

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 style="text-align: center;">Licensee</p> <p>1. Medi-Physics, Inc. dba GE Healthcare</p> <p>2. 4380 Brockton SE, Ste. 3 Kentwood, MI 49512</p> | <p>In accordance with letter dated February 19, 2008, and facsimile dated May 6, 2008,</p> <p>3. License number 21-26707-01MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date June 30, 2011</p> <hr/> <p>5. Docket No. 030-34090 Reference No.</p> |
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any unsealed byproduct material, except iodine-131, technetium-99m and xenon-133 used to prepare radioactive drugs for medical use</p> <p>B. Molybdenum-99</p> <p>C. Technetium-99m</p> <p>D. Xenon-133</p> <p>E. Iodine-131</p> | <p>7. Chemical and/or physical form</p> <p>A. Any unsealed byproduct material used to prepare radioactive drugs for medical use, except iodine-131, technetium-99m and xenon-133</p> <p>B. Any molybdenum-99/technetium-99m generator initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations</p> <p>C. Unsealed</p> <p>D. Unit dose containers of gas or gas in solution initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations</p> <p>E. Any form initially distributed in accordance with a specific license issued pursuant to 10 CFR 32.72 or equivalent Agreement State regulations</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 1 curie</p> <p>B. 200 curies</p> <p>C. 200 curies</p> <p>D. 5 curies</p> <p>E. 990 millicuries</p> |
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| F. Any byproduct material listed in 10 CFR 35.400 | F. Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations | F. 4 curies |
| G. Any byproduct material listed in Sections 35.500 | G. Any sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations | G. 4.5 curies total and no single source to exceed 1.5 curies |
| H. Any byproduct material listed in 10 CFR 31.11(a) | H. Prepackaged units for <u>in vitro</u> diagnostic tests | H. 50 millicuries |
| I. Any byproduct material authorized under 10 CFR 35.57(a) | I. Any sealed source listed in 10 CFR 35.57(a) that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to 10 CFR 32.74 or equivalent Agreement State regulations | I. 50 millicuries |
| J. Uranium (depleted in the isotope Uranium 235) | J. Metal encased in stainless steel | J. 400 kilograms |

9. Authorized Use:

- A. through E. Preparation and distribution of radioactive drugs (includes Mo-99/Tc-99m generators) to authorized recipients.
- F. and G. Redistribution of sealed sources as received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.

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- H. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged.
- I. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to 10 CFR 32.74, the licensee is authorized to redistribute sources to persons licensed pursuant to 10 CFR 35.57(a) or under equivalent licenses of Agreement States.
- J. Shielding for Mo-99/Tc-99m generators.

Pursuant to 10 CFR 32.72 and 32.74, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 A. through J. of this license to persons licensed pursuant to Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35, or under equivalent licenses of Agreement States.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 4380 Brockton SE, Kentwood, Michigan.
11. 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) and (4), or
 - 2) authorized nuclear pharmacists: Phillip F. Heim, R.Ph., Mary Beth Prefontaine, R.Ph., James Pancy, R.Ph., Kevin Romanyk, R.Ph., Jonathan Winters, R.Ph., or Stephen Williams, R.Ph.
- B. The Radiation Safety Officer for this license is Jonathan Winters, R.Ph.
12. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals as specified by the certificate of registration 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 received from another person shall not be put into use until tested.
- C. Sealed sources need not be leak 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 not 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 appropriate U.S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20.
- 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 or sources removed from source holders by the licensee.
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 is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. 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 in ordinary trash provided:
- A. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- B. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in application dated March 11, 1996.
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.
19. The license does not authorize distribution to persons exempt from licensing.

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20. 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 March 11, 1996 (excluding request for analytical samples with atomic numbers between 3 and 83);
 - B. Facsimiles dated March 14, 1996, November 22, 1999, and **May 6, 2008**;
 - C. Letters dated March 28, 1996 (with attached ALARA policy dated July 13, 1995), March 28, 1996 (received April 19, 1996, including attachments and letter dated April 18, 1996), April 22, 1996, May 12, 1998, March 2, 1999 (with attachment A), and September 27, 1999; December 20, 2000 (with two attached diagrams), October 15, 2001, November 5, 2001, November 13, 2001, December 19, 2001, November 12, 2002, July 8, 2004, February 28, 2005 (with attachment), **April 27, 2007, and February 19, 2008**.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 20 2008 By Colleen Carol Casey
Colleen Carol Casey
Materials Licensing Branch
Region III