

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.

21-05432-04

316934

Licensee

- 1. Marquette General Health System
- 2. 580 West College
Marquette, MI 49855-2705

In accordance with **letters dated February 21, 2008, and April 22, 2008, and the facsimile dated March 20, 2008,**

3. License number 21-05432-04 is amended in its entirety to read as follows:

4. Expiration date July 31, 2014

5. Docket No. 030-18133
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 permitted by 10 CFR 35.100
- B. Any byproduct material permitted by 10 CFR 35.200
- C. Any byproduct material permitted by 10 CFR 35.300
- D. Cesium-137 as permitted by 10 CFR 35.400
- E. Iridium-192 as permitted by 10 CFR 35.400
- F. Yttrium-90 as permitted by 10 CFR 35.1000
- G. Iodine-125 as permitted by 10 CFR 35.1000
- H. Uranium (depleted in Uranium-235)

- A. Any
- B. Any
- C. Any
- D. Sealed sources (Amersham Model No. CDC.T1, 3M Model No. Series 6501 - 6503, inclusive, and Isotope Products Laboratories Model 67-6500 Series)
- E. Sealed sources (Best Medical International, Inc. Model 81-01)
- F. Sealed sources as SIR-Spheres (AEA Technology QSA, Inc.)
- G. Liquid as Iotrex™
- H. Solid metal

- A. As needed
- B. As needed
- C. As needed (not to exceed nine curies of iodine-131)
- D. 1400 millicuries
- E. 600 millicuries
- F. 1.08 curies
- G. 3 curies
- H. As needed

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9. Authorized Use:

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. and E. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- F. **For medical use, as permitted by 10 CFR 35.1000, in a Sirtex Medical Limited brachytherapy afterloader delivery system.**
- G. **For use in the Proxima Therapeutics' GliaSite® Radiotherapy System for medical use permitted by 10 CFR 35.1000.**
- H. **Shielding in generators.**

CONDITIONS

- 10. Locations of Use: 420 W. Magnetic Street, Marquette, Michigan, and 580 W. College Avenue, Marquette, Michigan.
- 11. Radiation Safety Officer: Julia M. (Shan) Marlette, M.S.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

John Michael Pap, M.D.

10 CFR 35.100 and 35.200.

Paul O. Thieme, Jr., D.O.

10 CFR 35.300, 35.400, yttrium-90 SIR-spheres in a Sirtex Medical Limited brachytherapy afterloader delivery system, and iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy system.

Raymond Wood, D. O.

10 CFR 35.200.

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Christopher J. Mehall, M.D.	10 CFR 35.100, 35.200, 35.300 and yttrium-90 SIR-spheres in a Sirtex Medical Limited brachytherapy afterloader delivery system.
Nelson E. Gencheff, D.O.	10 CFR 35.200.
Gary M. Friesen, M.D.	10 CFR 35.200.
Muhammed Imran Choudhry, M.D.	Oral administration of iodine-131.
Arthur Greene, M.D.	10 CFR 35.100 and 35.200.
John Dahlin, M.D.	10 CFR 35.100, 35.200 and 35.300.

C. The following individual is an Authorized Medical Physicist:

Julia M. (Shan) Marlette, M.S.	Iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System; for calibration, spot checks and training.
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13. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

- 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 or detector cell 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;
 - (ii) they are not designed to emit alpha particles, 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - (iii) the half-life of the isotope is 30 days or less; or
 - (iv) 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

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- (v) they are not designed to emit alpha particles, 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 or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- 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.
- 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.
14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
15. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, 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.
16. 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.
17. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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18. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 December 30, 2003; and,
- B. Letters dated December 30, 2003, July 1, 2004, April 11, 2005, and May 25, 2005.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 02 2008By *Colleen Carol Casey*
Colleen Carol Casey
Materials Licensing Branch
Region III