

MATERIALS LICENSE

Amendment No. 46

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 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

1. Stamford Hospital
Department of Nuclear Medicine
2. P. O. Box 9317 - Shelburne Road
Stamford, Connecticut 06904-9317

In accordance with the letter dated
August 6, 1996,3. License Number 06-06697-02 is amended in
its entirety to read as follows:

4. Expiration Date September 30, 2004

5. Docket or
Reference No. 030-012656. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. 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 except gas | B. As needed |
| C. Any byproduct material
identified in 10 CFR
35.300 | C. Any radiopharmaceutical
identified in 10 CFR
35.300 | C. 1000 millicuries |
| D. Any byproduct material
identified in 10 CFR
35.400 | D. Any brachytherapy source
identified in 10 CFR
35.400 | D. 2000 millicuries |
| E. Any byproduct material
identified in 10 CFR
31.11 | E. Prepackaged Kits | E. 5 millicuries |
| F. Cesium 137 | F. Sealed sources (3M Models
6D6C-CA, Nos. 6500, 6501,
6502 and 6503) | F. 260 millicuries |

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. In vitro studies.
- F. Non-human use. For calibrations and checking of the licensee's instruments.

CONDITIONS

10. A. Licensed material may be used at the licensee's facilities located at Stamford Hospital, 190 West Broad Street, Stamford, Connecticut.

9610280203 961016
PDR ADOCK 03001265
C PDR

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SUPPLEMENTARY SHEET

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- B. Licensed material in Items 6.A. and 6.B may be used at the licensee's facilities located at the Diagnostic Imaging Center of Stamford, 1290 Summer Street, Suite 3500, Stamford, Connecticut.
11. The Radiation Safety Officer for this license is Harvey L. Hecht, M.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:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|-----------------------------|---|
| Steven M. Cohen, M.D. | 35.100; 35.200
<u>In vitro</u> studies |
| Kristan D. Zimmermann, M.D. | 35.100; 35.200
<u>In vitro</u> studies |
| William Harley, M.D. | 35.200 |
| Richard J. Fleming, M.D. | 35.100; 35.200; 35.300; 35.400
<u>In vitro</u> studies |
| Harvey L. Hecht, M.D. | 35.100; 35.200; 35.300; 35.400
<u>In vitro</u> studies
Cesium 137 for instrument calibrations |
| Thomas Di Bartholomeo, M.D. | 35.100; 35.200; 35.300; <u>In vitro</u> studies
Cesium 137 for instrument calibration |
| Sean W. Dowling, M.D. | 35.300; 35.400 |
| Frank A. Masino, M.D. | 35.300; 35.400 |
| Arnold J. Schwartz, M.D. | 35.300; 35.400 |
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. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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15. 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. (2) Letters dated March 11, 1994
- B. Letter dated July 5, 1994
- C. Letter dated July 28, 1994
- D. Letter dated August 18, 1994
- E. Letter dated September 9, 1994

For the U.S. Nuclear Regulatory Commission

Date OCT 16 1996

ORIGINAL SIGNED BY:
By JO ANN V. STAMBAUGH
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

OCT 16 1996

Mr. Frederick H. Kuriger
Vice President, Clinical Services
Stamford Hospital
P.O. Box 9317, Shelburne Road
Stamford, CT 06904-9317

Dear Mr. Kuriger:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the 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:
JO ANN V. STAMBAUGH
JoAnn V. Stambaugh
Division of Nuclear Materials Safety

License No. 06-06697-02
Docket No. 030-01265
Control No. 123549

Enclosure:
Amendment No. 46

DOCUMENT NAME: R:\WPS\MLTR\L0606697.02

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	N	DNMS/RI				
NAME	Stambaugh/jvs						
DATE	08/11/96	8/11/96	08/ /96	08/ /96	08/ /96	08/ /96	

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030-01265



August 6, 1996

USNRC
Region 1
License Division
475 Allendale Road
King of Prussia, PA 19406-1415

Dear NRC:

As Radiation Safety Officer at The Stamford Hospital, I would like to recommend Thomas DiBartholomeo, M.D. to be added to our Nuclear License (06-06697-02) in all of the following categories: 35.100; 35.200; 35.300; in vitro studies; cesium 137 for instrument calibration.

