

CARDIAC DIAGNOSTIC  
SERVICES OF VIRGINIA

8505 Arlington Boulevard, Suite 320  
Fairfax, Virginia 22031  
(703) 641-0500  
Fax (703) 204-9056

*NUM 58 2*

March 5, 2007

Brian A. Parker  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
475 Allendale Road  
King of Prussia, Pennsylvania 19406

RE: Cardiac Diagnostic Services of Virginia  
License Amendment  
45-24867-01

*03029501*

RECEIVED  
REGION I  
2007 MAR -7 AM 10:23

Dear Mr. Parker,

Please amend the above referenced license to add Todd Matros, M.D. as an authorized user to the above referenced license. Documentation in support of this physician's credentials is enclosed.

Any questions regarding this request may be directed to me at (703) 641-0500 or Wendy Charlton, Krueger-Gilbert Health Physics, Inc. at (410) 665-5447.

Sincerely,

Neil C. Smarte, C.N.M.T.  
Radiation Safety Officer.

*140179*

NMCC/REGIONAL MATERIALS-002

**MEDICAL USE TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**

**PART I -- TRAINING AND EXPERIENCE**

**Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Todd Matros, M.D. Authorized User 10 CFR 35.290

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

Virginia

**3. CERTIFICATION**

- a. Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.  
Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

**4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS**

- a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

**5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)**

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Scacacus, NJ	100	3/12/03-3/16/03 10/15/03-10/19/03
Radiation Protection	"	30	"
Mathematics Pertaining to the Use and Measurement of Radioactivity	"	20	"
Radiation Biology	"	20	"
Chemistry of Byproduct Material for Medical Use	"	30	"
OTHER See Attached Certificate	"	Total = >200 Hours	"

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Ordering, receiving and unpacking radioactive materials safely and performing radiation surveys	David Gutstein, MD	New York University Hospital Center 75-2955-01	7/01 - 6/04 16 Hrs.
Calibrate instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	"	7/01 - 6/04 8 Hrs.
Calculating, measuring and safely preparing patient dosages	"	"	7/01 - 6/04 12 Hrs.
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	"	7/01 - 6/04 24 Hrs.
Using procedures to safely contain spilled radioactive material and using proper decontamination procedures	"	"	7/01 - 6/04 12 Hrs.
Administering dosages of radioactive drugs to patients	"	"	7/01 - 6/04 24 Hrs.
Eluting generators, measuring and testing the eluate and processing the eluate with reagent kits to prepare labeled radioactive drugs	"	"	7/01 - 6/04 24 Hrs.
Reviewing case history and interpreting scans	"	"	7/01 - 6/04 376 Hrs.

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
<sup>99m</sup> Tc	Cardiac	750	David Gutstein, MD	New York University Hospital Center 75-2955-01	7/01 - 6/04 188
<sup>201</sup> Tl	Cardiac	750	"	"	188
Co-57	QC	None	"	"	3
Cs-137	QC	None	"	"	3

**MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)**

Training Element	Type of Training *	Location and Dates

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

**7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists**

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

**8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE**

- YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
- N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

**9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE**

- YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of \_\_\_\_\_
- N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

**and**

- YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) \_\_\_\_\_
- N/A under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each) :

A. Name of Supervisor

David Gutstein, MD

B. Supervisor is:

Authorized User

Radiation Safety Officer

Authorized Medical Physicist

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.290

for medical uses in Part 35, Section(s) 35.100 + 35.200

D. Address

New York University Hospital Center  
550 First Avenue  
New York, NY 10016

E. Materials License Number

75-2955-01

PART II -- PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 290 (c)(1)(i)(ii) as documented in section(s) 5, 6a, 6b of this form.

11b. Select one

meets the requirements in  35.50(e)  35.51(c)  35.390(b)(1)(ii)(G)  35.690(c) for \_\_\_\_\_ types of use, as documented in section(s) \_\_\_\_\_ of this form.

11c.

