

U.S. NUCLEAR REGULATORY COMMISSION

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.

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<p>Licensee</p> <p>1. Radiopharmacy Incorporated</p> <p>2. 1409 East Virginia Street Evansville, IN 47711</p>	<p>In accordance with facsimile dated March 17, 2010,</p> <p>3. License number 13-26246-01MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date February 28, 2011</p> <hr/> <p>5. Docket No. 030-31910 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 1 through 83.</p> <p>B. Any byproduct material in a brachytherapy source as listed in 10 CFR 35.400</p> <p>C. Any byproduct material authorized under 10 CFR 35.65(a)(b)</p> <p>D. Depleted uranium</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Sealed sources</p> <p>C. Sealed sources</p> <p>D. Metal</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 1000 millicuries total except for the following nuclides; Molybdenum-99, 100 Curies, technetium-99m, 100 curies, Iodine-131, 2 curies and Xenon-133, 800 millicuries</p> <p>B. 1 curie total</p> <p>C. 75 millicuries total</p> <p>D. 999 kilograms total</p>
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9. Authorized use:
- A. Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of unused molybdenum-99/technetium-99m 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 unused molybdenum 99/technetium 99m generators to authorized recipients for non-medical use.
 - B. 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 sources.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
13-26246-01MDDocket or Reference Number
030-31910

Amendment No. 16

- C. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 or under an equivalent license of an Agreement States to authorized recipients and to authorized recipients for non-medical user.
- D. Shielding for molybdenum 99/technetium-99m generators.

CONDITIONS

1. Licensed material shall be used only at the licensee's facilities located at 1409 East Virginia Street, Evansville, Indiana.
2. A. Licensed material shall be used by, or under the supervision of:
 - 1) a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) and (4).
 - 2) Authorized Nuclear Pharmacists: Timothy M. Quinton, R. Ph., Trenton Rees, R. Ph., Mark E. Brown, R. Ph., Leroy G. Candelaria, R. Ph., David Newbaker, R. Ph., E. Dean Dome, R. Ph., Lynette M. Schaefer, R. Ph., Jeffrey A. Albrecht, R. Ph., Nicole M. Spurling, R. Ph., Matthew O. Broshears, R. Ph., Jason J. Wilson, R.Ph., John E. Haney, R. Ph., Charles E. Bockelman, R.Ph or Phillip B. Harris, R.Ph.B. The Radiation Safety Officer for this license is Timothy M. Quinton.
3. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
C. Sealed sources need not be leak tested if:
 - (i) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
 - (ii) 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 Number
13-26246-01MDDocket or Reference Number
030-31910

Amendment No. 16

- D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(b)(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 Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
- E. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
13. Sealed sources containing licensed material shall not be opened.
14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.
15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 16. 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;**
 - 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.**
17. The licensee is authorized to retrieve, receive and dispose of radioactive waste from it's customers limited to radiopharmacy supplied syringes and vials and their contents.
18. 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

13-26246-01MD

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030-31910

Amendment No. 16

19. 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 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.

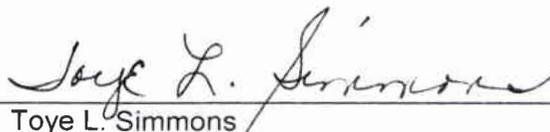
- A. Application dated June 6, 1996, and;
- B. Letters dated February 8, 2001, August 29, 1996 and September 8, 2008;
- C. Facsimiles dated October 15, 2008.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

MAR 18 2010

By



Toye L. Simmons
Materials Licensing Branch
Region III