

July 9, 2008

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

Re: Radioactive Materials license No. 29-12109-01

Dear Sir/Madam:

The hospital has just entered into a contractual arrangement to replace the current group of radiologists with a new group effective on **July 25, 2008**. The physicians listed below need to be added to our license by the date to ensure the hospital's nuclear medicine service may continue to operate without interruption. Your prompt attention to this matter will be greatly appreciated.

Please add the following physicians to our radioactive material license No. 29-12109-01 as authorized users:

Steven Leffler, PhD, M.D. groups I and II  
Kenneth S. Schwartz, M.D. groups I, II, and III  
Robert M. Wilkens, M.D. groups I, II, and III

Enclosed are their C.V.s' American Board of Radiology certifications, a copy of The City of New York Radioactive Materials license naming Dr Schwartz, and Dr Wilkens as authorized users.

A copy of NRC license No. 29-10313-01 naming Dr. Leffler as an authorized user is also enclosed.

The current authorized users on our license will be leaving Robert Wood Johnson University Hospital at Rahway on July 24, 2008. An amendment request reflecting this change will be forthcoming.

All other conditions of our radioactive material license remain the same at this time.

Please contact Mr. Robert White, Director of Clinical Services should you need any additional information at 732-815-7512.

Sincerely,

Kirk C. Tice  
President and CEO

*[Handwritten signature of Kirk C. Tice]*  
*[Handwritten signature of Lynn Leary]*  
*[Handwritten signature of Robert M. Wilkens]*  
142599

**ROBERT MICHAEL WILKINS, M.D.**

**RESIDENCE:**

[REDACTED]  
[REDACTED]

**OFFICE TELEPHONE:**

(914) 666-2220

**OFFICE FAX:**

(914) 666-2987

**HOME PHONE:**

[REDACTED]

**DATE AND PLACE OF BIRTH:**

[REDACTED]  
[REDACTED]

**SOCIAL SECURITY NUMBER:**

[REDACTED]

**EDUCATION:**

University of Maryland  
College Park, MD 20742  
Bachelors, *June 1975*

Howard University Medical School  
2041 Georgia Avenue  
Washington DC 20060  
M.D. *August 25<sup>th</sup>, 1975 - May 12<sup>th</sup>, 1979*

**POST DOCTORAL TRAINING:**

Howard University Hospital  
2041 Georgia Avenue  
Washington DC 20060  
*Internal Medicine Intern*  
*July 1979 – June 1980*

Mount Sinai Hospital  
One Gustave I Levy Place  
1190 5<sup>th</sup> Avenue  
New York, NY 10029  
Resident Radiology:  
*July 1980 – June 1983*

Mount Sinai Hospital  
One Gustave I Levy Place  
1190 5<sup>th</sup> Avenue  
New York, NY 10029  
Mini Fellowship Special Procedures  
*July 1982 – June 1983*

**LICENSURE:**

New York State, *August 1<sup>st</sup>, 1980, 143114-1*  
New Jersey, *25M408254200*

**DEA REGISTRATION NUMBER:**

AW2172699

**PERSONAL INFORMATION WAS REMOVED  
BY NRC. NO COPY OF THIS INFORMATION  
WAS RETAINED BY THE NRC.**

**SOCIETY MEMBERSHIPS:**

American College of Radiology

**ACCREDITATION:**

American Board of Radiology  
Certified in Radiology: *June 3<sup>rd</sup>, 1983*

**HOSPITAL APPOINTMENTS:**

Bon Secours Community Hospital  
160 East Main Street  
Port Jervis, NY 12771-2245  
*September 2007 – Present*

Chief of Radiology  
St. Anthony Community Hospital  
15 Maple Avenue  
Warwick, NY 10990  
*July 2007 – Present*

Mercy Medical Center  
1000 North Village Avenue  
Rockville Centre, NY 11570  
*July 2007 – Present*

Unite Health Center  
275 Seventh Avenue  
New York, NY 10001  
*August 2006 – Present*

Coler-Goldwater Specialty Hospital  
One Main Street  
Roosevelt Island, NY 10044  
*March 2006 – Present*

Ellenville Regional Hospital  
Route 209  
Ellenville, NY 12428  
*September 2005 – June 2006*

SouthSide Hospital  
301 East Main Street  
Bayshore, NY 11706  
*June 2005 – Present*

New York Downtown Hospital  
170 Williams Street  
New York, NY 10038  
*May 2005 – Present*

Forest Hills Hospital  
102-01 66<sup>th</sup> Road  
Forest Hills, NY 11375  
*March 2005 – Present*

Kingsbrook Jewish Medical Center  
585 Schenectady Avenue  
Brooklyn, NY 11203  
*March 2005 – Present*

Columbus Medical Institute  
97-85 Queens Boulevard  
Rego Park, NY 11374  
*March 2004 – October 2005*

St. Vincent's Midtown Hospital (closed)  
415 51<sup>st</sup> Street  
New York, New York 10019  
*February 1990 – 8/31/07*

Terence Cardinal Cooke Health Care Center  
1249 Fifth Avenue  
New York, NY 10029  
*July 1998 – November 2005*

NYO Hotel Trade Council  
773-775 9<sup>th</sup> Avenue  
New York, New York 10019  
*September 1995 – Present*

**EMPLOYMENT:**

S & D Medical, LLP  
52 Main Street  
Bedford Hills, NY 10507  
*December 2004 – Present*

83<sup>rd</sup> Street Radiology (*closed 7/1/07*)  
121 East 83<sup>rd</sup> Street  
New York, New York  
*January 2001 – March 2004*

Messina, Liebeskind, Liebeskind and Halpern  
50 East 72<sup>nd</sup> Street  
New York, New York  
*July 1983 – January 1990*

*The American*

*Board of Radiology*

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association  
and the American Society of Therapeutic Radiologists  
Hereby certifies that*

**Robert M. Wilkins, M.D.**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of  
The American Board of Radiology*

**On this third day of June, 1983**

*Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of*

**Diagnostic Radiology**



# CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

Pursuant to the New York City Charter and Article 175 of the New York City Health Code and in reliance on statements and representations heretofore made by licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

In accordance with Application dated 20 August 2006 from Len Walsh, C.E.O., St. Vincent's Midtown Hospital; License number 91-2882-01 is hereby amended in its entirety to read:

## LICENSEE

1. Name: St. Vincent's Midtown Hospital

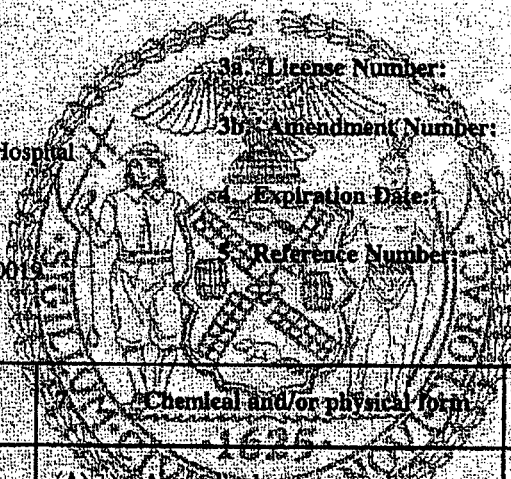
2. Address: 415 West 51<sup>st</sup> Street  
New York, New York 10019

3a. License Number: 91-2882-01

3b. Amendment Number: 6

4. Expiration Date: 30 September 2011

5. Reference Number: 634-3



| 6. Radioactive materials (element number)                                      | Chemical and/or physical form  | 8. Maximum quantity licensee may possess at any one time |
|--|--|--|
| (A) Any radioactive material identified in §175.103(d) (1)(i), NYC Health Code | (A) Any radiopharmaceutical or radiobiologic with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA.  | (A) As necessary for uses authorized in Subitem 9(A)     |
| (B) Any radioactive material identified in §175.103(e)(1)(i), NYC Health Code  | (B) Any radiopharmaceutical or radiobiologic with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA (GENERATORS AEROSOLS AND GASES ONLY AS LISTED BELOW)<br>***** | (B) As necessary for uses authorized in Subitem 9(B)     |

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

Page 2 of 5 Pages

License Number: 91-2882-01

Amendment Number: 6

Reference Number: 634-3

| 6. Radioactive materials (element number) | 7. Chemical and/or physical form   | 8. Maximum quantity licensee may possess at any one time   |
|---|--|--|
| (C) Technetium-99m                        | (C) DTPA Aerosol with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA  | (C) 3.7 Gigabecquerels                                     |
| (D) Technetium-99m                        | (D) Pertechnetate  | (D) Individual amounts not to exceed 1.85 Gigabecquerels   |
| (E) Cobalt-57                             | (E) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (E) 5 Sources not to exceed 925 Megabecquerels per source  |
| (F) Cobalt-57                             | (F) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (F) 5 Sources not to exceed 740 Megabecquerels per source  |
| (G) Barium-133                            | (G) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (G) 5 Sources not to exceed 18.5 Megabecquerels per source |
| (H) Cesium-137                            | (H) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (H) 5 Sources not to exceed 18.5 Megabecquerels per source |
| (I) Technetium-99m                        | (I) Pyro. and Trimeta-Phosphate Kit (Mallinckrodt, NDA 17-538; Bracco Diagnostics, NDA 17-680; DuPont Merck, NDA 17-684)   | (I) 14.8 Gigabecquerels                                    |
| (J) Technetium-99m                        | (J) Sestamibi Kit (DuPont Merck, NDA 20-372)<br>*****  | (J) 37 Gigabecquerels                                      |



**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

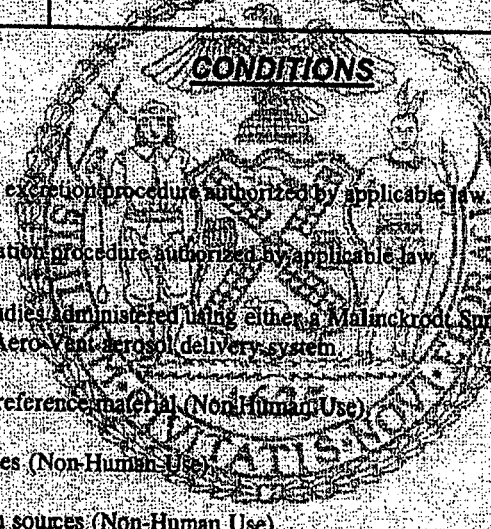
License Number: 91-2882-01

Amendment Number: 6

Reference Number: 634-3

| 6. Radioactive materials (element number) | 7. Chemical and/or physical form  | 8. Maximum quantity licensee may possess at any one time |
|---|---|--|
| (K) Technetium-99m                        | (K) Tetrofosmin Kit (Amersham, NDA 20-372)  | (K) 37 Gigabecquerels                                    |
| (L) Thallium-201                          | (L) Thallous Chloride (DuPont Merck, NDA 17-806; Mallinckrodt, NDA 18-150; Medi-Physics, NDA 18-110; Bracco Diagnostics, NDA 18-548)<br>***** | (L) 14.8 Gigabecquerels                                  |

**9. Authorized Use:**

- 
- (A) Any uptake, dilution or excretion procedure authorized by applicable law.
- (B) Any imaging or localization procedure authorized by applicable law.
- (C) Pulmonary function studies administered using either a Mallinckrodt-Snisco, Inc., a Cadema System, Inc., or a Medi-Nuclear Corporation Aero-Vent aerosol delivery system.
- (D) Calibration check and reference material (Non-Human Use).
- (E) Flood calibration sources (Non-Human Use).
- (F) through (H) Calibration sources (Non-Human Use).
- (I) As a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction, and for gated cardiac blood pool imaging.
- (J) Myocardial imaging agent used to distinguish normal from abnormal myocardium, to localize abnormality in patients with suspected myocardial infarction, and for evaluation of myocardial function using first pass technique.
- (K) Imaging of the myocardium following separate administrations under exercise and resting conditions, and in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.
- (L) Myocardial perfusion imaging, the diagnosis and localization of myocardial infarction, and prognosis regarding survival after onset of symptoms of acute myocardial infarction to assess site and size of perfusion defect.

10. The licensee shall comply with the provisions of Article 175 of the New York City Health Code entitled "Radiation Control."

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**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

Page 4 of 5 Pages

License Number: 91-2882-01

Amendment Number: 6

Reference Number: 634-3

11. Failure to pay the fee for inspection of a radioactive material site, upon notification from the Department, will result in termination of this license.
12. The radioactive material may be used only in The New Department of Nuclear Medicine Suite, St. Vincent's Midtown Hospital, 415 West 51st Street, New York, New York 10019.
13. Radioactive materials listed in Item 6 are authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Authorized User

Materials and Use

Jonathan Greenblatt, M.D.

Subitems 6(D) through 6(L)

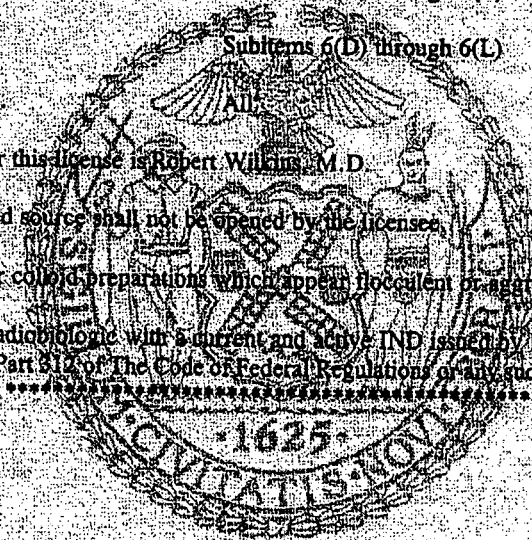
Tien Nguyen, M.D.

Subitems 6(D) through 6(L)

Robert Wilkins, M.D.