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **OR**  
has achieved a level of competency sufficient to function independently as an authorized user for 10 CFR 35.100 + 10 CFR 35.200 uses (or units); **OR**  
has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **OR**

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OR** I am a Radiation Safety Officer; **OR**

I meet the requirements of 35.290 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor  AU or  AMP

for the following byproduct material uses (or units): 35.100 and 35.200

A. Address

New York University Hospital Center  
550 First Avenue  
New York, NY 10016

B. Materials License Number

75-2955-01

C. NAME OF PRECEPTOR (print clearly)

David Gutstein, MD

D. SIGNATURE -- PRECEPTOR

[Signature]

E. DATE

2/23/07

Current Active - Medicine & Surgery

Number: 0101226323

Issued: 11/08/2000

Expires: 12/31/2008

Todd G. Matros, MD

8505 Arlington Blvd

Suite 200

Fairfax VA 22031



Written Notification of Change of Address Required Within 30 Days of Change

\*Name Change Request Must be Accompanied by a Photocopy of Marriage License or Court Order

For Name\*/Address Changes, Mail to:

Department of Health Professions

c/o Board of Medicine

6603 West Broad Street, 5<sup>th</sup> Floor

Richmond, VA 23230-1712

My New Name\* is:

My New Address is:

City, State

Zip Code

Signature (0101226323)

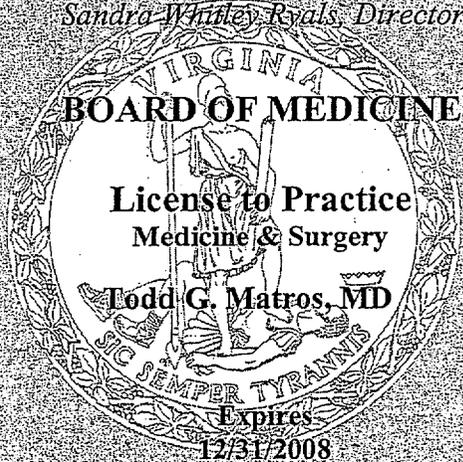
FOLD, CREASE AND TEAR ALONG PERFORATION

# COMMONWEALTH OF VIRGINIA

DEPARTMENT OF HEALTH PROFESSIONS

*Sandra Whitley Ryals, Director*

William L. Harp, M.D.  
Executive Director  
(804) 662-9908



6603 West Broad Street, 5<sup>th</sup> Floor  
Richmond, VA 23230-1712  
[www.dhp.virginia.gov/medicine](http://www.dhp.virginia.gov/medicine)

Issued  
11/08/2000

Expires  
12/31/2008

Number  
0101226323

To Provide Information or File a Complaint About a Licensee, Call: 1-800-533-1560



New York University  
**School of Medicine**

David E. Gutstein, M.D.  
Assistant Professor of Medicine  
Division of Cardiology

Veterans Administration Medical Center  
432 E. 23rd Street  
6-West Room 6005BW  
New York, NY 10010  
Tel: (212) 263-4131  
Fax: (212) 263-4129  
E-Mail: david.gutstein@med.nyu.edu

March 29, 2004

Re: Certification Board of Nuclear Cardiology

To Whom It May Concern:

Dr. Todd Matros has completed a fellowship training program in nuclear cardiology that meets the requirements as outlined in the ACC/ASNC COCATS Guidelines [revised 2000].

Dr. Todd Matros is competent to independently function as an authorized user under NRC 10 CFR 35.290 uses.

Sincerely,

A handwritten signature in black ink, appearing to read "DEG", written over a horizontal line.

David E. Gutstein, M.D.

NYUMC operates under an Agreement State Broad license #75-2955-01 issued by New York City Department of Health. David E. Gutstein, M.D., has been approved to supervise imaging and localization studies (restricted to nuclear cardiology). For verification, please contact the Radiation Safety Office at (212) 263-6888.

**THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY**

Incorporated 1996

CERTIFIES THAT

*Todd Gregg Matros, M.D.*

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING  
IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,  
IS HEREBY DESIGNATED

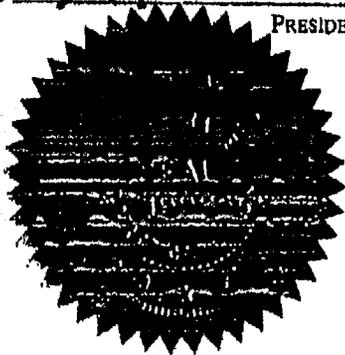
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

**NUCLEAR CARDIOLOGY**

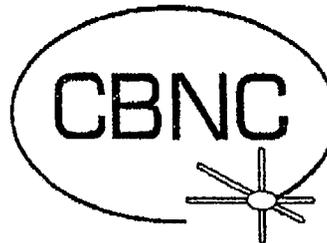
FOR THE PERIOD 2005 THROUGH 2015

*M. D. C. Pereira*  
PRESIDENT

*Jan A. Arigli*  
SECRETARY



CERTIFICATE # 4070



OCTOBER 23, 2005

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion & Competency

*This document is to attest that*

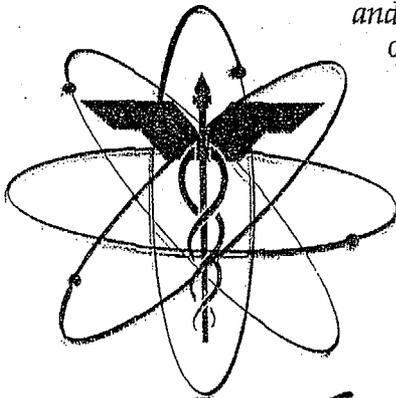
Todd Gregg Matros, MD

*has successfully completed the didactic program*

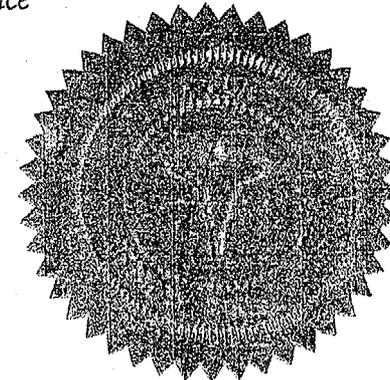
## MEDICAL RADIATION INSTRUMENTATION

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)  
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,  
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on  
Education (ACE), American Association for  
Collegiate Registrars



  
Certifying Official

19 October 2003  
Date Completed

201756  
Certification

## Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class II-Compl&Comp 1/00

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion & Competency

*This document is to attest that*

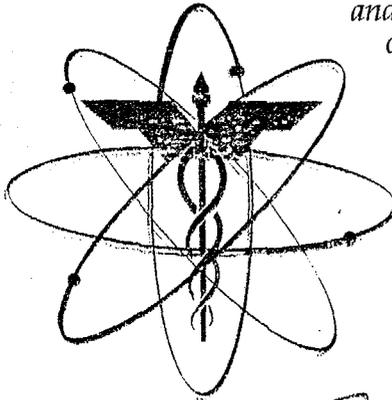
Todd G. Matros, MD

*has successfully completed the didactic program*

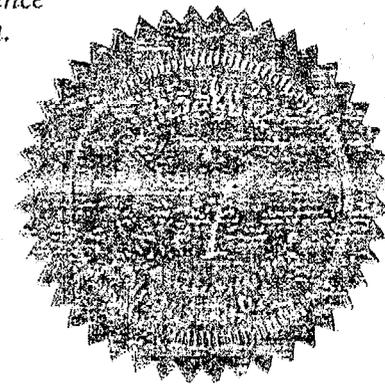
## MEDICAL RADIATION PROTECTION

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)  
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,  
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on  
Education (ACE), American Association for  
Collegiate Registrars



  
Certifying Official

12 March 2003  
Date Completed

201114  
Certification

## Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.

