PHARMA-LOGIC
THE LOGICAL CHOICE

September 6, 2011

Regional Administrator
United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 201
Lisle, IL 60532-4352

RE: License Number 21-32190-01MD

To whom it may concern,

This letter is to request an amendment of US NRC Radioactive Materials License # 21-32190-01MD.

1. Addition of William Espie Gillette, RPh as an Authorized Nuclear Pharmacist. Enclosed are the completed NRC Form 313A(ANP), Certificate of Completion for the required 200 didactic hours in Nuclear Pharmacist Education granted from the University of Arkansas for Medical Sciences and The University of New Mexico Health Sciences Center and copy of his Michigan Pharmacist License.

   William has been employed with PharmaLogic since June 20, 2011 and has completed the minimum 500 hours of experiential training. During that time, he has gained the clinical knowledge and practical skills which will enable William to operate a nuclear pharmacy without preceptor supervision. He has completed the requirements listed in 10 CFR 35.980 and the State of Michigan State Board of Pharmacy to be designated an authorized nuclear pharmacist.

2. Addition of the following individuals as authorized nuclear pharmacists. Each nuclear pharmacist has been listed and currently practice as an Authorized Nuclear Pharmacist on a US NRC License. Enclosed is the US NRC Radioactive Materials License for reference.

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Pharmalogic MI, L.L.C. • 1144 Boon Street • Traverse City, MI 49686
231-929-7200 • Fax 231-929-4457

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INDIVIDUAL	RAM LICENSE #
Joseph Lofaro, RPh	US NRC RAM Lic # 09-29398-01MD
Shawn Lorrain, RPh	US NRC RAM Lic # 09-29398-01MD
Tamiko Ushio, RPh	US NRC RAM Lic # 09-29398-01MD
Matthew Witt Hinton, RPh	US NRC RAM Lic # 09-29398-01MD
Garth Kistner, RPh	US NRC RAM Lic # 09-29398-01MD
Richard Sucese, RPh	US NRC RAM Lic # 09-29398-01MD
Laurie Stallings, RPh	US NRC RAM Lic # 09-29398-01MD

If you have any questions, please contact me at 231-929-7200.

Kindest regards,

Dana Suttle, RPh, RSO

Dana Suttle, R.Ph, RSO
Pharmacy Manager

Pharmalogic MI, L.L.C. • 1144 Boon Street • Traverse City, MI 49686
231-929-7200 • Fax 231-929-4457

NRC FORM 313A (ANP)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.55]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized Nuclear Pharmacist	State or Territory Where Licensed
William Espie Gillette	Michigan

PART I -- TRAINING AND EXPERIENCE
(Select one of the two methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

☐ 1. **Board Certification**

a. Provide a copy of the board certification.

b. Skip to and complete Part II Preceptor Attestation.

☑ 2. **Structured Educational Program for Proposed Authorized Nuclear Pharmacist**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of Arkansas for Medical Sciences & University of New Mexico Health Sciences Center	100	July 1, 2010 - October 22, 2010
Radiation protection	University of Arkansas for Medical Sciences & University of New Mexico Health Sciences Center	30	July 1, 2010 - October 22, 2010
Mathematics pertaining to the use and measurement of radioactivity	University of Arkansas for Medical Sciences & University of New Mexico Health Sciences Center	20	July 1, 2010 - October 22, 2010
Chemistry of byproduct material for medical use	University of Arkansas for Medical Sciences & University of New Mexico Health Sciences Center	30	July 1, 2010 - October 22, 2010
Radiation biology	University of Arkansas for Medical Sciences & University of New Mexico Health Sciences Center	20	July 1, 2010 - October 22, 2010
	Total Hours of Training:	200	

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

2. **Structured Educational Program for Proposed Authorized Nuclear Pharmacist** (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys	PharmaLogic Michigan LLC 1144 Boon Street Traverse City, MI 49686 NRC License # 21-32190-01MD	50	June 27, 2011 - September 2, 2011
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides	PharmaLogic Michigan LLC 1144 Boon Street Traverse City, MI 49686 NRC License # 21-32190-01MD	50	June 27, 2011 - September 2, 2011
Calculating, assaying, and safely preparing dosages for patients or human research subjects	PharmaLogic Michigan LLC 1144 Boon Street Traverse City, MI 49686 NRC License # 21-32190-01MD	250	June 27, 2011 - September 2, 2011
Using administrative controls to avoid medical events in administration of byproduct material	PharmaLogic Michigan LLC 1144 Boon Street Traverse City, MI 49686 NRC License # 21-32190-01MD	50	June 27, 2011 - September 2, 2011
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	PharmaLogic Michigan LLC 1144 Boon Street Traverse City, MI 49686 NRC License # 21-32190-01MD	100	June 27, 2011 - September 2, 2011
Total Hours of Experience:		500	
Supervising Individual **Dana Suttle, RPh, Facility Manager**			

c. Go to and complete Part II Preceptor Attestation.

