

Pharma
Take The Lead

Br. 1

5/29/2014

To: Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

From: Rich Sucese, Pharm.D., RPh, RSO
PharmaLogic, Ltd
1191 S Brownell Rd, Ste 40
Williston, VT 05495

Re: Request to renew materials license
License Number 44-30124-01MD/030-33449

REC'D 05/29/14 11:05

Dear Sir or Madam:

PharmaLogic, Ltd is requesting the renewal of our radioactive materials license, 44-30124-01MD.

Form 313 and a copy of our current license are attached. Please note a recently submitted license amendment, Docket No. 03033449, Control No. 579544, contains all information pertaining to items 5 – 11 on form 313.

Thank you in advance for your consideration of this request.

Sincerely,

Rich Sucese, Pharm.D, RPh, RSO
Pharmacy Manager
PharmaLogic, Ltd

ATT: NRC Form 313

PharmaLogic, Ltd license 44-30124-01MD

PharmaLogic Ltd
1191 S Brownell Rd, Ste 40 ♦ Williston, VT 05495
802-862-9944 ♦ Fax: 802-863-1633

584038
NMSS/RGNI MATERIALS-002

NRC FORM 313 (03-2014) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40 U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE	APPROVED BY OMB: NO. 3150-0120 Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollections.Resource@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection. EXPIRES: 05/31/2015																		
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.																			
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001 ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713	IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 Lisle, IL 60532-4352 ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON, TX 76011-4511																		
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.																			
1. THIS IS AN APPLICATION FOR <i>(Check appropriate item)</i> <input type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <input checked="" type="checkbox"/> C. RENEWAL OF LICENSE NUMBER <u>44-30124-01MD</u>	2. NAME AND MAILING ADDRESS OF APPLICANT <i>(Include ZIP code)</i> PharmaLogic, Ltd 1191 S. Brownell Road, Suite 40 Williston, VT 05495																		
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED 1191 S. Brownell Road, Suite 40 Williston, VT 05495	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Richard Sucece <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">BUSINESS TELEPHONE NUMBER 8028629944</td> <td style="width: 50%;">BUSINESS CELLULAR TELEPHONE NUMBER 8023559071</td> </tr> <tr> <td colspan="2">BUSINESS EMAIL ADDRESS rsucece@pharmalogic.info</td> </tr> </table>	BUSINESS TELEPHONE NUMBER 8028629944	BUSINESS CELLULAR TELEPHONE NUMBER 8023559071	BUSINESS EMAIL ADDRESS rsucece@pharmalogic.info															
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SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.																			
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.																		
8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.	7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.																		
10. RADIATION SAFETY PROGRAM.	9. FACILITIES AND EQUIPMENT.																		
12. LICENSE FEES <i>(Fees required only for new applications, with few exceptions*)</i> <i>(See 10 CFR 170 and Section 170.31)</i>	11. WASTE MANAGEMENT.																		
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13. CERTIFICATION. <i>(Must be completed by applicant)</i> THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.																			
CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE Richard Sucece, PharmD, RPh, RSO	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">SIGNATURE </td> <td style="width: 50%;">DATE <u>5/29/14</u></td> </tr> </table>	SIGNATURE 	DATE <u>5/29/14</u>																
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NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 6 PAGES

Amendment No. 27

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.

<p>Licensee</p> <p>1. PharmaLogic Ltd.</p> <p>2. 1191 S. Brownell Road, Suite 40 Williston, Vermont 05495</p>	<p>In accordance with the letter dated January 24, 2014,</p> <p>3. License number 44-30124-01MD is amended in its entirety to read as follows:</p> <p>4. Expiration date September 30, 2014</p> <p>5. Docket No. 030-33449 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 3 through 83, except as listed below</p> <p>B. Fluorine 18</p> <p>C. Gallium-67</p> <p>D. Strontium 89</p> <p>E. Yttrium 90</p> <p>F. Molybdenum 99</p> <p>G. Technetium 99m</p> <p>H. Indium 111</p> <p>I. Iodine 123</p> <p>J. Iodine 131</p> <p>K. Xenon 133</p> <p>L. Samarium 153</p> <p>M. Thallium 201</p> <p>N. Any byproduct material permitted by 10 CFR 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> <p>I. Any</p> <p>J. Any</p> <p>K. Any</p> <p>L. Any</p> <p>M. Any</p> <p>N. Prepackaged units for <u>in vitro</u> diagnostic tests</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 200 millicuries per radionuclide and 2 curies total</p> <p>B. 1 curie</p> <p>C. 500 millicuries</p> <p>D. 40 millicuries</p> <p>E. 500 millicuries</p> <p>F. 100 curies</p> <p>G. 100 curies</p> <p>H. 300 millicuries</p> <p>I. 50 millicuries</p> <p>J. 2.5 curies</p> <p>K. 1.5 curie</p> <p>L. 750 millicuries</p> <p>M. 1 curie</p> <p>N. 50 millicuries</p>

