

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 13, 2005

Docket No. 03002423 Control No. 136170 License No. 29-00232-08

Joseph Flamini Vice President St. Francis Medical Center 601 Hamilton Avenue Trenton, NJ 08629-1986

SUBJECT: ST. FRANCIS MEDICAL CENTER, ISSUANCE OF LICENSE AMENDMENT,

CONTROL NO. 136170

Dear Mr. Flamini:

This refers to your license amendment request dated November 19, 2004. 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 available at the NRC Web sites listed below or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST. Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Sandra Gabriel

Sandra Gabriel Senior Health Physicist Medical Branch Division of Nuclear Materials Safety

Enclosure:

Amendment No. 69

J. Flamini 2

St. Francis Medical Center

NRC Web site addresses

NRC regulations

http://www.nrc.gov/reading-rm/doc-collections/cfr/

Licensing guidance

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/

General Policy and Procedure for NRC Enforcement Actions

http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf

206 of the Energy Reorganization Act of 1974

http://www.nrc.gov/who-we-are/governing-laws.html

CC:

Ethan Tarasov, M.D., Radiation Safety Officer

J. Flamini	3
St. Francis Medical Center	

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DATE	3/13/2005				

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 4 PAGES
Amendment No. 69

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	the letter dated
			November 19, 2	2004	1,
1. S	t. Francis Medical Center		3. License numbe	er 29	-00232-08 is amended in
		c)	its entirety to re	ead	as follows:
2. 6	01 Hamilton Avenue)~	4. Expiration date	Ap	ril 30, 2014
T	renton, New Jersey 08629-1986		5. Docket No. 03	0-02	423
	4		Reference No.	2	2
6.	Byproduct, source, and/or special nuclear material	Tonne	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	Α.	As needed
В.	Any byproduct material permitted by 10 CFR 35.200	В.	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 (Amersham Model CDC.J)	D.	1100 millicuries
E.	Strontium 90 permitted by 10 CFR 35.400	E.	Sealed Source (3M Company Model 3M6D1A)	E.	60 millicuries
F.	Strontium 90/Yttrium 90	F.	Sealed Sources (BEBIG Model Sr0.S03 or AEAT SICW Series,SICW.1 and SICW.2)	F.	5.0 millicuries per source; 800 millicuries total

- 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. For possession only.

		374	

U.S. NUCLEAR REGULATORY COMMISSION

License Number 29-00232-08

Docket or Reference Number

030-02423

Amendment No. 69

MATERIALS LICENSE SUPPLEMENTARY SHEET

F. For medical use in a Novoste A1000 Series models for intravascular brachytherapy.

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 601 Hamilton Avenue, Trenton, New Jersey.
- 11. The Radiation Safety Officer for this license is Ethan Tarasov, 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, 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 medical use as indicated:

Authorized Users	Material and Use
Lawrence H. Oliver, M.D.	35.100; 35.200; 35.300; 35.400
Joel Namm, M.D.	3 <mark>5.100</mark> ; 35.200; 35.300; 35.400
Paul Weiser, M.D.	35.100; 35.200; 35.300 except thyroid carcinoma
Steven L. Meshkov, M.D.	35.100; 35.200; 35.300
William S. Mechanic, M.D.	35.100; 35.200; 35.300
Lawrence Ratner, M.D.	35.100; 35.200
Ethan Tarasov, M.D.	35.100; 35.200; 35.300 except thyroid carcinoma
Sofia Chan Yeung, M.D.	35.100; 35.200
Roy Prager, M.D.	35.100; 35.200
William Ross, M.D.	35.100; 35.200; 35.300
Michael Rieder, M.D.	35.100; 35.200
Daniel Jonathan Cohen, M.D.	35.100; 35.200
Larry A. LeCavalier, M.D.	35.100; 35.200
Roy Greenbaum, M.D.	35.100; 35.200
Teresa Ecker, M.D.	35.100; 35.200

NRC FORM 374A

U.S. NUCLEAR REGULATORY COMMISSION

License Number 29-00232-08

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030-02423

MATERIALS LICENSE SUPPLEMENTARY SHEET

Amendment No. 69

<u>Authorized Users</u> <u>Material and Use</u>

Gustavo Sanchez, M.D. 35.100; 35.200

JoAnn Chalal, M.D. 35.400; Strontium 90/Yttrium 90 in Novoste

A1000 series systems

Sangeeta K. Tyrech, M.D. 35.300; 35.400; Strontium 90/Yttrium 90 in

Novoste A1000 series systems

Eric Bosworth, M.D. 35.100; 35.200; 35.300

Ricardo Eng, M.D. 35.100; 35.200

Lisa Marie Sheppard, M.D. 35.100; 35.200

Derek Plakyda, M.D. 35.100; 35.200

Stephen Ling, M.D. 35.100; 35.200; 35.300

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

Authorized Medical Physicists

Christopher A. Gouin, M.S.

Material and Use

Strontium 90/Yttrium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot-checks, and training; Sr-90 eye applicator for possession only

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.

NRC	FORM	374A

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE SUPPLEMENTARY SHEET License Number 29-00232-08

Docket or Reference Number

030-02423

Amendment No. 69

- 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. 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.
- 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 January 5, 2004 [ML040220539]
- B. Letter dated March 31, 2004 [ML041050565]
- C. Letter dated September 10, 2004 [ML042600366]
- D. Letter dated November 19, 2004 [ML050060292]
- E. Letter dated February 18, 2005

For the U.S. Nuclear Regulatory Commission

King of Prussia, Pennsylvania 19406

Date <u>March 13. 2005</u>	Ву	Original signed by Sandra Gabriel	
•	_	Sandra Gabriel	
		Medical Branch	
		Division of Nuclear Materials Safety	
		Region I	