

By

Dennis R. Lawyer
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406
Wednesday, December 15, 2010 10:13:18

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pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF RADIATION PROTECTION

RADIOACTIVE MATERIALS LICENSE

Page 1 of 5 Pages

License No. PA-0730

Amendment No. 20

Pursuant to the Radiation Protection Act, the Act of July 10, 1984 (No. 147, P.L. 688)(35 P.S. §§ 7110.101 – 7110.703) and Title 25, Rules and Regulations, Article V, Radiological Health of the Pennsylvania Department of Environmental Protection, and in reliance on statements and representations heretofore Licensee to receive, acquire, possess, transfer, and use radioactive material listed below for the purposes and at the places designated below. This license shall be deemed subject to all applicable rules, regulations, or orders of the Pennsylvania Department of Environmental Protection now or hereafter in effect and to any conditions specified below.

Licensee	In response to correspondence dated October 17, 2011
1. Pharmalogic Penn Ltd.	3. License No. PA – 0730 is amended as follows:
2. 2608 Elmira Street Suite 3 Sayre, PA 18840	4. Expiration Date: August 31, 2014
	5. Client ID: 2009 Program Code: 2500 Priority: 2

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 3 through 83, except fluorine 18(FDG), yttrium 90, molybdenum 99, technetium 99m, xenon 133, iodine 131, samarium 153 and thallium 201	A. Any, except sealed sources	A. Not to exceed 100 millicuries per total radionuclide and 1 curie total
B. Fluorine 18	B. Fludeoxyglucose (FDG)	B. 1 curie
C. Yttrium 90	C. Any, except sealed sources	C. 300 millicuries
D. Molybdenum 99	D. Any, except sealed sources	D. 100 curies
E. Technetium 99m	E. Any, except sealed sources	E. 100 curies
F. Iodine 131	F. Any, except sealed sources	F. 5 curies
G. Xenon 133	G. Any, except sealed sources.	G. 1.5 curies
H. Samarium 153	H. Any, except sealed sources.	H. 800 millicuries
I. Thallium 201	I. Any, except sealed sources	I. 2.5 curies
J. Any byproduct material in a brachytherapy source as permitted by 10 CFR 35.400	J. Sealed sources (North American Scientific Model No. MED3631	J. 500 millicuries
K. Any byproduct material listed in 10 CFR 31.11 (a)	K. Prepackaged kits for in-vitro diagnostic tests	K. 50 millicuries

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pennsylvania DEPARTMENT OF ENVIRONMENTAL PROTECTION	COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF ENVIRONMENTAL PROTECTION BUREAU OF RADIATION PROTECTION	Page 2 of 6 Pages License No. PA-0730
	RADIOACTIVE MATERIALS LICENSE	Amendment No. 20

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
L. Any byproduct material authorized under 10 CFR 35.65(a)	L. Sealed sources (Analytics, Inc., Model EGAG60; Dupont Model NES-356; International Isotopes Idaho, Inc, Models BM06-33 & BM06-37; Radqual Model BM06-157	L. 60 millicuries
M. Any byproduct material with atomic numbers 1 through 83	M. Analytical samples	M. 1 millicurie

9. Authorized use:

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

J. Distribution and/or redistribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

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

L. Calibration and checking of the licensee's instruments. Redistribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

M. For possession incident to the performance of leak testing of customer's sealed sources.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located 2608 Elmira Street, Suite 3, Sayre, PA 18840.

11. The Radiation Safety Officer for this license is: Zonker K. White, R.Ph.

12. Licensed material shall be used by, or under the direct 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. The following individuals are authorized nuclear pharmacists:

William Chatoff, R.Ph., Thomas DeFranco, R.Ph., Joseph Lofaro, R.Ph., Shawn P. Lorrain, R.Ph., Laurie E. Stallings, PharmD., R.Ph., Gerald Strugal, R.Ph., BCNP, Zonker K. White, R.Ph.

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C. Authorized Users: Robert Cole

Authorized Uses: 9.J, 9.K, 9.L and 9.M only. Any uses permitted by 9.A through 9.I may only be performed under the supervision of an Authorized Nuclear Pharmacist.

13. Sealed sources shall not be opened.

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. 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 and incorporated by reference in 10 CFR 30.35(d) for establishing financial assurance for decommissioning.

16. The licensee shall conduct a physical inventory every six (6) 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 (5) 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.

17. The licensee may transport licensed material or deliver licensed material to a carrier for transport, in accordance 25 Pa Code Chapter 230, "Packaging and Transportation of Radioactive Material" and the provisions of 10 CFR Part 71 incorporated by reference.

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

B. 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.

C. 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.

D. 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 Department 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 Department regulations.

E. 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 the US Regulatory Commission or an Agreement State to perform such services.

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F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.

G. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

19. Notwithstanding the requirements of 10 CFR 20.1904(b), the licensee is authorized to remove or dispose of empty uncontaminated containers (syringes and vials) to unrestricted areas without removing or defacing the radioactive material labels or otherwise indicating that the container no longer contains radioactive materials provided the waste containers are deposited in waste barrels that will be incinerated and are delivered directly from the licenee's facility to the incinerator without being opened at any point and for any reason, prior to incineration.

20. 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.

21. 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 it:

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

C. Maintains records of disposal of licensed material for 3 years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, 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.

22. Notwithstanding the requirements set forth in this license, the licensee shall comply with the regulations set forth in Title 25 of the Pennsylvania Code, Article V "Radiological Health" and the U.S. Nuclear Regulatory Commission, Title 10 Code of Federal Regulations Parts 19-150 incorporated by reference.

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23. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The Department of Environmental Protection's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Renewal Application dated May 20, 2004 (DEP)
B. Application dated July 15, 2005 (NRC)
C. Letter dated September 16, 2005 (NRC)
D. Facsimile received September 28, 2005 (NRC)
E Letter dated October 21, 2005 (DEP)
F Letter dated December 16, 2005 (DEP)
G Letters dated April 4, 2007 and April 9, 2007 (DEP)

For the Pennsylvania Department of Environmental Protection

John S. Chippo
Bureau of Radiation Protection
P. O. Box 8469
Harrisburg, PA 17105-8469

Date: November 1, 2011

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This is to acknowledge the receipt of your letter/application dated

12/8/2011, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (44-30124-01 MD)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 576519.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader