

## MATERIALS LICENSE

Amendment No. 73

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.

OFFICIAL RECORD COPY

Licensee		In accordance with the letter dated May 13, 1997, 3. License Number 06-00854-03 is amended in its entirety to read as follows:	
1. St. Francis Hospital & Medical Center		4. Expiration Date April 30, 2004	
2. 114 Woodland Street Hartford, Connecticut 06105		5. Docket or Reference No. 030-01246/06-14734-01	
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 identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed	
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed	
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. 500 millicuries	
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 1150 millicuries	
E. Uranium depleted in the isotope Uranium 235	E. Metal	E. 160 kilograms	
F. Cesium 137	F. Sealed sources (Amersham Corp. Model CDC-SP1)	F. 1000 millicuries	
G. Iridium 192	G. Sealed sources (BYK Mallinckrodt Model CI L BV)	G. 2 sources not to exceed 10 curies each	
H. Hydrogen 3	H. Any	H. 150 millicuries	
I. Carbon 14	I. Any	I. 30 millicuries	
J. Phosphorus 32	J. Any	J. 25 millicuries	
K. Sulfur 35	K. Any	K. 20 millicuries	
L. Calcium 45	L. Any	L. 20 millicuries	
M. Iodine 125	M. Any	M. 40 millicuries	
N. Strontium 90	N. Sealed source	N. 1 millicurie	
O. Cesium 137	O. Sealed sources (Technical Operations Model No. 77302)	O. 200 millicuries	
P. Any byproduct material identified in 10 CFR 31.11	P. Prepackaged Kits	P. 5 millicuries	

9706240066 970609  
PDR ADOCK 03001246  
C PDR

ML 10

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

06-00854-03

Docket or Reference number

030-01246/06-14734-01

Amendment No. 73

9. Authorized use

- A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
- B. Any imaging and localization procedure approved in 10 CFR 35.200.
- C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
- D. Any brachytherapy procedure approved in 10 CFR 35.400.
- E. Shielding in a linear accelerator.
- F. For use in a Nucletron Corporation Model SEL 103 and SEL 106 remote afterloading device for interstitial, intracavitary, or bronchial therapy.
- G. One source to be used in a Nucletron Corporation Model Microselectron High Dose Rate Remote Afterloading Brachytherapy Device for interstitial, intracavitary, or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.
- H. through M. Research and development as defined in 10 CFR 30.4.
- N. Non-human use. For calibrations and checking of the licensee's instruments.
- O. For use in a Nuclear Associates or Technical Operations Model 773 calibrator for calibrations and checking of the licensee's survey instruments.
- P. In vitro diagnostic studies

CONDITIONS

- 10. Licensed material may be used only at the licensee's facilities located at 114 Woodland Street, Hartford, Connecticut and 500 Blue Hills Avenue, Hartford, Connecticut.
- 11. A. The Radiation Safety Officer for this license is Howard R. Shapiro, M.D.  
B. The Medical Physicist for this license is J. Robin Rice, Ph.D.
- 12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

James D. Slavin, Jr., M.D.

35.100; 35.200; 35.300

Neal F. Epstein, M.D.

35.100; 35.200

Iodine 131 for treatment of hyperthyroidism and cardiac dysfunction

Harold Hawkins, M.D.

35.200

Richard Shumway, M.D.

35.300; 35.400

Depleted uranium; Strontium 90; Cesium 137; Iridium 192 in a high dose rate remote afterloading brachytherapy device for the treatment of humans

Bruce Kaplan, M.D.

35.300; 35.400

Depleted uranium; Strontium 90; Cesium 137; Iridium 192 in a high dose rate remote afterloading brachytherapy device for the

**MATERIALS LICENSE**  
SUPPLEMENTARY SHEET

License number	06-00854-03
Docket or Reference number	030-01246/06-14734-01
Amendment No. 73	

Eric Van Rooy, M.D.

treatment of humans

35.300; 35.400; Iridium 192 in a high dose rate remote afterloading brachytherapy device for the treatment of humans

Ernesto M. Canalis, M.D.

Hydrogen 3; Carbon 14; Phosphorus 32; Sulfur 35; Calcium 45; and Iodine 125

Samuel Varghese, Ph.D.

Hydrogen 3; Carbon 14; Sulfur 35; Calcium 45; and Iodine 125

Robert D. Bona, M.D.

Calcium 45

George H. Barrows, M.D.

Phosphorus 32

Mozafareddin Karemeddini, M.D.

35.100; 35.200; 35.300  
In vitro studies

Patricia Luhan, Ph.D.

Phosphorus 32  
In vitro studies

Howard R. Shapiro, M.D.

35.100; 35.200; 35.300  
In vitro studies

Richard P. Spencer, M.D.

35.100; 35.200; 35.300  
In vitro studies

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 financial assurance for decommissioning.
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location 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.
15. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiation survey shall be made of:
  - A. The source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 millirem per hour.
  - B. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:
    - (1) That radiation doses to occupationally exposed individuals do not exceed the limits specified in 10 CFR 20.1201(a), 20.1207 and 20.1208.

**MATERIALS LICENSE**  
SUPPLEMENTARY SHEET

License number	06-00854-03
Docket or Reference number	030-01246/06-14734-01
Amendment No. 73	

(2) That radiation doses to individual members of the public do not exceed the limits specified in 10 CFR 20.1301(a).