All

14. The radiation safety officer for this license is Robert Wilkins, M.D.
15. Radioactive material as a sealed source shall not be opened by the licensee.
16. Technetium-99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.
17. Any radiopharmaceutical or radiopharmaceutical with a current and active IND issued by FDA shall be used in accordance with Title 21, Part 312 of The Code of Federal Regulations or any successor regulation.



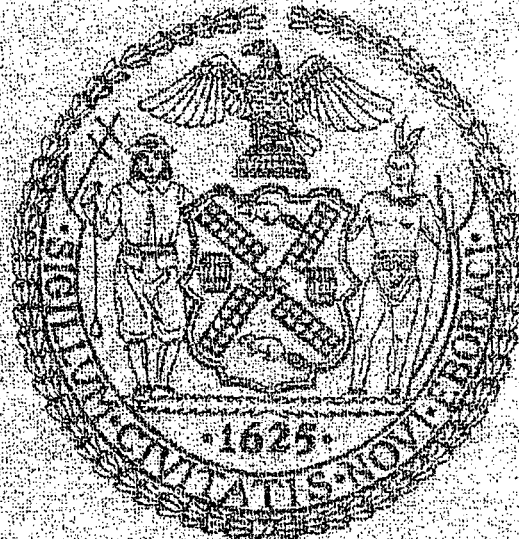
**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

Page 5 of 5 Pages

License Number: 91-2882-01  
Amendment Number: 6  
Reference Number: 634-3

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. Article 175 of the New York City Health Code shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(A) Application dated 20 August 2006



FOR THE NEW YORK CITY DEPARTMENT  
OF HEALTH AND MENTAL HYGIENE

Date:

DEC 04 2006

RP/h

*Raymond Ford*  
Raymond Ford  
Scientist

Radioactive Materials Division  
Office of Radiological Health

**STEVEN LEFFLER PhD, MD**

**RESIDENCE:**

[REDACTED]

**HOME TELEPHONE:**

[REDACTED]

**OFFICE TELEPHONE:**

(914) 666-2220

**OFFICE FAX:**

(914) 666-2987

**DATE AND PLACE OF BIRTH:**

[REDACTED]

**SOCIAL SECURITY NUMBER:**

[REDACTED]

**EDUCATION:**

New York University  
550 First Avenue  
New York, NY 10016  
BA Biology: *September 1965 – June 1969*

New York University  
550 First Avenue  
New York, NY 10016  
PhD Biochemistry: *September 1969 – October 1973*

Hahnemann Medical College  
245 North 15<sup>th</sup> Street  
Philadelphia, PA 19102  
MD: *October 1982 – June 1984*

**POST DOCTORAL TRAINING:**

Graduate Hospital of  
The University of Pennsylvania  
3400 Spruce Street, 1 Maloney  
Philadelphia, PA 19104  
Internship General Surgery: *June 1984 – June 1985*

St. Vincent's Hospital & Medical Center  
170 West 12<sup>th</sup> Street  
New York, NY 10011  
Resident Diagnostic Radiology: *July 1985 – June 1989*

New York Medical College  
100 Grasslands Road  
Valhalla, NY 10595  
Fellowship Interventional Radiology: *July 1989 – June 1990*

**PERSONAL INFORMATION WAS REMOVED  
BY NRC. NO COPY OF THIS INFORMATION  
WAS RETAINED BY THE NRC.**

**LICENSURE:**

New York: 162767 *July 1<sup>st</sup>, 1985*  
New Jersey: 25M405491100 *July 1<sup>st</sup>, 1985*  
Pennsylvania: MD041418L *March 23<sup>rd</sup>, 1990*  
Florida: ME95225 *February 14<sup>th</sup>, 2006*

**DEA:**

BL2308042

**ACCREDITATION:**

American Board of Radiology  
Certified in Radiology: *December 11<sup>th</sup>, 1989*

**SOCIETY MEMBERSHIPS:**

ACR  
RSNA  
SIR

**HOSPITAL APPOINTMENTS:**

Forest Hills Hospital  
102-01 66<sup>th</sup> Road  
Forest Hills, NY 11375  
*March 2008 - Present*

Mercy Medical Center  
1000 N. Village Avenue  
Rockville Centre, NY 11570  
*November 2007 – Present*

Bon Secours Community Hospital  
160 East Main Street  
Port Jervis, NY 12771-2245  
*November 2007 – Present*

St. Anthony Community Hospital  
15 Maple Avenue  
Warwick, NY 10990  
*October 2007 – Present*

Union Hospital (closing)  
1000 Galloping Hill Road  
Union, NJ 07083  
Attending Radiologist: *February 2006 – October 2007*  
(908) 851-7131

Clifton Springs Hospital  
2 Coulter Road  
Clifton Springs, NY 14432  
Attending Radiologist: *December 2005 – February 2006*  
(315) 462-9561

Barnert Hospital  
680 Martin Luther King Way  
Paterson, NJ 07514  
Attending Radiologist: *April 2003 – November 2005*  
(973) 977-6600

Chilton Memorial Hospital  
97 West Parkway  
Pompton Plains, NJ 07444  
Attending Radiologist: *April 2003 – November 2005*  
(973) 831-5740

Palisades Medical Center  
7600 River Road  
North Bergen, NJ 07047  
Attending Radiologist: *August 1991 – December 2002*  
(201) 854-5000

Passaic Beth Israel Medical Center  
70 Parker Avenue  
Passaic, NJ 07055  
Attending Radiologist: *August 1990 – August 1991*  
(973) 365-5000

**EMPLOYMENT:**

S & D Medical, LLP  
52 Main Street  
Bedford Hills, NY 10507  
*November 2007 – Present*

Radiology Affiliates  
3120 Princeton Pike  
Lawrenceville, NJ 08648  
Attending Radiologist: *July 1990 – August 1990*  
(609) 219-1000

Mt. Sinai Hospital  
One Gustave L. Levy Place  
1190 5<sup>th</sup> Avenue  
New York, NY 10029  
Lab Technician – Nuclear Medicine  
*June 1969 – September 1969*

**LOCUM TENENS:**

**Radiology Associates of NJ**

**Staff Radiologist: May 2005 – August 2006**

- *Kennedy Health Systems*  
18 East Laurel Road  
Stratford, NJ 08084  
(856) 346-7844  
Staff Radiologist: *May 2005 – August 2006*

**Kennedy Imaging P.C.**

**Staff Radiologist: September 2004 – May 2005**

- *Kennedy Imaging P.C.*  
500 Marlboro Avenue  
Cherry Hill, NJ 08002  
(856) 346-6000  
Staff Radiologist: *September 2004 – May 2005*

**Excalibur Kennedy Imaging**

**Staff Radiologist: June 2003 – August 2004**

- *Kennedy Health System Hospital*  
18 East Laurel Road  
Stratford, NJ 08084  
(856) 346-7844  
Staff Radiologist: *June 2003 – August 2004*

**SouthEastern Emergency SE**

**Staff Radiologist: April 2002 – March 2003**

- *Capital Health Systems*  
446 Bellevue Avenue  
Trenton, NJ 08607  
(609) 394-4000  
*October 2002 – March 2003*
- *Kaleida Millard Fillmore*  
3 Gates Circle  
Buffalo, NY 14209-1120  
(716) 887-4600  
*April 2002 – September 2002*