INME1132-Class III-Compl&Comp 1/00

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion & Competency

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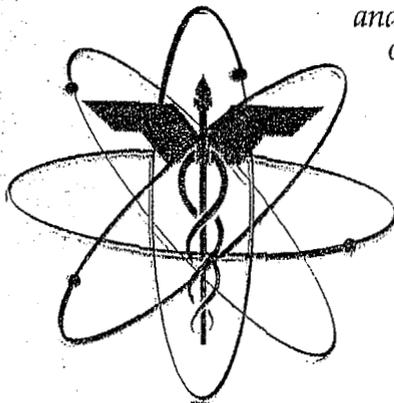
Todd Gregg Matros, MD

*has successfully completed the didactic program*

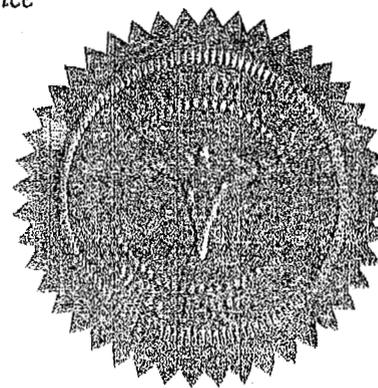
## PRINCIPLES OF RADIATION PHYSICS

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)  
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,  
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on  
Education (ACE), American Association for  
Collegiate Registrars



  
Certifying Official

15 October 2003

Date Completed

201694

Certification

## Institute for Nuclear Medical Education

Certified, Approved and Regulated by the Division of Private Occupational Schools, Department of Higher Education in Colorado. Validated by the Accrediting Commission of the Accrediting Council for Continuing Education Training, a national accrediting agency listed by the US Secretary of Education. Validated by the American Council on Education, recognized by the American Association for Collegiate Registrars, Council on Post-Secondary Education. Licensed by NRC & Agreement States.  
INME1132-Class I-Compl&Comp 1/00

# NUCLEAR MEDICAL EDUCATION PROGRAM

## Affidavit of Academic Completion & Competency

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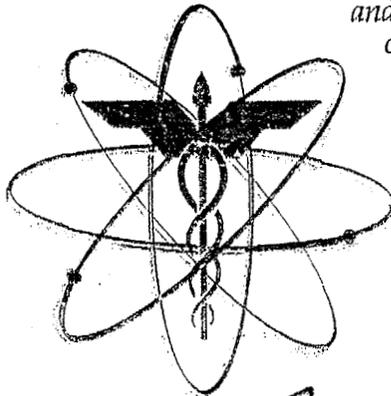
Todd G. Matros, MD

*has successfully completed the didactic program*

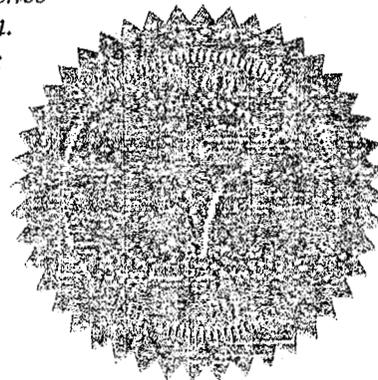
## RADIOPHARMACEUTICALS AND CHEMISTRY

*and has provided evidence of attendance in this program and evidence of achieving the objectives of this program through examination.*

*This program provides the following levels of accomplishment:*



- 5.0 Continuing Education Units (CEU)
- 50 Didactic Instructional Hours (DIH)  
In compliance with 10CFR35/AEA 73-689
- 50 Board Accepted Hours NUSPEX, NMTCB III b,  
ABMRSO, CBNC, MRLB
- 3.0 Semester Hours American Council on  
Education (ACE), American Association for  
Collegiate Registrars



  
Certifying Official

16 March 2003

Date Completed

201190

Certification

## Institute for Nuclear Medical Education

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INME1132-Class IV-Compl&Comp 1/00

**NYU Medical Center**  
**Radiation Safety Office**  
550 First Avenue, MSB, Room G58  
New York, NY 10016  
212.263.6888 Phone  
212.263.8581 Fax

December 18, 2006

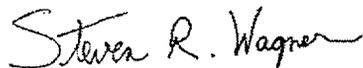
Cardiac Diagnostic Services of Virginia  
8508 Arlington Boulevard, Suite 320  
Fairfax, VA 22031

Dear Ms. Pattie,

This is to verify that David Gutstein, M.D. is an authorized user, as approved by our Medical Isotopes Committee, for imaging and localization studies for diagnostic cardiac imaging. The broad license that covers this work is license number 75-2955-01, issued by the New York City Department of Health under the agreement state program of New York State. A copy is attached

Please contact me if there are further questions.

