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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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.

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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

/RA/

Date February 16, 2011

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