

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.

<p>Licensee</p> <p>1. St. James Healthcare</p> <p>2. 400 S. Clark Street P.O. Box 3300 Butte, Montana 59702</p>	<p>In accordance with letters dated April 4 and May 1, 2008</p> <p>3. License number 25-13173-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date August 31, 2013</p> <hr/> <p>5. Docket No. 030-12143 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> <p>E. Iodine-125 permitted by 10 CFR 35.1000</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed sources (Minnesota Mining & Manufacturing [3M] Model 6D6A)</p> <p>E. Liquid as Proxima Therapeutics, Inc. lotrex™</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 300 millicuries</p> <p>D. 1 curie</p> <p>E. 8 curies</p>

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 use permitted by 10 CFR 35.300
 - D. Any manual brachytherapy procedure permitted by 10 CFR 35.400
 - E. For temporary manual brachytherapy use in Proxima Therapeutics' GliaSite® RTS system permitted by 10 CFR 35.1000.

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SUPPLEMENTARY SHEET**

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Docket or Reference Number
030-12143

Amendment No. 43

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 400 S. Clark Street, Butte, Montana.
11. The Radiation Safety Officer for this license is Rodney J. Wimmer, Ph.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized Medical physicist in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the material and medical uses indicated:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|--------------------------|--|
| Anna Chacko, M.D. | 35.100; 35.200; 35.300 |
| Rashmikant B. Shah, M.D. | 35.100; 35.200; 35.300 |
| John M. Stevenson, M.D. | 35.400; 35.1000 only Iodine-125 Gliasite® RTS system |
- C. The following individual is an authorized medical physicist as indicated:
- | <u>Authorized Medical Physicist</u> | <u>Material and Use</u> |
|-------------------------------------|--|
| Rod Wimmer, Ph.D. | Strontium-90 eye applicator calibration and Iodine-125 Iotrex™ for activity calculation in association with the Proxima Therapeutics' Gliasite® RTS system |
13. 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.
14. 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 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.
- B. 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.

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- C. 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 regulation 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.
- D. 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.
- 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. 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 IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
- G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
15. 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. Records of inventories shall be maintained for 3 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. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
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 January 22, 2003 (ML030660393)
 - B. Facsimile received August 10, 2003 (ML032230037)
 - C. Letter dated October 7, 2003 (ML033160633)
 - D. Letter dated October 28, 2003 (ML033160633)
 - E. Letter dated January 26, 2004 (ML040500453)
 - F. Letter dated August 14, 2004 (ML042660275 and ML042520549)
 - G. Electronic mail received November 8, 2004 (ML043350348)
 - H. Facsimile dated November 17, 2004 (ML043350348)
 - I. Letter dated November 23, 2004 (ML043630244)
 - J. Letter dated April 4, 2008 (ML081420597)
 - K. Letter dated May 1, 2008 (ML081440160)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: July 11, 2008By: IRA
James L. Montgomery, Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4125