Respectfully submitted,

Harvey L. Hecht, M.D.
Radiation Safety Officer

123549

AUG - 8 1996



United to Improve
America's Health™

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EXHIBIT 2
SUPPLEMENT A

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION	
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER			
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER <i>Thomas Di Bartholomeo</i>		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED <i>Connecticut</i>	
3. CERTIFICATION			
SPECIALTY SCARD <i>A</i>	CATEGORY <i>B</i>	MONTH AND YEAR CERTIFIED <i>C</i>	
<i>The American Board of Radiology</i>	<i>Diagnostic Radiology</i>	<i>June, 1995</i>	
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING <i>A</i>	LOCATION AND DATES OF TRAINING <i>B</i>	TYPE AND LENGTH OF TRAINING CLOCK HOURS IN LECTURE OR LABORATORY CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
<i>a. RADIATION PHYSICS AND METROLOGY</i>	<i>Montefiore Med. Center 111 EAST 210 ST BRONX, NY 10467</i>	<i>200</i>	<i>100</i>
<i>b. RADIATION PROTECTION</i>	<i>"</i>	<i>150</i>	<i>50</i>
<i>c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY</i>	<i>"</i>	<i>150</i>	<i>50</i>
<i>d. RADIATION BIOLOGY</i>	<i>"</i>	<i>100</i>	<i>50</i>
<i>e. RADIOPHARMACEUTICAL CHEMISTRY</i>	<i>"</i>	<i>100</i>	<i>50</i>
5. EXPERIENCE WITH RADIATION (Actual use of Radioisotopes or Equivalent Experiences)			
ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS
<i>99mTc</i>	<i>400 mCi</i>	<i>Montefiore Med. Center</i>	<i>Over 4 Year period 7/1/91 - 6/30/95 - SPECIFIC 1000 HR Conc. in Nuclear Med.</i>
<i>111In</i>	<i>20 mCi</i>	<i>"</i>	<i>① Organ Counting + imaging</i>
<i>131I</i>	<i>100 mCi</i>	<i>"</i>	<i>② 131I Thyroid Rx</i>
<i>201Tl</i>	<i>20 mCi</i>	<i>"</i>	<i>③ 32p Therapy</i>
<i>32P</i>	<i>15 mCi</i>	<i>"</i>	

EXH-5

EXHIBIT 3
SUPPLEMENT B

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<p>Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, submit a separate statement from each.</p>			
1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS		KEY TO COLUMN C	
<p>FULL NAME Thomas J. DiBartholomeo</p> <p>STREET ADDRESS Stanford Hospital, Shelburne Rd</p> <p>CITY Stanford</p> <p>STATE CA</p> <p>ZIP CODE 06907</p>		<p>PERIODICAL PARTICIPATION SHOULD CONSIST OF:</p> <p>1. Documented participation of patients to determine the suitability for radioactive diagnosis and/or treatment and reimbursement for procedure charges.</p> <p>2. Documentation in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and timing of dose.</p> <p>3. Adequate period of training to enable physician to manage radioactive patients and follow protocols through diagnosis and/or course of treatment.</p>	
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN			
CONCENTRATION	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVING PERIODICAL PARTICIPATION	COMMENTS (Additional information or comments only in substance or duplicate on separate sheet.)
A	B	C	D
123I or 99mTc	Thyroid scan	105	
99mTc	Thyroid uptake	105	
	Long perfusion scan	90	
	Zoned ventilation study	5	
99mTc	Aerosol ventilation scan	85	
99mTc	Renal flow scan	145	
99mTc	Brain scan	28	
99mTc	Liver/spleen scan	47	
"	Bone scan	210	
"	Gastroesophageal study	8	
"	Left ventricle study	4	
"	Cystogram	12	
"	Barium esophagram	7	
99mTc or 201Tl	Cardiac perfusion scan	145	
99mTc	Cardiac stress ventriculogram	35	
	Cardiac rest ventriculogram	60	
	Gallium scan	110	