**Cambria-Somerset Radiology & Nuc**

**Staff Radiologist: May 2002**

- *Conemaugh Memorial Medical*  
1086 Franklin Street  
Johnstown, PA 15905-4398  
(814) 533-1000  
*May 2002*

**Advanced Radiology, Ser.  
Staff Radiologist: March 2002**

- *Our Lady of Lourdes Memorial Hospital*  
169 Riverside Drive  
Binghamton, NY 13850  
(607) 798-5111  
*March 2002*

**UMDNJ-School of Osteopath  
Staff Radiologist: February 2002 – March 2002**

- *Kennedy Health System Hospital*  
18 East Laurel Road  
Stratford, NJ 08084  
(856) 346-7844  
*February 2002 – March 2002*

**Guyette MD PSC William  
Staff Radiologist: April 1990 – May 1990**

- *Crittenden County Hospital*  
Highway 60 South  
Marion, KY 42064  
(270) 965-1013  
*April 1990 – May 1990*

**TEACHING APPOINTMENTS:**

Mt. Sinai Hospital  
One Gustave L. Levy Place  
1190 5<sup>th</sup> Avenue  
New York, NY 10029  
Research Assistant Professor  
*June 1978- June 1980*

Baruch College, CUNY  
55 Lexington at 24<sup>th</sup> Street  
New York, NY 10010  
Adjunct Asst. Professor in Biochemistry  
*September 1977 – June 1981*

NYU School of Medicine  
550 First Avenue  
New York, NY 10016  
Asst. Research Scientist-Dept. of Biochemistry  
*October 1973 – February 1974*

**PUBLICATIONS:**

**Leffler, S, Hierowski, M, Poindexter, JS and Szer, W**  
(1971), Large Scale Isolation of the Caulobacter  
bacteriophage PhiCb5 and its RNA genome, FEBS Letters,  
19, 112-114



**Leffler, S** and Szer, W (1973), Polypeptide chain initiation in *Caulobacter crescentus*. Absence of an IF-1 like protein in ribosomal washes, Federation Proc 32, 533 Abs

**Leffler, S** and Szer, W (1973), Ribosomal specificity in translation, 9<sup>th</sup> International Congress of Biochemistry, Stockholm, 158 Abs

**Leffler, S** and Szer, W (1973), Messenger selection bacterial ribosomes, Proc Nat Acad Sci USA 70, 2364-2368

Szer, W and **Leffler, S** (1973), Ribosomal specificity in translation of phage RNAs, Cold Spring Harbor Mtg. on Ribosomes, 21 Abs

**Leffler, S** and Szer, W (1974), Purification and properties of initiation factor IF-3 from *Caulobacter crescentus*, J.Biol.Chem, 249, 1458-1464

**Leffler, S** and Szer, W (1974), Polypeptide chain initiation in *Caulobacter crescentus* without IF-1, J.Biol.Chem, 249, 1465-1468

Szer, W and **Leffler, S** (1974), Interaction of *E.coli* 30s ribosomal subunits with MS2 phage RNA in the absence of initiation factors, Proc.Nat.Acad.Sci, USA 71, 3611-3615

Szer, W, Hermoso, J and **Leffler, S** (1975), Ribosomal protein S1 and polypeptide chain initiation in bacteria, Proc.Nat.Acad.Sci, USA 72, 2325-2329.

Yamasaki, H, **Leffler, S**, Poupko, J and Weinstein, IB (1976), Modification of DNA with N-2-acetylaminofluorene (AAF): effect on chromatin structure and template activity, Federation Proc. 35, 1518 Abs.

Yamasaki, H, **Leffler, S**, Poupko, J and Weinstein, IB (1976), Effect on N-2\_Acetyl aminofluorene modification on the structure and template activity of DNA and reconstituted chromatin, Cancer Res. 37, 684-691.

**Leffler, S**, Pulkrabek, P, Grunberger, D and Weinstein, IB (1977), Template activity of DNA modified with benzo(a)pyrene in vitro, Amer. Assoc.Adv.Sci. Meeting, Denver, 137 Abs.

Pulkrabek, P, **Leffler, S**, Weinstein, IB and Grunberger, D (1977), Conformation of DNA modified with a dihydrodiol epoxide derivative of benzo(a)pyrene, *Biochemistry* 16, 3127-3132.

**Leffler, S**, Pulkrabek, P, Grunberger, D and Weinstein, IB (1977), Template activity of calf thymus DNA modified by a dihydrodiol epoxide derivative of benzo(a)pyrene, *Biochemistry* 16, 3133-3136.

Weinstein, IB, Jeffrey, AM, **Leffler, S**, Pulkrabek, P, Yamasaki, H and Grunberger, D (1978), Interactions between polycyclic aromatic hydrocarbons and cellular macromolecules, In: *Polycyclic Hydrocarbons and Cancer 2, Molecular and Cell Biology* (eds.) HV Gel-Boin and POP Ts'o, Academic Press, New York.

**Leffler, S**, Pulkrabek, P, Grunberger, D and Weinstein, IB (1978), Structural and functional changes in plasmid and phage DNA modified by a diol epoxide derivative of benzo(a)pyrene (BP), *Federation Proc.* 37, 1383.

Pulkrabek, P, **Leffler, S**, Weinstein, IB and Grunberger, D (1978), Restriction enzyme analysis and structural changes in superhelical DNA modified in vitro with benzo(a)pyrene 7,8, dihydrodiol, 9,10 oxide, *Amer.Chem.Soc. Meeting*, Miami, 101 Abs.

Pulkrabek, P, **Leffler, S**, Grunberger, D, and Weinstein, IB (1979), Modification of DNA by a diol epoxide of benzo(a)pyrene: Relation to conformation, distribution and transfectional activity, *Biochemistry* 18, 5128-5134.

**Leffler, S** (1981), Direct Conversion of biomass to alcohol, In: *Spirit of Enterprise, 1981 Rolex Awards*, ed., GB Stone, WH Freeman & Co. San Francisco, p. 136.

