

**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.

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<p>Licensee</p> <p>1. St. Joseph Health Center</p> <p>2. 300 First Capitol Drive St. Charles, MO 63301</p>	<p>In accordance with the letter dated <b>June 27, 2006,</b></p> <p>3. License number 24-15159-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date July 31, 2014</p> <p>5. Docket No. 030-08664 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. Strontium-90 as 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 (North American Scientific Model MED 3631 and 3M Model 6711)</p> <p>E. Sealed sources (BEG Model Sr-90 of AEAT 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. As needed</p> <p>D. 500 millicuries</p> <p>E. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries</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 diagnostic study or therapy procedure permitted by 10 CFR 35.300.
  - D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
  - E. Sources permitted by 10 CFR 35.1000 may be used in Novoste Model A1000 series devices for intravascular brachytherapy, physics calibrations and quality assurance testing.

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SUPPLEMENTARY SHEET**

License Number  
24-15159-01

Docket or Reference Number  
030-08664

Amendment No. 50

CONDITIONS

10. Locations of use:

- A. Licensed material in Subitems 6.A. through 6.E. may be used at the licensee's facilities located at St. Joseph Health Center, 300 First Capitol Drive, St. Charles, Missouri.
- B. Licensed material in Subitems 6.A., 6.B., and 6.C. may be used at the licensee's facilities located at St. Joseph Hospital-West, 100 Medical Plaza, Lake Saint Louis, Missouri.

11. A. The Radiation Safety Officer for this license is Sidney D. Machefsky, M.D.

B. The Assistant Radiation Safety Officer for this license is Edward Cohen, 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 and/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 Jablonski, M.D.	10 CFR 35.100, 35.200 and 35.300.
Sidney D. Machefsky, M.D.	10 CFR 35.100, 35.200 and 35.300.
Harley J. Hammerman, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for thyroid carcinoma therapy).
Mark Hoffman, M.D.	10 CFR 35.100, 35.200 and 35.300.
Richard Koch, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for thyroid carcinoma therapy).
Lewis Halverson, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for thyroid carcinoma therapy).
Phillip Trotta, M.D.	10 CFR 35.100, 35.200 and 35.300.
Edward Cohen, M.D.	10 CFR 35.100, 35.200 and 35.300 (limited to iodine-131 for treatment of hyperthyroidism).
Gene Spector, M.D.	10 CFR 35.100 and 35.200.

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John Bedwinek, M.D.	10 CFR 35.300, 35.400 and strontium-90 in the Novoste Model A1000 series intravascular brachytherapy devices.
Scott C. St. Amour, M.D.	10 CFR 35.100, 35.200 and 35.300.
Dennis Schmidt, M.D.	10 CFR 35.300 and 35.400.
William N. Floyd, Jr., M.D.	10 CFR 35.100 and 35.200.
Lannis Elese Hall-Daniels, M.D.	10 CFR 35.300, 35.400 and strontium-90 in the Novoste Model A1000 series intravascular brachytherapy devices.
Jonathan D. Root, M.D.	10 CFR 35.100, 35.200 and 35.300 (excluding iodine-131 for thyroid carcinoma therapy).
Mohammed F. Majeed, M.D.	10 CFR 35.100 and 35.200.
Ian Roderick Graham, M.D.	10 CFR 35.100 and 35.200.
Peter L. Litzow, M.D.	10 CFR 35.100 and 35.200.
David Pohl, M.D.	10 CFR 35.100, 35.200, and 35.300.
Karen H. Gladden, M.D.	10 CFR 35.100 and 35.200.
Jonas Singer, M.D.	10 CFR 35.100 and 35.200.
Jeffrey Scott Gilroy, M.D.	10 CFR 35.400.

C. The Authorized Medical Physicists for this license are Gilbert H. Nussbaum, Ph.D. and Loretta Lewandowski, Ph.D.

13. Licensed material listed in Subitem No. E. of Items 6., 7., 8., and 9. shall be used by or under the supervision of an authorized user named in Condition No.12., and in the physical presence of an authorized user named in Condition No.12. or a medical physicist who meets the requirements in 10 CFR 35.961. The authorized user named in Condition No.12. shall consult with a medical physicist who meets the requirements in 10 CFR 35.961 and an interventional cardiologist prior to each treatment.
14. Immediately after retracting the source from the patient into its shielded position in the Novoste Model A1000 series intravascular brachytherapy device, a radiation survey shall be made of the patient and the Novoste Model A1000 series intravascular brachytherapy device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(c).

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15. The licensee shall:

- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each Novoste A1000 series intravascular brachytherapy device treatment.
- B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
- C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr ( $\mu$ Sieverts/hr), time, date and name of the individual making the survey.
- D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(c).

16. 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.

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. 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 received May 13, 2004, and
- B. Letters dated June 25, 2001 and April 16, 2006.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date SEP 21 2006

By William P. Reichhold  
William P. Reichhold  
Materials Licensing Branch  
Region III