Sincerely,



Steven R. Wagner, M.S.  
Associate Director of Radiation Safety

"CORRECTED COPY"

### 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 5 February 2004 from Robert Glickman, M.D., Dean, New York University School of Medicine and CEO, New York University Hospital; License number 75-2955-01 is hereby amended to change Items 1, 3b, 8(B), 8(C), 8(D), 8(E), 7(H), 8(H), 6(K), 7(K), 8(K), 8(L), 8(M), 8(N), 8(R), Conditions 9(H), 9(K), 9(R), 10, 13, 24, 28, The Total Possession Limit, to add Item's 6(S), 7(S), 8(S), 6(T), 7(T), 8(T), Conditions 9(S), 9(T), and Item 10 is corrected to read:

#### LICENSEE

	<b>3a. License Number:</b>	75-2955-01
<b>1. Name:</b> New York University Hospitals Center	<b>3b. Amendment Number:</b>	7
<b>2. Address:</b> 550 First Avenue New York, New York 10016	<b>4. Expiration Date:</b>	28 February 2007
	<b>5. Reference Number:</b>	86-96

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(A) Any radioactive material between atomic numbers 3 and 83, inclusive, except as listed below	(A) Any	(A) 18.5 Gigabecquerels each, except as listed below
(B) Molybdenum-99	(B) Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(B) 300 Gigabecquerels
(C) Technetium-99m	(C) Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(C) 300 Gigabecquerels
(D) Technetium-99m	(D) Pertechnetate	(D) 80 Gigabecquerels
(E) Iodine-131	(E) Any	(E) 50 Gigabecquerels
(F) Xenon-133	(F) Gas or Ventilation Study System with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA *****	(F) 5 Gigabecquerels

CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE

License Number: 75-2955-01

Amendment Number: 7

Reference Number: 86-96

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(G) Cesium-137	(G) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(G) 25 Gigabecquerels
(H) Fluorine-18	(H) Fluorodeoxyglucose F-18 Injection and F-18 Labeling	(H) 100 Gigabecquerels
(I) Cesium-137	(I) Sealed Sources (CIS-US Inc. Model #CEA-ORIS-LAPIB Model 437C)	(I) 150 Terabecquerels total, 3 sources of not more than 62.9 Terabecquerels each
(J) Cesium-137	(J) Sealed Sources (Nordion, Model C-3001)	(J) 112.8 Terabecquerels total, 2 sources of not more than 56.4 Terabecquerels each
(K) Strontium-90	(K) Sealed Source (Nuclear Enterprises, Model 2503-3)	(K) 200 Megabecquerels
(L) Cobalt-57	(L) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(L) 14 Sources not to exceed 925 Megabecquerels per source
(M) Barium-133	(M) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(M) 7 Sources not to exceed 18.5 Megabecquerels per source
(N) Cesium-137	(N) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(N) 7 Sources not to exceed 18.5 Megabecquerels per source
(O) Gadolinium-153	(O) Line Sources (North American Scientific, Inc., Model MED 3601) *****	(O) 67 Gigabecquerels total

CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE

License Number: 75-2955-01

Amendment Number: 7

Reference Number: 86-96

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(P) Strontium-90/Yttrium-90	(P) Brachytherapy Seed Sources (Novoste Corporation, BEBIG Model Sr0.S03)	(P) 19.5 Gigabecquerels, no source to exceed 185 Megabecquerels
(Q) Strontium-90/Yttrium-90	(Q) Brachytherapy Sealed Sources (Novoste Corporation, AEAT Model SIC W.2)	(Q) 8.3 Gigabecquerels, No source to exceed 185 Megabecquerels
(R) Iridium-192	(R) Sealed Sources (Varian Medical Systems, Model SL-777V and VS2000; Omnitron International, Model SL-777V)	(R) 1.776 Terabecquerels Total, 4 Sources not more than 481 Gigabecquerels each
(S) Germanium-68	(S) Sealed Sources (CTI Services, Inc. Line Sources and Uniformity Phantom)	(S) 250 Megabecquerels
(T) Strontium-90	(T) Sealed Source (PTW, Model T48012)	(T) 33 Megabecquerels
(U) Strontium-90	(U) Sealed Source (Nuclear Enterprises, Model 2503-3) *****	(U) 200 Megabecquerels