EXH-3

1011 1011

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ABSTRACT	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS (Additional information or experience may be submitted in duplicate on separate sheet.)
A	B	C	D
P-32 (continued)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	4	
P-32 (continued)	INTRACAVITARY TREATMENT	—	
I-121	TREATMENT OF THYROID CARCINOMA	6	
	TREATMENT OF HYPERTHYROIDISM	26	
As-180	INTRACAVITARY TREATMENT	—	
Co-60 or Co-137	INTERSTITIAL TREATMENT	—	
	INTRACAVITARY TREATMENT	—	
I-125 or P-32 or Co-60 or Co-137	INTERSTITIAL TREATMENT	—	
	TELETERAPY TREATMENT	—	
Q-90	TREATMENT OF EYE DISEASE	—	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATION	7	
Mo-113/ Mo-113m	GENERATION	—	
Tc-99m	REAGENT KITS	80	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION: Montefiore Med. Center
111 EAST 210 ST
BRONX, NY 10467
DATES: 7/1/91 - 6/30/95
CLOCK HOURS OF EXPERIENCE: 1000 HOURS

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
LEONARD M. FREEMAN MD
b. NAME OF INSTITUTION
Montefiore Med. Center
c. ADDRESS
111 EAST 210 ST
BRONX, NY 10467
d. PHONE NUMBER
NY 75-2885-01
NEW YORK CITY

5. PRECEPTOR'S SIGNATURE
Leonard M. Freeman MD

6. PRECEPTOR'S NAME PRINTED HERE
LEONARD M. FREEMAN MD

7. DATE
8/5/96

EXH-7

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001Stamford Hospital
ATTN: Harvey L. Hecht, M.D.
Radiation Safety Officer
Shelburne Road at West Broad Street
Stamford, CT 06904-9317

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE

8-6-96

LICENSE NUMBER

06-06697-02

CONTROL NUMBER

123549

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	\$	\$	\$ 440.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	440.00
PAYMENT RECEIVED	\$	0.00
AMOUNT DUE	\$	440.00

- ☒ Your request was received without the prescribed application fee.
- ☐ We received your Check No. _____ in the amount of \$ _____. Payment of the additional fee noted above is required.
- ☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

☐ We received your Check No. _____ in payment of the fee.

☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.

☐ Your request was combined, prior to review, with your request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- ☐ License No. _____, Amendment No. _____, issued on _____, was issued without the required fee being collected. The fee required is noted in Section I of this form.
- ☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section I of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section I of this form.

SIGNATURE - LICENSE FEE ANALYST

Brenda Brown

LFDCB

BB/LA

8/14/96

LFDCB

Distribution:

MAF Correspondence

LFDCB Chief

Invoice File w/encl

LFDCB Analyst

LFDCB R/F

DATE

8-14-96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20040930
FEE COMMENTS: -----
DECOM FIN ASSUR REQD: N
.....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: STAMFORD HOSPITAL
RECEIVED DATE: 960808
DOCKET NO.: 3001265
CONTROL NO.: 123549
LICENSE NO.: 06-06697-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: -----
CHECK NO.: -----

3. COMMENTS

SIGNED
DATE

M. A. Perkins
8/9/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ✓)

1. FEE CATEGORY AND AMOUNT: 7C 8440

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED
DATE

Log	<u>Aug 10</u>
Remitter	
Check No.	<u>0281248</u>
Amount	<u>8440</u>
Fee Category	<u>7C</u>
Type	<u>AmS</u>
Date	<u>10/11/96</u>
Date Compted	
By	<u>BR</u>

07 for 10/11/96

1996 AUG 12 PM 3:52