

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 style="text-align: center;">Licensee</p> <p>1. St. Michael's Medical Center, Inc.</p> <p>2. 111 Central Avenue Newark, New Jersey 07102</p>	<p>In accordance with the letter dated July 24, 2008,</p> <p>3. License number 29-06759-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date July 31, 2011</p> <hr/> <p>5. Docket No. 030-02490 Reference No.</p>
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<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 31.11</p> <p>E. Americium 241</p> <p>F. Phosphorus 32</p> <p>G. Strontium 90</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Prepackaged Kits</p> <p>E. Sealed Source (Amersham Model No. AMC.24)</p> <p>F. Sealed Sources (Guidant Corp. VI Model GDT P-32 series)</p> <p>G. Sealed Sources (BEBIG Model Sr0.S03 or AEAT Model SICW.2)</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. 400 millicuries</p> <p>D. 2 millicuries</p> <p>E. 30 millicuries</p> <p>F. 600 millicuries per source assembly; 2 source assemblies total</p> <p>G. 5 millicuries per source and 800 millicuries total</p>
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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. In vitro studies.
 - E. Use as an anatomical marker.
 - F. For use in Guidant Corporation VI Model GALILEO Intravascular Brachytherapy High Dose Rate Afterloader devices for intravascular brachytherapy.

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G. For use in Novoste A1000 Series models for intravascular brachytherapy.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 111 Central Avenue, Newark, New Jersey.
11. The Radiation Safety Officer for this license is Suresh Mody, 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.
- B. The following individuals are authorized users for medical use as indicated:

<u>Authorized Users</u>	<u>Material and Use</u>
Raymond Carnes, M.D.	35.100; 35.200; Americium 241 <u>In vitro</u> studies
Suresh Mody, M.D.	35.100; 35.200; 35.300
Mahendra R. Modi, M.D.	35.100; 35.200; 35.300; Americium 241 <u>In vitro</u> studies
Patrick Conte, M.D.	35.100; 35.200; 35.300
Candido Quinones, M.D.	35.100; 35.200; 35.300
Loren Godfrey, M.D.	Phosphorus-32 or Strontium-90 for intravascular brachytherapy procedures
Glen Gejerman, M.D.	Phosphorus-32 or Strontium-90 for intravascular brachytherapy procedures

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C. The following individuals are authorized medical physicists as indicated:

Authorized Medical Physicists

Eduard Mullokandov, Ph.D.

Material and Use

Phosphorus-32 or Strontium-90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training

D. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

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), 40.36(b), and 70.25(d) for establishing decommissioning financial assurance.
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. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services

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16. 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 May 4, 1990
 - B. Letter dated January 13, 1991
 - C. Letter dated November 22, 2002 (ML023360302)
 - D. Letter dated May 3, 2004 (ML041400218)
 - E. Letter dated July 24, 2008 (ML082100442)



For the U.S. Nuclear Regulatory Commission

Date August 6, 2008

By

Original signed by Tara L. WeidnerTara L. Weidner
Medical Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406