16. A high dose rate afterloading brachytherapy unit shall be used in accordance with the following conditions:
- A. The unit may only be used in a permanently shielded treatment room.
  - B. During all patient treatments, both the authorized user and either the medical physicist or radiation safety officer must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech.
  - C. The licensee shall have and post in the vicinity of the treatment console, written emergency procedures describing the actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. The licensee shall not begin any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded condition.
  - D. The licensee shall ensure that personnel are trained in both the routine use of the unit and emergency procedures necessary to return the source to a safe position.
  - E. The licensee shall immediately, after implanting the source, visually check the permanently installed room radiation monitor to verify that it indicates an exposed radiation source.
  - F. The licensee shall visually monitor the patient during treatment through a continuous observation system.
  - G. The licensee shall permit no visitors in the treatment room.
17. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, radiation survey shall be made of the patient and the remote afterloading 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(p).
18. In lieu of the source inventory described in 10 CFR 35.406, the licensee shall:
- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each high dose remote brachytherapy procedure.
  - B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

06-00854-03

Docket or Reference number

030-01246/06-14734-01

Amendment No. 73

- C. Make a record of the survey including survey instrument used, dose rate, 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(d).
19. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:
- A. Installation, and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.
  - B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
20. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
21. Notwithstanding the requirements of 10 CFR 35.92(a), the licensee may hold any radioactive material authorized by this license with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided the licensee stores the material for decay in accordance with all other requirements of 10 CFR 35.92.



MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

06-00854-03

Docket or Reference number

030-01246/06-14734-01

Amendment No. 73

22. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. 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 October 26, 1993
- B. Letter dated January 10, 1994
- C. Letter dated April 14, 1994
- D. Letter dated November 17, 1994
- E. Letter dated December 23, 1994
- F. Letter dated January 31, 1995
- G. Letter dated March 1, 1995
- H. Letter dated August 23, 1995
- I. Letter dated September 20, 1995
- J. Letter dated September 28, 1995
- K. Letter dated July 2, 1996
- L. Letter dated July 31, 1996
- M. Letter dated August 19, 1996

JUN - 9 1997

Date \_\_\_\_\_

For the U.S. Nuclear Regulatory Commission

Original Signed By:  
Michelle Beardsley

By

Nuclear Materials Safety Branch  
Region I  
King of Prussia, Pennsylvania 19406

JUN - 9 1997

Mary Ellen Doyle  
Vice President  
St. Francis Hospital and Medical Center  
114 Woodland Street  
Hartford, CT 06105

Dear Ms. Doyle:

This refers to your license amendment request. 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) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:  
Michelle Beardsley

Michelle R. Beardsley  
Division of Nuclear Materials Safety

License No. 06-00854-03  
Docket No. 030-01246  
Control No. 124571

Enclosure:  
Amendment No. 73

DOCUMENT NAME: R:\WPS\MLTR\L0600854.03

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	Beardsley	<i>MB</i>					
DATE	05/28/97		05/ /97	05/ /97	05/ /97	05/ /97	

OFFICIAL RECORD COPY

ML 10



SAINT FRANCIS

Hospital and Medical Center

Department of Radiology

114 Woodland Street  
Hartford, Connecticut  
06103-1299

860 714-4830

May 13, 1997

030-01246

United States Nuclear Regulatory Commission  
Region I  
Radioactive Materials Licensing Section  
475 Allendale Road  
King of Prussia, PA 19406

Dear Licensing Materials Staff:

This letter is to inform your office of a recent change in our radioactive materials license. Kenneth S. Schwartz, M.D., has resigned his position and duties as Radiation Safety Officer for the St. Francis Hospital and Medical Center (NRC License #06-00854-03) located at 114 Woodland Street, Hartford, Connecticut. During a recent inspection of our license, Ms. Neelam Bhalla, NRC inspector informed us that a formal amendment request had not been submitted as indicated in our letter dated October 25, 1996.

Effective immediately, the duties and responsibilities of the Radiation Safety Officer have been assigned to Howard R. Shapiro, M.D. Dr. Shapiro is listed on the license as an authorized user. Please refer to item 12 of license Amendment #72, page 3, to confirm Dr. Shapiro's approval as an authorized user of licensed radioactive materials.

We request that your office formally amend our radioactive materials license to recognize Dr. Shapiro as the Radiation Safety Officer. In addition, we request to amend the license to include Eric VanRooy, M.D. as an authorized user for Ir-192 as a HDR source. Dr. VanRooy is currently listed to use only 35.300 and 35.400 sources. Further, we wish to remove Dayee Jacob and Michael Caprio from the license as HDR physicists. A check for the amendment fee is enclosed.

If you require further clarification or additional information concerning this request, please call my office at your convenience. Thank you for your attention to this matter.

Sincerely,  
St. Francis Hospital and Medical Center

Mary Ellen Doyle, Vice President

Enclosure

124571

OFFICIAL RECORD COPY

ML 10

MAY 15 1997



BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LFMS USE)  
INFORMATION FROM LTS

Program Code: 02230  
Status Code: 0  
Fee Category: 7C 2B  
Exp. Date: 20040430  
Fee Comments: \_\_\_\_\_  
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: ST. FRANCIS HOSPITAL & MEDICAL CTR.  
Received Date: 970515  
Docket No: 3001246  
Control No.: 124571  
License No.: 06-00854-03  
Action Type: Amendment

2. FEE ATTACHED

Amount: \$440.00  
Check No.: 364991

3. COMMENTS

Signed M. A. Perkins  
Date 5/17/97

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ☒)

1. Fee Category and Amount: 7C \$440

2. Correct Fee Paid. Application may be processed for:

Amendment ☒  
Renewal \_\_\_\_\_  
License \_\_\_\_\_

3. OTHER \_\_\_\_\_

Signed SC  
Date 6/3/97

Log	<u>May 10 I</u>
Remitter	_____
Check No.	<u>364991</u>
Amount	<u>\$440</u>
Fee Category	<u>7C</u>
Type of Fee	<u>AMD</u>
Date Check Rec'd	<u>5/28/97</u>
Date Completed	<u>6/3/97</u>
By	<u>SC</u>