



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 4, 2007

Docket No. 03002466
Control No. 140911

License No. 29-03089-01

Michael Connelly
Clinical Director, Department of Radiology
Somerset Medical Center
110 Rehill Avenue
Somerville, NJ 08876-2598

SUBJECT: SOMERSET MEDICAL CENTER, LICENSE AMENDMENT, CONTROL NO.
140911

Dear Mr. Connelly:

This refers to your license amendment request dated July 30, 2007. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 54

cc: Vincent M. Immerso, Radiation Safety Officer

M. Connelly
Somerset Medical Center

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SUNSI Review Complete: S Xu

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DATE	9/4/07		9/4/07					

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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. Somerset Medical Center</p> <p>2. 110 Rehill Avenue Somerville, New Jersey 08876-2598</p>	<p>In accordance with the letter dated July 30, 2007,</p> <p>3. License number 29-03089-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date December 31, 2015</p> <hr/> <p>5. Docket No. 030-02466 Reference No.</p>
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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. 500 millicuries |
| D. Any byproduct material permitted by 10 CFR 35.400 | D. Sealed Sources (Draximage, LLC Model LS-1; Bard Brachytherapy, Inc. Model STM1251) | D. 1 curie |
| E. Any byproduct material permitted by 10 CFR 35.500 | E. Sealed Sources (North American Scientific Model MED 3601) | E. 0.3 curie per source and 3 curies total |
| F. Gadolinium 153 | F. Sealed Sources (Isotope Products Laboratories, Inc. Model 3409) | F. 90 millicuries |
| G. Iodine 125 | G. Liquid Iotrex as part of the GliaSite RTS System | G. 8 curies |
| H. Strontium 90 permitted by 10 CFR 35.400 | H. Sealed Source (New England Nuclear Model NB-1) | H. 55 millicuries |

9. Authorized use:

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- 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. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. Storage with intent to dispose.
- G. For brachytherapy use in the Proxima Therapeutics' GliaSite Radiotherapy System.
- H. Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 110 Rehill Avenue, Somerville, New Jersey.
- 11. The Radiation Safety Officer for this license is Vincent M. Immerso, 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 nuclear pharmacist in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated:

Authorized UsersMaterial and Use

Grant Jay Price, M.D.

35.100; 35.200; 35.500; oral administration of sodium iodide iodine-131 for imaging and localization studies

Flavius F. Guglielmo, M.D.

35.100; 35.200; 35.500; oral administration of sodium iodide Iodine 131 for imaging and localization studies

Steven P. Honickman, M.D.

35.200; 35.500

Bernard Terry, M.D.

35.100; 35.200; 35.500

Gordon E. Melville, M.D.

35.100; 35.200; 35.500

Barry H. Katz, M.D.

35.100; 35.200; 35.500

S. Howard Lee, M.D.

35.100; 35.200; 35.500

Roger S. Yang, M.D.

35.100; 35.200; 35.500

Richard W. Epstein, M.D.

35.100; 35.200; 35.500

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Authorized Users

Robert M. Jaffe, M.D.

Joel K. Braver, M.D.

Laura Bond, M.D.

Material and Use

35.100; 35.200; 35.300; 35.500

35.300; 35.400; Iodine 125 for use in the GliaSite RTS System; Strontium-90 for ophthalmic radiotherapy

35.400; Iodine 125 for use in the GliaSite RTS System; Strontium-90 for ophthalmic radiotherapy

C. Authorized medical physicist: Kenneth Kopecky, Ph.D.

D. The following individuals are authorized users for non-medical uses as indicated:

Users

Vincent M. Immerso, M.S.

Material and Use

Gadolinium 153 (storage)

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 six months or at 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 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.
- 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.

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- 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, 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 5 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 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. 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. Letter dated April 18, 2005 (ML051380170)
- B. Letter dated July 18, 2005 (ML052140209)
- C. Application dated June 30, 2005 (ML051870195)
- D. Letter dated October 18, 2005 (ML053000616)
- E. Letter dated October 21, 2005 (ML053000617)
- F. Letter dated April 7, 2006 (ML061110428)
- G. Letter dated May 31, 2006 (ML061520089)
- H. Letter dated February 6, 2007 (ML070400307)



For the U.S. Nuclear Regulatory Commission

Original signed by Penny LanziseraDate September 4, 2007By _____
Penny Lanzisera
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406