THE TOTAL POSSESSION LIMIT FOR (A) THROUGH (U) SHALL NOT EXCEED 270 TERABECQUERELS

CONDITIONS

9. Authorized Use:

- (A) through (H) Medical research, diagnosis and therapy (Broad Human-Use). Research involving the use of licensed material in or on human subjects may only be conducted if such material is covered by a current IND or NDA, or such research has the approval of the Institutional Review Board, the Medical Radiation Safety Committee, and a Radioactive Drug Research Committee (RDRC) authorized by FDA.
- (I) In a Model IBL-437C Irradiator for Biological Materials (manufactured by Compagnie ORIS Industrie and distributed by CIS-US, Inc.) for the irradiation of biological samples (Non-Human Use). To be used in Room 11N23, Bellevue Hospital Center.
- (J) In a MDS/Nordion Gammacell 3000 Elan-Type II Gamma Irradiator for the irradiation of biological samples (Non-Human Use). To be used in Room RRG19, Tisch Hospital, NYU Medical Center.
- (L) Flood calibration sources (Non-Human Use).
- (K), (M), (N), (S), (T), (U) Calibration and quality control (Non-Human Use).

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(O) For use in gamma cameras.

(P) and (Q) In up to ten (five for use and five for replacement) Novoste A1000 Series Transfer Devices for routine use in coronary intravascular brachytherapy as part of the Beta-Cath 5 Fr and 3.5Fr Systems as authorized under FDA PMA P00018/S18 and P000018/S15, respectively.

(R) In two (2) Varian Medical Systems, VariSource HDR Remote Afterloader Brachytherapy Units (but not the low-speed drive design of this model) for interstitial, intracavity, superficial, and bronchial treatment of cancer in humans. No source greater than 370 Gigabecquerels shall be installed in any unit. To be used in Room HC101, Tisch Hospital, NYU Medical Center, and in the New York University Medical Center Cancer Center.

- 10. The radioactive material may be used only at the New York University Hospitals Center campus bounded by E 30th Street, First Avenue, E 34th Street and the FDR Drive, at the Bellevue Hospital Center campus bounded by E 25th Street, First Avenue, E 30th Street and the FDR Drive, and at the New York University Medical Center Cancer Center, 160 E. 34th Street; New York, New York.
- 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 shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee of New York University Medical Center and Bellevue Hospital Center, Manfred Blum, M.D., Chairman.
- 14. The radiation safety officer for this license is Christopher Marshall, Ph.D.
- 15. The therapy physicists for this license are Susan Brownie, D.A.B.R., Keith De Wyngaert, D.A.B.R., Christine Hitchen, D.A.B.R., Kerry Han, D.A.B.R., and Eugene Lief, D.A.B.M.P.
- 16. Radioactive material as sealed sources shall not be opened by the licensee.
- 17. The possession limit, when specified in Subitem 8, includes all radioactive material possessed by the licensee under this license whether in storage, implanted and or inserted in hospitalized patients or otherwise in use.
- 18. The use of radioactive materials in or on humans shall be by, or under the supervision of, physicians.
- 19. Technetium-99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.
- 20. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Section 175.103 of the New York City Health Code are detected.

Personnel performing tests to detect and quantify molybdenum-99 shall be given specific training in performing these tests prior to conducting such tests.

The licensee shall maintain for inspection by the Office of Radiological Health, results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests. These records shall be maintained for three (3) years following the performance of these tests and the training of personnel.

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21. For individuals who open and/or prepare oral solutions of iodine-131 for therapeutic doses, surveys (e.g. measurement of iodine-131 in the thyroid gland of laboratory personnel and contamination surveys of personnel, equipment and facilities) shall be performed to determine compliance with Section 175.103(f)(3) of the New York City Health Code.
22. 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.
23. 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.