NRC FORM 374A

PAGE 2 OF 6 PAGES

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number
44-30124-01MD

Docket or Reference Number
030-33449

Amendment No. 27

O. Any byproduct material
permitted by 10 CFR 35.65(a)

O. Sealed Sources
(E.I. DuPont Model NES-356;
International Isotopes Model
BM03-57L and BM03-57A;
International Isotopes Idaho,
Inc., Model, BM06-37, BM06-
90, BM08-37, BM08-371,
BM06E series, and BM06S
series; North American
Scientific Model MED3550,
MED3400, MED3402,
MED3550, and MED3503; and
Isotope Products Laboratories
Model GF-152-R2, GF-152-R3,
RV-XXX series, and EG-133-
MX6-5U)

O. 100 millicuries

P. Any byproduct material
permitted by 10 CFR 35.400

P. Sealed Sources (Bard
Brachytherapy Model STM
1251; IsoAid, LLC Model IAI-
125A; Teragenics Theraseed
Model 200; North American
Scientific Model MED3631 and
MED 3633)

P. 500 millicuries

Q. Any byproduct material with
atomic numbers 2 through 83

Q. Analytical samples

Q. As needed (see Item 9.Q.)

R. Depleted Uranium

R. Solid

R. 400 kilograms

9. Authorized use:

A. through M. Preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

F. and G. Redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients.

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

NRC FORM 374A

PAGE 3 OF 6 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
44-30124-01MDDocket or Reference Number
030-33449

Amendment No. 27

- O. 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.
- P. Redistribution for medical use of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution for non-medical use of sealed sources that have been registered either with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess and use the devices.
- Q. For possession incident to the performance of leak testing of customers' sealed sources.
- R. Shielding for molybdenum-99/technetium-99m generators.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 1191 S. Brownell Road, Suite 40, Williston, Vermont.
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., 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, Gerard Strugala, R.Ph., BCNP, Richard Sucese, R.Ph., Timothy Summers, R.Ph., Dana Suttle, R.Ph., Teresa Tribe, R.Ph., Tamiko Ushio, R.Ph., Richard L. Van Sant, R.Ph., Ruth Mary Wetzel, R.Ph., or Zonker White, R.Ph.
12. The Radiation Safety Officer for this license is Richard Sucese, 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 generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.

NRC FORM 374A

PAGE 4 OF 6 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

44-30124-01MD

Docket or Reference Number

030-33449

Amendment No. 27

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 3 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.
- 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 5 years.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

NRC FORM 374A

PAGE 5 OF 6 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

44-30124-01MD

Docket or Reference Number

030-33449

Amendment No. 27

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 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.
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 3 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. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the statements, representations and procedures in the letter dated March 14, 1994.
21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

NRC FORM 374A

PAGE 6 OF 6 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
44-30124-01MDDocket or Reference Number
030-33449

Amendment No. 27

22. 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. Letter dated March 14, 1994 (ML090890396)
- B. Letter dated April 29, 1994 (ML090890393)
- C. Letter dated May 25, 1994 (ML090890214)
- D. Letter dated July 8, 1994 (ML090890361)
- E. Letter dated September 6, 1994 (ML090890245)
- F. Application dated November 16, 2012 (ML12342A318)
- G. Letter dated January 18, 2013 (ML13024A274)

For the U.S. Nuclear Regulatory Commission

Date April 15, 2014

By



Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Tuesday, April 15, 2014 14:02:20

This is to acknowledge the receipt of your letter application dated

05/29/2014, and to inform you that the initial processing which includes an administrative review has been performed.

44-30124-01MD (renewal)
☒ 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

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** 584038.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.