License No.: NJSL-70159/01/034

Amendment No.: 034

Page 1 of 5

# State of New Jersey

Department of Environmental Protection

Bureau of Environmental Radiation

Radioactive Materials Section

PO Box 415, Trenton, NJ 08625-0415

Phone (609) 984-5462

## New Jersey Radioactive Materials License

Pursuant to the New Jersey Radiation Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive or use the naturally occurring and/or accelerator produced material(s) (NARM) designated below; and to such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the State Department of Environmental Protection, now or hereafter in effect, and to any conditions specified below.

|  |  |
|--|--|
| 1. License No.<br>NJSL-70159/01/034                | 2. Expiration Date<br>03/31/2008                             |
| 3. Licensee:<br>UNION HOSPITAL                     | Address:<br>1000 Galloping Hill Road<br>Union, NJ 07083-0000 |
| Radiation Safety Officer:<br>Vincent Immerso, M.S. | County: Union<br>Telephone: (908) 687-1200                   |
| Administrator:<br>Kathryn W. Coyne                 | Reference No.: 13450   |

| RADIOACTIVE MATERIALS DATA (A)   |                |  |
|--|----------------|--|
| 6. Material  | 7. Limit (mCi) | 8. Form  |
| A. Any naturally occurring and/or accelerator produced material included under Group I Section 4.7 of NJAC 7:28-4. | 5.0000         | Any radiopharmaceutical included under Group I Section 4.7 of NJAC 7:28-4.   |
| B. Any NARM included under Group II Section 4.7 of NJAC 7:28-4.  | 300.0000       | Any radiopharmaceutical included under Group II Section 4.7 of NJAC 7:28-4.  |
| C. Any NARM included under Group III Section 4.7 of NJAC 7:28-4.   | 50.0000        | Any radiopharmaceutical included under Group III Section 4.7 of NJAC 7:28-4. |
| D. CO-57   | 30.0000        | Sealed Source  |
| E. PD-103  | 5000.0000      | Sealed Source  |

### RADIOACTIVE MATERIALS DATA (B)

#### 9. Authorized Use

- A. Any diagnostic procedure under Group I of NJAC 7:28-4, Section 4.7
- B. Any diagnostic procedure under Group II of NJAC 7:28-4, Section 4.7
- C. Preparation and use of radiopharmaceuticals for any diagnostic procedure under Group III of NJAC 7:28-4, Section 4.7
- D. Reference and/or calibration source.
- E. Therapeutic procedures under Group VI of NJAC 7:28-4, Section 4.7.

Conditions begin on the following page.

License No.: NJSL-70159/01/034  
 Amendment No.: 034  
 Page 2 of 5

## New Jersey Radioactive Materials License

10. Radioactive material shall only be used at The Department of Nuclear Medicine, 1000 Galloping Hill Road, Union, New Jersey.

11. Radioactive materials shall be used as follows:

A. Radioactive material listed in items 6a, 6b, 6c shall be used by or under the supervision of the following:

Douglas Noble, M.D.  
 George Vellath, M.D.  
 Jeffrey Blonstein, M.D.  
 Steven Leffler, Ph.D., M.D.

B. Radioactive material listed in item 6d shall be used by Stewart Berlowitz, M.D. and Perry A. Williams, M.D.

12. Compliance with other U.S. Agencies having jurisdiction and regulations for radiopharmaceuticals must be maintained.

13. The licensee shall retain records of misadministration in the use of the licensed radioactive materials. Misadministrations being defined as a radiopharmaceutical or radiation from a sealed source which is improperly used as follows:

- A. Administration of the wrong radiopharmaceutical or sealed source.
- B. Administration to the wrong patient.
- C. Administration by a route other than that intended by the prescribing physician.
- D. Administered diagnostic dose differing by more than 50 percent of the prescribed dose.
- E. Administered therapeutic dose differing by more than 10 percent of the prescribed dose.

Records of misadministrations are to include the following information: name of the referring physician, description of the event, the effect on the patient and the action taken to prevent recurrence.

14. The licensee shall not open sealed sources containing radioactive material.

15. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months.

A. The test shall be capable of detecting the presence of 0.005 microcuries of removable radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored.

B. If the test reveals the presence of 0.005 microcuries of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with the Department regulations. Within five days after obtaining results of the test, a report shall be filed with the Department describing the circumstances, the test results and the corrective action taken.

C. The sealed sources shall be tested for leakage and/or contamination by appropriately trained personnel.

16. Repair, initial leak tests and disposal of sealed sources containing radioactive material shall be performed only by the manufacturer or by other persons specifically licensed by New Jersey or the Federal Government to perform this service.

# The American Board of Radiology

*Organized through the cooperation of the  
American College of Radiology, the American Roentgen Ray Society,  
the American Radium Society, the Radiological Society of North America,  
the Section on Radiology of the American Medical Association,  
the American Society for Therapeutic Radiology and Oncology,  
and the Association of University Radiologists*

*Hereby certifies that*

**Steven Leffler, Ph.D., M.D.**

*Has pursued an accepted course of graduate study  
and clinical work, has met certain standards and qualifications and  
has passed the examinations conducted under the authority of  
The American Board of Radiology*

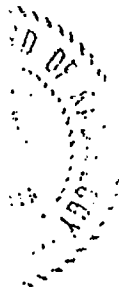
*On this eleventh day of December, 1989*

*Thereby demonstrating to the satisfaction of the Board  
that he is qualified to practice the specialty of*

**Diagnostic Radiology**

*Robert S. Parner*  
President

*Frank H. Jankowsky*  
Secretary



FILED IN

55 Park Avenue, Apt 10E  
New York, NY 10016  
Office: (914) 666-2220  
Fax: (914) 666-2987  
Cell phone: (914) 980-8357  
Email: [kschwartz@arksradiology.com](mailto:kschwartz@arksradiology.com)

**Kenneth S. Schwartz, MD**

**Current Employment:**

**S and D Medical LLP, Bedford, New York**

- Founder and Managing Partner 1999-Present  
55+ person radiology group providing radiology services to ten hospitals and imaging centers in the New York metropolitan area

**Arks Radiology Management, Inc. Bedford, New York**

- President Board of Directors 1999-Present

**Professional Experience:**

**11/98 – 11/99**

- American Imaging Management, Inc. *Northbrook, Illinois*  
Radiology Practice Management Company  
Chief Medical Officer  
-Responsible for supervision of utilization of radiology services – three million lives.  
-Supervised five Medical Directors.

**8/96 – 12/98**

- Complete Management, Inc., New York, New York  
New York Stock Exchange Physician Practice Management Company  
Senior Executive Vice President – Business Development and  
Chief Medical Officer

**6/96 – 12/98**

- Northern Metropolitan Medical P.C., Jefferson Valley, New York  
President & CEO  
-Directed a 50 multi-specialty provider group practice.

**1996 – 1998**

- St. Francis Hospital, Poughkeepsie, New York  
Director of Radiology

**3/95 – 11/96**

- St. Francis Hospital & Mount Sinai Hospital, *Hartford, Connecticut*  
System Director Diagnostic Imaging  
Director of Residency Program-University of Connecticut at St. Francis Hospital

**2/91 – 3/95**

- Putnam Hospital Center, Carmel, New York  
Medical Director

**10/84 – 8/96**

- Advanced Alliance Management Corporation, Jefferson Valley, New York  
President and CEO

**CURRICULUM VITAE: KENNETH S. SCHWARTZ, MD**

**12/83 – 3/95**

- Northern Metropolitan Radiology Associates, P.C., Jefferson Valley, New York  
President & CEO

**1982 – 1997**

- Clinical Reviewer IPRO Westchester-Putnam Division  
Board of Directors **1995-1997**

**Current Academic Appointments:**

**7/07 – Present**

- Adjunct Clinical Associate Professor Department of Medical Imaging, NYCOM of NYIT

**Present Hospital Appointments:**

Queens Long Island Medical Group  
*Garden City, NY 11530*  
**5/08**

Bon Secours Community Hospital  
*Port Jervis, NY*  
Attending Radiologist  
**9/07**