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- (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.
  - (c) The radiation safety guidance required by Section 175.103(h)(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.
24. The following subitems refer to the high dose rate remote afterloader brachytherapy units possessed by the licensee, henceforth referred to as the Unit (which presently are two (2) Varian Medical Systems VariSource HDR Remote Afterloader Brachytherapy Units):
- (a) All operators of the Unit other than authorized physician users must be New York State licensed radiation therapy technologists.
  - (b) When treatments are performed with the Unit, only the patient shall be in the treatment room.
  - (c) The Unit shall be labeled with the radiation symbol and the appropriate wording, "Caution" or "Danger" and "Radioactive Material".
  - (d) The written instruction for operation and safety contained in the manufacturer's Instruction Manual shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of the Unit.
  - (e) The Unit facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation. The patient shall be visually monitored during treatment.

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- (f) Daily (or on each day of use) checks of the Unit shall be performed to ascertain:
  - (1) Guide tubes are free of kinks or other imperfections.
  - (2) Reproducibility of source positioning within catheter to within  $\pm 1$ mm.
  - (3) Proper functioning of room interlocks
  - (4) Proper functioning of source position indicators (e.g. lights, alarms, room monitor).
  
- (g) Written emergency instructions shall be posted at the Unit console. These instructions shall inform the Unit operator of the procedure to be followed should he/she be unable to return the source(s) to the shielded position with controls outside the treatment room. These instructions shall caution individuals to avoid exposure to the unshielded source(s) when in the treatment room and shall include specific instructions for:
  - (1) Locating and using the device for manually returning the source(s) to the shielded position.
  - (2) Removing the patient from the treatment room.
  - (3) Securing the room against unauthorized entry.
  - (4) Notifying the responsible physician or radiation safety officer.
  
- (h) Prior to initiation of a treatment program using the Unit and subsequent to each installation of iridium-192 source, radiation surveys and tests shall be performed in accordance with the following:
  - (1) A radiation survey shall be made of:
    - (i) The Unit's source housing with the iridium-192 source in the shielded position. The exposure rate shall not exceed the values specified in the Registry of Radioactive Sealed Sources and Devices.
    - (ii) All areas adjacent to the treatment room with the Unit's source in the treatment position. The survey shall be performed with a phantom and clearly establish:
      - (A) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 175.03(c) of the New York City Health Code.
      - (B) That radiation levels in unrestricted areas do not exceed the limits specified in Section 175.03(d) of the New York City Health Code.

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- (2) Tests shall be made to determine proper operation of:
  - (i) Electrical interlocks on entrance doors to the Unit treatment room.
  - (ii) The Unit's source shielded/unshielded indicators both at the source housing and on the control panel outside the treatment room.
  - (iii) The Unit's treatment timing device.
- (3) A report of the results of the above surveys and tests shall be sent to the Radioactive Materials Section, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007, not later than thirty (30) days following each installation of the Unit's source.
  - (i) Any changes made in treatment room shielding, location, or use of the Unit which could result in an increase in radiation levels in unrestricted areas outside of the treatment room and made subsequent to the completion of the initial radiation survey performed in accordance with Subitem (h) shall be evaluated by a radiation survey made in accordance with the requirements of Subitem (h)(1)(ii). A report describing the change(s) and giving the results of the survey(s), shall be sent to the Radioactive Materials Section, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007, not later than thirty (30) days following completion of the change(s).
  - (j) Each Unit shall be fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism. This inspection and servicing shall be performed by Varian Medical Systems, or by persons specifically authorized to do so by the U.S. Nuclear Regulatory Commission or an Agreement State.
  - (k) The following shall be performed by Varian Medical Systems, or by persons specifically authorized to do so by the U.S. Nuclear Regulatory Commission or an Agreement State:
    - (1) Installation, relocation or removal of the Unit containing sources.
    - (2) Source exchange
    - (3) Any maintenance or repair operations on the Unit involving work on any 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.
  - (l) Following source exchange and/or any source repairs and before its medical use, the licensee shall calibrate each iridium-192 sealed source in the Unit. The source output shall be determined to within an accuracy of  $\pm 3$  percent.
  - (m) The entrance to the room where the Unit is located shall be equipped with an electrical interlock system that will return the device's source to the shielded position immediately upon opening the entrance door. The interlock system shall be connected in such a manner that the device's source cannot be moved into the irradiation position until the treatment room entrance door is closed and the source "on-off" control is reset at the control panel.
  - (n) The Unit room shall be equipped with a radiation monitoring device which continuously monitors the source condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make the operator continuously aware of source condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor.

