UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

July 3, 2007

St. James Healthcare
ATTN: Rod Wimmer, Ph.D.
Radiation Safety Officer
400 S. Clark Street
P.O. Box 3300
Butte, Montana 59702

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 40 to NRC License No. 25-13173-02, **authorizing Dr. Anna Chacko for 10 CFR 35.100, 35.200, and 35.300 modalities, which includes all uses of sodium iodide I-131 permitted under 35.300.** An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review the enclosed document carefully and be sure that you understand all conditions. If you have any questions, please contact me at 817-276-6552.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC in writing of any change in mailing address.

3. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:

   a. The date that the licensee permits an individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);

   b. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;

   c. The licensee's mailing address changes;

   d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or

   e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;

   c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or

   d. Change the name or ownership of your organization.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available on the following internet address: http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf.

The NRC no longer publishes the NRC Rules and Regulations loose leaf supplements. However, an electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

/RA/

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-12143
License: 25-13173-02
Control: 471383

Enclosure: As stated

Amendment No. 40

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.

Licensee	In accordance with letter dated May 21, 2007
1. St. James Healthcare	3. License number 25-13173-02 is amended in its entirety to read as follows:
2. 400 S. Clark Street P.O. Box 3300 Butte, Montana 59702	4. Expiration date August 31, 2013
	5. Docket No. 030-12143 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	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. 300 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed Sources (Minnesota Mining and Manufacturing [3M] Model 6D6A)	D. 1 curie
E. Iodine-125 permitted by 10 CFR 35.1000	E. Liquid brachytherapy source Proxima I-125 Iotrex™	E. 8 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 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® Radiotherapy system permitted by 10 CFR 35.100.

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.

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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 medical uses indicated:

Authorized User	Material and Use
Dennis O. Wright, M.D.	35.100; 35.200; 35.300
Trent D. Mihalick, M.D.	35.300; 35.400; 35.1000 only Iodine-125 Gliasite RTS system
Jeffrey D. Lovin, M.D.	35.100; 35.200; 35.300 including parenteral administration of any radionuclide, except oral administration of greater than 33 millicuries of sodium iodide I-131
Ross W. Barnett, M.D.	35.100; 35.200; oral administration of sodium iodide I-131
Anna Chacko, M.D.	35.100; 35.200; 35.300

    C. The following individual is an authorized medical physicist as indicated:

Authorized Medical Physicist	Material and Use
Rod Wimmer, Ph.D.	Strontium-90 eye applicator calibration

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.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals spcified 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.

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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.

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.”

18. Notwithstanding the requirements in 10 CFR 35.400, the licensee may use iodine-125 in the form of Iotrex™ liquid brachytherapy source in the Proxima Therapeutics’ GliaSite® Radiotherapy system.

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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. 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
    B. Facsimile received August 10, 2003
    C. Letter dated October 7, 2003
    D. Letter dated October 28, 2003
    E. Letter dated January 26, 2004
    F. Letter dated August 14, 2004
    G. Electronic mail received November 8, 2004
    H. Facsimile dated November 17, 2004
    I. Letter dated November 23, 2004

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date: July 3, 2007

By: _____

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, TX 76011