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Check one of the following:

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Nuclear Pharmacist

10 CFR 35.55(a)(1), (a)(2), and (a)(3) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

OR

Structured Educational Program

☑ I attest that **William Espie Gillette** has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by 10 CFR 35.55(b)(1) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Second Section
Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for **PharmaLogic Michigan LLC** ,
Nuclear Pharmacy or Medical Facility

21-32190-01MD ·
License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
Dana Suttle, RPh	Dana Suttle, RPh	**(231) 929-7200**	**09/06/2011**

Certificate of Completion

The University of Arkansas for Medical Sciences
and the
University of New Mexico Health Science Center
certify that

William Gillette

neo
Nuclear Education Online

has completed the didactic education requirements for
Authorized User of Radioactivity education
as specified by the Nuclear Regulatory Commission.

Authorized User of Radioactivity
Education and Training

Dean, UNM College of Pharmacy

Executive Committee, Professor

Dean, UAMS College of Pharmacy

Nicki Hilliard
Executive Committee, Professor

October 22, 2010

University of Arkansas for Medical Sciences
and
The University of New Mexico Health Sciences Center

Nuclear Pharmacist Education

William Gillette

Didactic Courses	Nuclear Physics	Instrumentation	Radiochemistry	Radiation Safety	Radiation Biology	Radio-Pharmacology	Total
Radiation Physics & Instrumentation	60	40					100
Radiation Protection				30			30
Math & Measure of Radioactivity	10	5		5			20
Radiation Biology					20		20
Radiochemistry			30				30
TOTALS	70	45	30	35	20		200

Course dates: July 1 – October 22, 2010

Nicki Hilliard

Nicki L. Hilliard, Pharm.D., BCNP
Associate Professor of Nuclear Pharmacy

Jeffrey Norenberg, Pharm.D., M.S., BCNP
Associate Professor of Nuclear Pharmacy

Revised April 2006

VERIFY A LICENSE/REGISTRATION

Name and Address

Name : WILLIAM ESPIE GILLETTE
Address : West Hartford, CT 06107

Profession and License/Registration Information

Profession : Pharmacy **Type :** Pharmacist

Permanent ID #	Status	Issue Date	Expiration Date
5302040554	Active	08/29/2011	06/30/2012

Complaint(s)

Open Formal Complaints
None

Disciplinary Action

Disciplinary Action
None

New Search Return to Search

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DISCLAIMER

The **Issue Date** is the date the license/registration was first issued. Please note this information is not always available in the database. The **Expiration Date** given above is the date the license/registration expired or will expire. The license/registration may not have been active from the **Issue Date** to the **Expiration Date**. There may have been periods of non-licensure or registration.

For those licensees/registrants who have actions listed in the **Disciplinary Action** section above, the date the licensee/registrant complied with their board order is listed for all disciplinary actions subsequent to January 1, 2005. The date of compliance is not listed for disciplinary actions that began prior to that date. You should check with our office to confirm the status of the cases if the date of compliance is not listed.

You may fax a request for additional information under the Freedom of Information Act (FOIA) at 517-241-1212 or contact Mary E. Hess, Asst. FOIA Coordinator at BHP-FOIAINFO@michigan.gov for directions on how to obtain more information regarding the license/registration history or disciplinary actions.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

February 16, 2011

Pharmalogic MT, Inc.
ATTN: Cynthia Tindall, R.Ph.
Radiation Safety Officer
1 South Ocean Blvd., Suite 206
Boca Raton, Florida 33432

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 01 to NRC License Number 09-29398-01MD **reflecting the addition and removal of personnel as requested in letter dated January 13, 2011.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iii). You should review this license carefully and be sure that you understand all conditions. You can contact me at 817-860-8189 if you have any questions about this license.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC in writing of any change in mailing address.

