

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.

OC 02240 574578

Licensee [] [] 1. Hurley Medical Center Department of Radiology [] 2. One Hurley Plaza Flint, MI 48503 [] []	In accordance with letter dated February 9, 2011, [] 3. License number 21-00338-02 is amended in its entirety to read as follows: 4. Expiration date November 30, 2015 5. Docket No. 030-01993 [] Reference No. []
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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
A. Any byproduct material permitted by 10 CFR 35.100 []	A. Any []	A. As needed []
B. Any byproduct material permitted by 10 CFR 35.200 []	B. Any []	B. As needed []
C. Any byproduct material permitted by 10 CFR 35.300 []	C. Any []	C. As needed (not to exceed 1 curie of iodine-131) []
D. Any byproduct material permitted by 10 CFR 35.400 []	D. Sealed sources (3M Model Nos. 6511, 6512, 8513, Amersham Model No. CDCT1, Nuclear Associates Model Nos. 67-81X-35, 67-614 and 67-601 and S.K.A.E. Model Nos. SIA1, SIA3 and SIA4) []	D. 1.5 curies []
E. Any byproduct material permitted by 10 CFR 31.11 []	E. Prepackaged Kits []	E. 2 millicuries []
F. Uranium depleted in uranium-235 []	F. Solid metal []	F. Not to exceed 999 kilograms total possession limit []

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SUPPLEMENTARY SHEET**

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Amendment No. 131

G. Iodine-125, as permitted by 10
CFR 35.1000

G. Liquid as Iotrex™

G. 8.0 curies

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 therapy procedure permitted by 10 CFR 35.300.
- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400. Cesium-137 Model Nos. Nuclear Associates Model Nos. 67-81X-35, 67-614 and 67-601 and strontium-90 Models Nos. W.K.A.E. SIA1, SIA3 and SIA4 that are listed in Sub-item 7.D. are only authorized for storage incident to disposal.
- E. In vitro studies.
- F. For shielding in a linear accelerator.
- G. For medical use permitted by 10 CFR 35.1000, in the Proxima Therapeutics' GliSite® Radiotherapy System.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at Hurley Medical Center, One Hurley Plaza, Flint, Michigan.
- 11. Radiation Safety Officer: Appa Rao Mukkamala, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

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B. The following individuals are authorized users for medical use as indicated:

Authorized Users

P. B. Lauber, M.D.

Ahmed M. Akl, M.D.

Appa Rao Mukkamala, M.D.

M. Rao Tummala, M.D.

Douglas D. Congdon, D.O.

Material and Use

10 CFR 35.100, 35.200 and 35.300.

10 CFR 35.300, 35.400, and iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System.

10 CFR 35.100, 35.200, 35.300, 35.400, 35.500 and 31.11

10 CFR 35.100, 35.200, and iodine-131 for treatment of hyperthyroidism and cardiac dysfunction.

10 CFR 31.11.

C. The following individuals are Authorized Medical Physicists

Authorized Users

Ibrahim Abdulhay, Ph.D.

Leslie L. Boulay, M.S.

Material and Use

Iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and for calibrations, spot checks and training.

Iodine-125 in the Proxima Therapeutics' GliaSite® Radiotherapy System and for calibrations, spot checks and training.

13. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- 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 the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 - Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

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- D. 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 the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- E. 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.
- F. 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.
- G. 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. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. 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.
16. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.
17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

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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. 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 July 21, 2005; and

B. Letters dated October 18, 2005, November 10, 2005, September 21, 2005, October 19, 2005, November 10, 2005, September 20, 2007, September 10, 2008, and **February 9, 2011 (with attachments, excluding request to delete all sources authorized by 10 CFR 35.400).**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date MAY 31 2011 By Colleen Carol Casey
Colleen Carol Casey
Materials Licensing Branch
Region III