NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 61

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. DC 02240 31 8695

Licensee	In accordance with letter dated **December 7, 2009,**
1. St. Joseph Health Center	3. License number 24-15159-01 is amended in its entirety to read as follows:
2. 300 First Capitol Drive St. Charles, MO 63301	4. Expiration date July 31, 2014
	5. Docket No. 030-08664 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. As needed
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (North American Scientific Model MED 3631,3M Model 6711, Mills Biopharmaceuticals, LLC, Inc. Model Nos. I-125SL, I-125SH and Pd-103SL)	D. 500 millicuries
E. Strontium-90 as permitted by 10 CFR 35.1000	E. Sealed sources (BEBIG Model Sr0.S03 or AEAT SICW.2)	E. No single source to exceed 5 millicuries; total possession not to exceed 800 millicuries

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-15159-01

Docket or Reference Number
030-08664

Amendment No. 61

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.

CONDITIONS

10. **Licensed material in Subitem Nos. 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 and 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:

Authorized Users	Material and Use
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 (for iodine-131, oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).
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 (for iodine-131, oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).
Lewis Halverson, M.D.	10 CFR 35.100, 35.200 and 35.300 (for iodine-131, oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).
Phillip Trotta, M.D.	10 CFR 35.100, 35.200 and 35.300.
Edward Cohen, M.D.	10 CFR 35.100, 35.200 and oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries.
Gene Spector, M.D.	10 CFR 35.100 and 35.200.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-15159-01

Docket or Reference Number
030-08664

Amendment No. 61

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 (for iodine-131, oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries).
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.
Gregg Dickerson, M.D.	**10 CFR 35.400**
Daniel T. Cohen, M.D.	10 CFR 35.100, 35.200 and oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries .
Anna L. Fu, M.D.	10 CFR 35.300, 35.400 and iridium-192 in high dose rate remote afterloading brachytherapy device.

C. The Authorized Medical Physicists for this license are Gilbert H. Nussbaum, Ph.D., Mark Pohlman, Ph.D. and Matthew J. White, M.S.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-15159-01

Docket or Reference Number
030-08664

Amendment No. 61

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).

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 (μSieverts/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. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.

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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
24-15159-01

Docket or Reference Number
030-08664

Amendment No. 61

A. Application received May 13, 2004;

B. Application dated April 17, 2008; and,

C. Letters dated June 25, 2001, April 16, 2006, December 8, 2006, February 5, 2007, April 27, 2007, May 12, 2007, September 7, 2007, April 17, 2008, **and December 7, 2009**.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JAN 25 2010

By _____
James R. Mullauer, M.H.S.
Materials Licensing Branch
Region III