Whenever the continuous radiation monitoring device is not operational, any person entering the treatment room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the source condition.

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- (o) Relocation of the Unit to a new location is not permitted without a license amendment from the New York City Department of Health. Following such amendment and relocation, a radiation survey shall be made and reported to the Office of Radiological Health within thirty (30) days after completion of the move.
- (p) Immediately after completing patient treatment with the Unit, the licensee shall conduct a radiation survey to ensure that the source has been removed from the patient. The area of use shall also be surveyed to ensure proper return of the source to the shielded position. The licensee shall make a record of each survey and retain the results for at least three (3) years.

25. The following conditions apply for the Compagnie ORIS Industrie Model IBL-437C Irradiator for Biological Materials:

- (a) The procedures contained in the instruction manuals for the device shall be followed and copies of these manuals shall be made available to each person using or having responsibility for use of the radioactive material.
- (b) The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- (c) After installation of the irradiator and its cesium-137 sources and prior to the initiation of the irradiation programs, instrument surveys shall be conducted to determine radiation levels around, above and below the irradiator with the sources in the irradiate position and with the sources in the shielded position. A detailed report of the results of the survey shall be sent to the Radioactive Materials Section, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007, not later than thirty (30) days following the installation of the source(s).
- (d) The gamma irradiator operators shall wear a film badge at all times while on duty and an extremity radiation monitoring device (in the form of a ring dosimeter) when operating the irradiator.

26. Conditions for use of tritium (more than 3.7 gigabecquerels in noncontained form):

- (a) Individuals involved in operations which utilize, at any one time, more than 3.7 gigabecquerels of hydrogen-3 in a noncontained form (other than metallic foil) shall have bioassays performed within one (1) week following a single operation, and at weekly intervals for continuing operations.
- (b) Tritium shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 740 kilobecquerels of tritium per liter when averaged over a calendar quarter.
- (c) Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities in which tritium is used. If the average concentration of tritium in urine for any single individual during a calendar quarter is less than 370 kilobecquerels per liter, urinalysis shall be performed on that individual at monthly intervals for the following calendar quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 370 kilobecquerels per liter. The urine specimen shall be collected on the same day of the week insofar as possible.

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- (d) A report of an average concentration in excess of the limits specified in subitem c above for any individual shall be filed, in writing, within thirty (30) days of the end of the calendar quarter with the Radioactive Materials Division, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007. The report shall contain the results of all urinalyses for the individual during the calendar quarter, the cause of the excessive concentration and the corrective steps, taken or planned, to assure against recurrence
- (e) Any single urinalysis which discloses a concentration greater than 1.85 megabecquerels per liter shall be reported in writing, within seven (7) days of the licensee's receipt of the results, to the Radioactive Materials Division, Office of Radiological Health, 11th Floor, 2 Lafayette Street, New York, New York 10007.

- 27. 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.
- 28. 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) Two (2) letters dated 14 February 2002
- (B) Application dated 19 February 2002
- (C) Letter dated 20 February 2002
- (D) Letter dated 22 February 2002
- (E) Letter dated 25 February 2002
- (F) Letter dated 17 April 2002
- (G) Letter dated 25 April 2002
- (H) Letter dated 25 June 2002
- (I) Letter dated 5 November 2002
- (J) Application dated 5 February 2004 with ancillary materials
- (K) Letter dated 6 February 2004
- (L) Letter dated 18 May 2004

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APR 11 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

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This is to acknowledge the receipt of your letter/application dated

3/15/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 45-29867-01  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 140179.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.