Huntington Hospital  
*Huntington, NY*  
Interim Director of Radiology  
**9/06**

Mercy Medical Center  
*Rockville Centre, NY*  
Interim Director of Radiology  
**5/06**

New York Downtown Hospital  
*New York, NY*  
Interim Director of Radiology  
**12/05**

Brookhaven Memorial Hospital Medical Center  
*Patchogue, NY*  
Attending Radiologist  
**6/04**

Kingsbrook Jewish Medical Center  
*Brooklyn, New York*  
Attending Radiologist  
**3/01**

Coler-Goldwater Specialty Hospital  
*Roosevelt Island, New York*  
Director of Radiology  
**1/04**

**Past Hospital Appointments:**

St. Vincent's Midtown Hospital (Hospital Closed)  
*New York, NY*  
Attending Radiologist  
**11/04 – 8/07**

St. Agnes Hospital (Hospital Closed)  
*White Plains, New York*  
Director of Radiology  
**1/02 – 10/03**

Ellenville Hospital  
*Ellenville, NY*  
Director of Radiology  
**3/02 – 6/06**

Hudson Valley Hospital Center  
*Peekskill, NY*  
Director of Radiology  
**9/81 – 3/95**

Putnam Hospital Center  
*Carmel, NY*  
Director of Radiology  
**1/84 – 2/91**

Nyack Hospital  
*Nyack, NY*  
Attending Radiologist  
Clinical Radiology  
Supervised Ultrasonography Department  
**1/77 – 9/81**



SouthSide Hospital  
Bayside, NY  
Attending Radiologist  
12/03

Forest Hills Hospital  
Forest Hills, New York  
Director of Radiology  
4/03

**Medical School:**

1972

- Albert Einstein College of Medicine, Bronx, New York  
M.D. Degree

**Postgraduate Training:**

7/72 – 6/73

- North Shore University Hospital, Memorial Hospital-Sloan Kettering  
Cornell Cooperating Program  
Internship, Medicine

7/73 – 6/76

- North Shore University Hospital, Memorial Hospital-Sloan Kettering  
Cornell Cooperating Program  
Residency, Diagnostic Radiology

**Professional Appointments:**

1973 National Board of Medical Examiner (#129048)

1976 Diplomate, American Board of Radiology

1988 American Board of Quality Assurance and Utilization Review Physicians

**Professional Organizations:**

|             |   |
|-------------|---|
| 1981 – 1995 | Radiation Safety Officer, Hudson Valley Hospital Center                                   |
| 1982 – 1984 | Member, Board of Directors, Area 9 PSRO   |
| 1985 – 1987 | Member, Board of Health, Putnam County  |
| 1985 – 1996 | Chief Executive Officer, Advanced Alliance Management Corporation                         |
| 1985 – 1997 | Member, Board of Directors, IPRO, and Westchester-Putnam Division                         |
| 1989        | Medical Director, Department of Radiologic Technology, Orange County<br>Community College |
| 1989        | Board of Directors, Hudson Valley IPA   |
| 1993 – 2002 | Member, Board of Governors, Albert Einstein College of Medicine Alumni<br>Association     |

**Professional Memberships:**

- Member, American Medical Association
- Member, American Institute of Ultrasound in Medicine
- Member, Radiological Society of North America
- Member, American College of Radiology
- Member, Society of Breast Imaging

**Licensure:**

- New York, License #116358, *July 2<sup>nd</sup>, 1973*
- New Jersey, License #MA47781, *July 1<sup>st</sup>, 2001*
- Connecticut, License #029282 *July 22<sup>nd</sup>, 1988*
- Florida, License #ME78378 *January 27<sup>th</sup>, 1997*
- Illinois, License #036-102318 *April 10<sup>th</sup>, 2000*

**Poster Exhibit:**

Diagnosis and Management of Breast Calcifications, Sehgal, Cinti, Weigert, Friar, Schwartz, Ramsby, Association of University Radiologists, Birmingham, Alabama, April 17, 1996.

**Presentations:**

- 2/80 Exhibit: "Arthrography and Arthroscopy", American Academy of Orthopedic Surgeons  
10/95 New Advances in Radiology, Medical Grand Rounds, St. Francis Hospital and Medical Center  
10/95 Case Presentation, Professor Rounds, St. Francis Hospital and Medical Center  
1/96 Symposium at the Culinary Institute of America for Saint Francis Hospital of Poughkeepsie Neurological Consequences of Spinal Pathology  
1998 Robertson Stevens Healthcare Conference, CMI Presentation  
3/98 Albert Einstein Alumni Student, New Forms of Healthcare Organizations  
4/98 Healthcare Financial Management Educational Foundation PPM Seminar

**Publications:**

"Spinal Epidural Hematoma", Liebeskind, Schwartz, et al, Neuroradiology, 8: 191-193, 1975

"The Big Rib Sign", Naidich, Hyman, Schwartz, et al, Radiology, Vol. 131, No. 1:1-8, July 1979

"Adrenal Pseudotumor on CT", Mitty, Cohen, Sprayregen, Schwartz, American Journal of Roentgenology, Vol. 141, No. 4:727-730, October 1983

"Prevalence and Clinical Features of Mitral Annular Calcium in Women and Men Over 62 Years of Age", Arnow, Starling, Schwartz, American Journal of Cardiology, August 1986

"Correlation of Aortic Cuspal and Aortic Root Disease with Aortic Systolic Ejection Murmurs and with Mitral Annular Calcium in Persons Older than 62 Years in a Long-Term Health Care Facility", Arnow, Schwartz, Koenigsberg, American Journal of Cardiology, Vol. 58, 651-652, September 1986

"Ambulatory Electrocardiographic Monitoring and Left Ventricular Ejection Fraction in Elderly Patients", Arnow, Epstein, Schwartz, Koenigsberg, Clinical Research, Vol. 35, No. 1, 1987

"Correlation of Murmurs of Mitral Stenosis and Mitral Regurgitation with Presence or Absence of Mitral Annular Calcium in Persons Older than 62 Years in a Long-Term Health Care facility", Arnow, Schwartz, Koenigsberg, American Journal of Cardiology, Vol. 59, No. 1:181-182, January 1987

"Correlation of Serum Lipids, Calcium and Phosphorus, Diabetes Mellitus, Aortic Valve Stenosis and History of Systemic Hypertension with Presence or Absence of Mitral Annular Calcium in Persons Older than 62 Years in Long-Term Health Care Facility", Arnow, Schwartz, Koenigsberg, American Journal of Cardiology, Vol. 59, No. 2:381-382, February 1987

"Prevalence of Tricuspid Annular Calcium Diagnosed by Echocardiography in Elderly Patients", Arnow, Schwartz, Koenigsberg, American Journal of Noninvasive Cardiology, 1:275-277, 1987

"Value of Five Electrocardiographic Criteria Correlated with Echocardiography Left Ventricular Hypertrophy in Elderly Patients", Arnow, Schwartz, Koenigsberg, **American Journal of Noninvasive Cardiology**, No. 1:152-154, 1987