3. In accordance with 10 CFR 30.36(d), notify NRC, promptly, in writing within 60 days, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;

   b. If you decide not to acquire or possess and use authorized material; or

   c. When no principal activities under the license have been conducted for a period of 24 months.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;

c. Add or change the areas or address(es) of use identified in the license application or on the license; or

d. Change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; 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 on the following internet address: 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 use of radioactive materials may be obtained on the NRC Web site at http://www.nrc.gov/materials/miau/mat-toolkits.html. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

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,

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-38401
License: 09-29398-01MD
Control: 574445

Enclosure: As stated

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No 01

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 letter dated January 13, 2011
1 Pharmalogic MT, Inc.	3. License number 09-29398-01MD is amended in its entirety to read as follows:
2 1 South Ocean Blvd., Suite 206 Boca Raton, Florida 33432	4. Expiration date January 31, 2021
	5. Docket No. 030-38401 Reference No

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 molybdenum-99, technetium-99m, iodine-123, iodine-131, fluorine-18, indium-111, samarium-153, strontinum-89, thallium-201, yttrium-90, and xenon-133	A. Any	A. 200 millicuries per radionuclide and 2 curies total
B. Molybdenum-99	B. Any	B. 100 curies
C Technetium-99m	C. Any	C. 100 curies
D. Iodine-131	D. Any	D. 2.5 curies
E. Xenon-133	E. Any	E. 1.5 curies
F Fluorine-18	F. Any	F. 1 curie
G. Indium-111	G. Any	G. 300 millicuries
H. Iodine-123	H. Any	H 50 millicuries
I. Samarium-153	I. Any	I. 750 millicuries
J. Strontium-89	J. Any	J 40 millicuries
K. Thallium-201	K. Any	K. 1 curie

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Docket or Reference Number
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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. Yttrium-90	L. Any	L. 500 millicuries
M. Any byproduct material in a brachytherapy source as listed in 10 CFR 35.400	M. Sealed sources	M. 500 millicuries total
N. Any byproduct material listed in 10 CFR 31.11(a)	N. Prepackaged units for *in vitro* diagnostic tests	N. 50 millicuries
O. Any byproduct material authorized under 10 CFR 35.65	O. Sealed sources	O. 100 millicuries total
P. Depleted Uranium	P. Metal	P. 400 kilograms total

9. Authorized use:

A. through L. Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m and rubidium/strontium-82 generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals including compounding of iodine-131 and redistribution of used and unused molybdenum 99/technetium -99m and rubidium/strontium-82 generators authorized recipients for nonmedical use.

M. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. 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.

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

MATERIALS LICENSE
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O. Calibration and checking of the licensee's instruments. Redistribution of sources to initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for nonmedical use.

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

CONDITIONS

10. Licensed material shall be stored or used only at the licensee's facilities located at 4404 Expressway Road, Missoula, Montana.

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) and (4), or

    B. Authorized Nuclear Pharmacist(s): William Chatoff, R.Ph., Joseph Lofaro, R.Ph., Shawn Lorrain, R.Ph., Glen Palmer, R.Ph., Gerard A. Strugala, R.Ph., Cynthia Tindall, R.Ph., Tamiko Ushio, R.Ph., Alan J. Marvin, R.Ph., Matthew Witt-Hinton, R.Ph., Garth Kistner, R.Ph., Timothy Summers, R.Ph., Dana L. Suttle, R.Ph., Selina Mirjavadi, R.Ph., Thomas DeFranco, R.Ph., Richard Sucese, R.Ph., and Laurie E. Stallings, R.Ph.

12. Licensed material authorized under items 9.M., 9.N., and 9.O. shall be used by Robert Cole and Zonker K. White.

13. The Radiation Safety Officer for this license is Cynthia Tindall, R.Ph.

14. This license does not authorized distribution to persons exempt from licensing.

15. 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 NRC under 10 CFR 32.210 or by 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 NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

    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.

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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 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. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulator Commission, RegionIV, 612 East Lamar Boulevard, Suite 400, Arlington, Texas 76011-4125, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

16 Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by NRC, to account for all sealed 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. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 31.210 or by an Agreement State.

19. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days from 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;

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;

C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the 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.

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 transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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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. Application dated July 1, 2010 (ML102160361 & ML102160382)
B. Letter dated November 1, 2010 (ML103550575)
C. E-mail dated December 21, 2010 (ML103620807)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date February 16, 2011

By

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4125

From: (231) 929-7200
PHARMALOGIC MI
PHARMALOGIC MI
1144 BOON STREET

TRAVERSE CITY, MI 49686

Origin ID: TVCA

FedEx Express

J1201104290225

Ship Date: 06SEP11
ActWgt: 1.0 LB
CAD: 4783436/INET3180

Delivery Address Bar Code

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Regional Administrator
US Nuclear Regulatory Commission
2443 WARRENVILLE RD STE 201

LISLE, IL 60532

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