"Correlation of Complex Ventricular Arrhythmias Detected by Ambulatory Electrocardiographic Monitoring with Echocardiographic Left Ventricular Hypertrophy in Persons Older than 62 Years in a Long-Term Health Care Facility", Arnow, Epstein, Schwartz, Koenigsberg, **American Journal of Cardiology**, Vol. 60, No. 8:730-732, May 1988

"Correlation of Complex Ventricular Arrhythmias and Ejection Fraction with New Cardiac Events in Elderly Patients", Arnow, Epstein, Koenigsberg, Schwartz, **Clinical Research**, Vol. 36, No. 3, 1988

"Usefulness of Echocardiographic Ventricular Hypertrophy in Predicting New Coronary Events and Arterothrombotic Brain Infraction in Patients Over 62 Years of Age", Arnow, Koenigsberg, Schwartz, **American Journal of Cardiology**, Vol. 61, No. 15:1349-1351, June 1988

"Usefulness of Echocardiographic Left Ventricular Hypertrophy, Ventricular Tachycardia, and Complex Ventricular Arrhythmias in Predicting Ventricular Fibrillation or Sudden Cardiac Death in Elderly Patients", Arnow, Koenigsberg, Schwartz, **American Journal of Cardiology**, Vol. 62, 1124-1125, November 1988

"Usefulness of Echocardiographic and Electrocardiographic Left Ventricular Hypertrophy in Predicting New Cardiac Events and Arterothrombotic Brain Infraction in Elderly Patients with Systemic Hypertension or Coronary Artery Disease", Arnow, Koenigsberg, Schwartz, **American Journal of Noninvasive Cardiology**, 3:367-370, 1989

# The American Board of Radiology

Organized through the cooperation of the  
 American College of Radiology, the American Roentgen Ray Society,  
 the American Radium Society, the Radiological Society of North America,  
 the Section on Radiology of the American Medical Association  
 and the American Society of Therapeutic Radiologists  
 Hereby certifies that

Kenneth Stephen Schwartz, M.D.

Has pursued an accepted course of graduate study  
 and clinical work, has met certain standards and qualifications and  
 has passed the examinations conducted under the authority of  
 The American Board of Radiology

On this eighteenth day of June, 1976  
 Thereby demonstrating to the satisfaction of the Board  
 that he is qualified to practice the specialty of  
 Diagnostic Radiology

Robert W. Cooley  
 President

C. Allen Good  
 Secretary



# CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

Pursuant to the New York City Charter and Article 175 of the New York City Health Code and in reliance on statements and representations heretofore made by licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

In accordance with Application received 1 February 2005 from Robert Hettenbach, Executive Director, North Shore University Hospital at Forest Hills; License number 91-1515-02 is hereby amended in its entirety to read:

|   |   |  |
|---|---|--|
| <b>LICENSEE</b>   |   |  |
|   | 3a. License Number:   | 91-1515-02   |
| 1. Name:  | North Shore University Hospital<br>at Forest Hills  | 3b. Amendment Number: 17                                 |
| 2. Address:   | 102-01 66 Road<br>Queens, New York 11375  | 4. Expiration Date: 31 January 2010                      |
|   |   | Reference Number: 91-3118-01                             |
| 6. Radioactive materials (element number)                                     | Chemical and/or physical form   | 8. Maximum quantity licensee may possess at any one time |
| (A) Any radioactive material identified in §175.103(d)(1)(i), NYC Health Code | (A) Any radiopharmaceutical or radiobiologic with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA.   | (A) As necessary for uses authorized in Subitem 9(A)     |
| (B) Any radioactive material identified in §175.103(e)(1)(i), NYC Health Code | (B) Any radiopharmaceutical or radiobiologic with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA<br>(GENERATORS AEROSOLS AND GASES ONLY AS LISTED BELOW)<br>***** | (B) As necessary for uses authorized in Subitem 9(B)     |

# CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-1515-02

Amendment Number: 17

Reference Number:

| 6. Radioactive materials (element number) | 7. Chemical and/or physical form   | 8. Maximum quantity licensee may possess at any one time   |
|---|--|--|
| (C) Technetium-99m                        | (C) DTPA Aerosol with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA  | (C) 7.4 Gigabecquerels                                     |
| (D) Cobalt-57                             | (D) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (D) 5 Sources not to exceed 925 Megabecquerels per source  |
| (E) Cobalt-57                             | (E) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (E) 5 Sources not to exceed 740 Megabecquerels per source  |
| (F) Barium 133                            | (F) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (F) 5 Sources not to exceed 18.5 Megabecquerels per source |
| (G) Cesium-137                            | (G) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" | (G) 5 Sources not to exceed 18.5 Megabecquerels per source |
| (H) Technetium-99m                        | (H) Pertechnate<br>*****   | (H) Individual amounts not to exceed 1.85 Gigabecquerels   |

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

License Number: 91-1515-02

Amendment Number: 17

Reference Number:

| 6. Radioactive materials (element number) | 7. Chemical and/or physical form  | 8. Maximum quantity licensee may possess at any one time     |
|---|---|--|
| (I) Iodine-131                            | (I) Sodium Iodide Capsules with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA           | (I) 3.7 Gigabecquerels                                       |
| (J) Technetium-99m                        | (J) Sodium Pertechnetate (MediPhysics, NDA 17-267, 17-471; CIS-US, NDA 17-321; Mallinckrodt, NDA 17-725)                            | (J) 7.4 Gigabecquerels                                       |
| (K) Technetium-99m                        | (K) Sestamibi Kit (DuPont Merck, NDA 19-785)  | (K) 11.1 Gigabecquerels                                      |
| (L) Technetium-99m                        | (L) Tetrofosmin Kit (Amersham, NDA 20-372)  | (L) 11.1 Gigabecquerels                                      |
| (M) Thallium-201                          | (M) Thallous Chloride (DuPont Merck, NDA 17-806; Mallinckrodt, NDA 18-150; MediPhysics, NDA 18-110; Bracco Diagnostics, NDA 18-548) | (M) 1.9 Gigabecquerels                                       |
| (N) Strontium-89                          | (N) Strontium Chloride Sr-89 (MediPhysics/Amersham, NDA 20-174)   | (N) 740 Megabecquerels                                       |
| (O) Samarium-153                          | (O) Samarium SM-153-EDTMP (Cytogen Corp., NDA 20-570)   | (O) 7.4 Gigabecquerels                                       |
| (P) Palladium-103                         | (P) Sealed Brachytherapy Sources (Theragenics Corp., Model 200)   | (P) 37 Gigabecquerels  |
| (Q) Iodine-125                            | (Q) Therapeutic Seed Sources (Amersham/MediPhysics, Inc., Model 6711)<br>*****  | (Q) 37 Gigabecquerels, no seed to exceed 5.55 Gigabecquerels |



**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

License Number: 91-1515-02

Amendment Number: 17

Reference Number:

**CONDITIONS**

**9. Authorized Use:**

- (A) Any uptake, dilution or excretion procedure authorized by applicable law.
- (B) Any imaging or localization procedure authorized by applicable law.
- (C) Pulmonary function studies using either a Mallinckrodt Sunaco, Inc., a Biodex Inc. Venti-Scan II, a Cadema System, Inc. or a Medi-Nuclear Corporation Aero-Vent aerosol delivery system.
- (D) Flood calibration sources (Non-Human Use)
- (E) through (G) Calibration sources (Non-Human Use).
- (H) Calibration check and reference material (Non-Human Use).
- (I) Treatment of hyperthyroidism.
- (J) Blood pool imaging.
- (K) Myocardial imaging agent used to distinguish normal from abnormal myocardium, to localize abnormality in patients with suspected myocardial infarction, and for evaluation of myocardium.
- (L) Imaging of the myocardium following separate administrations under exercise and resting conditions, and in the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium.
- (M) Myocardial perfusion imaging, diagnosis and localization of myocardial infarction, and prognosis regarding survival after onset of symptoms of acute myocardial infarction to assess site and size of perfusion defect.
- (N) Relief of bone pain in patients with painful skeletal metastasis.
- (O) Relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on radionuclide bone scan.
- (P) For interstitial treatment of cancers.
- (Q) For interstitial treatment of cancers.

- 10. The radioactive material may be used only in the Nuclear Medicine Department, Rooms 3, 4, 5, 6, Hot Lab, and OR Suite 7, North Shore University Hospital at Forest Hills, 102-01 66 Road, Queens, New York 11375.**
- \*\*\*\*\*

# CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-1515-02

Amendment Number: 17

Reference Number:

11. The licensee shall comply with the provisions of Article 175 of the New York City Health Code entitled "Radiation Control."
12. Failure to pay the fee for inspection of a radioactive material site, upon notification from the Department, will result in termination of this license.
13. Radioactive materials listed in Item 6 are authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Authorized User

Edmond Balakhane, M.D.  
Bruce Campbell, M.D.  
Marsha Crofford, M.D.  
Dijan Golyan, M.D.  
Roberto Lipsztein, M.D.  
Stephen Robinson, M.D.  
Kenneth Schwartz, M.D.  
Javad Tabaec, M.D.  
Alan Tafler, M.D.

Materials and Use

Subitems 6(A) through 6(H), 6(J) through 6(M)  
Subitems 6(A) through 6(M)  
Subitems 6(A) through 6(H), 6(J) through 6(M)  
Subitems 6(J) through 6(M)  
Subitems 6(I), 6(P), 6(Q)  
Subitems 6(A) through 6(H), 6(J) through 6(M)  
Subitems 6(A) through 6(M)  
Subitems 6(J) through 6(M)  
All

14. The radiation safety officer for this license is Kenneth Schwartz, M.D.
15. Radioactive material as a sealed source shall not be opened by the licensee.  
The therapy physicists for this license are James Astarita, DABMP, James Avanzato, DABMP, and Raymond Beers, DABMP.
17. Technetium-99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.
18. Any radiopharmaceutical or radiobiologic with a current and active IND issued by FDA shall be used in accordance with Title 21, Part 312 of The Code of Federal Regulations or any successor regulation.

\*\*\*\*\*

# CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-1515-02

Amendment Number: 17

Reference Number:

19. The following conditions apply for Iodine-131 radiopharmaceutical therapy:

(a) Patient release shall be based on either of the following conditions:

(1) The activity administered to the patient or the patient's calculated activity has decreased to less than 1.2 Gigabecquerel, or the measured maximum dose rate at a distance 1 meter from the patient is less than 0.07 mSv/hr.

(2) Measured and documented patient-specific parameters which otherwise result in compliance with the requirements of Section 175.103(c)(9) of the New York City Health Code

(b) The radiation safety guidance required by Section 175.103(f)(3) of the New York City Health Code shall be provided by supplying the released patient, or the patient's competent representative, with both oral and written instructions on the risk of radiation and methods of reducing exposure to other individuals. The written instructions shall at least include the following items:

(1) The name and telephone number of a knowledgeable person to contact in the event the patient has any problems or questions.

(2) Information regarding the type of treatment given.

(3) Precautions regarding distances that should be maintained from other individuals, including separate sleeping arrangements.

(4) Precautions regarding minimizing time in public places.

(5) Precautions to reduce the spread of radioactive contamination (including, but not limited to, vomitus and urine).

(6) The length of time each of the precautions should be in effect.

(c) A "Record of Release" shall be maintained for each patient and shall contain at least the following items: activity at administration, any required decay calculations, date and time of patient release, copy of the patient's written instructions, and if required for patient release either patient's dose rate measurements (including the specific survey instrument used and the name of the individual performing the survey), or patient-specific parameters.

20. The following conditions apply for permanent brachytherapy implants:

(a) Iodine-125 implant patient's release shall be based on either of the following conditions:

(1) The activity administered to the patient or the patient's calculated activity has decreased to less than 0.33 Gigabecquerel.

(2) The measured maximum dose rate at a distance 1 meter from the patient's target organ is less than 0.01 mSv/hr.

(b) Palladium-103 implant patient's release shall be based on either of the following conditions:

(1) The activity administered to the patient or the patient's calculated activity has decreased to less than 1.5 Gigabecquerel.

(2) The measured maximum dose rate at a distance 1 meter from the patient's target organ is less than 0.03 mSv/hr

\*\*\*\*\*

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

License Number: 91-1515-02

Amendment Number: 17

Reference Number:

(c) The radiation safety guidance required by Section 175.103(b)(3) of the New York City Health Code shall be provided by supplying the released patient, or the patient's competent representative, with both oral and written instructions on the risk of radiation and methods of reducing exposure to other individuals. The instructions shall at least include the following items:

- (1) The name and telephone number of a knowledgeable person to contact in the event the patient has any problem or questions.
- (2) A description of the size and number of implanted radioactive seeds.
- (3) Specification of the length of time the patient should remain at specified distances from other individuals.
- (4) That any bandages or linens that come into contact with the implant as well as the patient's urine voided through a provided strainer shall be examined for any seeds that have been released from the implant site. Any released seeds shall be handled with a provided tweezers and placed in a provided container away from other persons. The individual referred to in Subcondition (c)(1) above shall be notified in order to properly remove and dispose of any dislodged and/or urinated seeds.

(d) A "Record of Release" shall be maintained for each patient which documents at least the following items: activity at administration, any required decay calculations, date and time of patient release, copy of patient's written instructions, and if required for patient release, patient's dose rate measurements including the specific survey instrument used and the name of the individual performing the survey.

2. 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. Article 175 of the New York City Health Code shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- (A) Application received February 2005
- (B) Letter dated 22 March 2005
- (C) Letter dated 13 April 2005

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MAY 31 2005

FOR THE NEW YORK CITY DEPARTMENT  
OF HEALTH AND MENTAL HYGIENE

Date:

DPH/ih

*Daniel P. Hayes*  
Daniel P. Hayes  
Scientist  
Radioactive Materials Division  
Office of Radiological Health