



Br. 1

U.S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

03002476

September 5, 2006

License: 29-04333-01

To Whom It May Concern,

This letter is to request an amendment to our radioactive materials license. Please add Dr. Marco Naguib to our license. Documentation to support our request is enclosed.

In addition, please delete Dr. Ralph Eastman.

Thank you,

Linda Veldkamp, MS, DABR  
Chief Physicist/ Radiation Safety Officer

139352

Aug. 25. 2006 6:21PM

No. 4967 P. 2

NRC FORM 312A (10-2005)	U.S. NUCLEAR REGULATORY COMMISSION <b>MEDICAL USE TRAINING AND EXPERIENCE          AND PRECEPTOR ATTESTATION</b>	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008	
<b>PART I - TRAINING AND EXPERIENCE</b>			
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 35.80)  Maroo Naguib, MD (Authorized User)			
2. For Physicians, Podiatrists, Dentists, Pharmacists - State or Territory Where Licensed  New Jersey			
<b>3. CERTIFICATION</b>			
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)(i)(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 35.890(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.			
<b>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</b>			
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)(i)(G) or 35.390(b)(1)(ii)(G) or 35.590(c); or AMP under 35.51(c). c. Complete Items 5, 6a, 8b, 10, and Preceptor Items 11a through 11d to meet AU requirements in 35.396(a).			
<b>5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)</b>			
Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	NY Methodist Hospital 506 6th Street Brooklyn, NY 11215	200 hours	June 2002 - June 2006
Radiation Protection	NY Methodist Hospital 506 6th Street Brooklyn, NY 11215	200 hours	June 2002 - June 2006
Mathematics Pertaining to the Use and Measurement of Radioactivity	NY Methodist Hospital 506 6th Street Brooklyn, NY 11215	200 hours	June 2002 - June 2006
Radiation Biology	NY Methodist Hospital 506 6th Street Brooklyn, NY 11215	300 hours	June 2002 - June 2006
Chemistry of Byproduct Material for Medical Use	NY Methodist Hospital 506 6th Street Brooklyn, NY 11215	100 hours	June 2002 - June 2006
OTHER			

NRC FORM 513A (10-2005)		U.S. NUCLEAR REGULATORY COMMISSION			
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		
Reviewing full calibration measurements and periodic spot checks for remote afterloader; checking and using survey instruments	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2008		
Preparing treatment plans and calculating treatment doses and times; selecting proper dose and how it is to be administered for afterloaders	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2006		
Using administrative controls to prevent a medical event involving the use of byproduct material (HDR, manual brachytherapy and unsealed sources);	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2008		
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console of an afterloader;	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2008		
Ordering, receiving and unpacking radioactive materials safely and performing radiation surveys for manual brachytherapy sources and unsealed	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2006		
Preparing, implanting and removing brachytherapy sources; maintaining running inventories of material on hand;	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2006		
Using emergency procedures to control byproduct material; using procedures to contain spilled byproduct material and decontamination procedures	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2006		
Performing QC procedures on instruments used to determine the activity of dosages; calculating measuring and preparing patient dosages;	Dr. Selim and Dr. Rafia	NY Methodist Hospital Brooklyn, NY	June 2002-June 2008		
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
I-131	Therapy < 30 mCi	5	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2008
I-131	Therapy > 30 mCi	5	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2006
I-125	seed implantation	50	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2008
Au-82	seed implantation	2	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2008
P-32	unsealed; intracavitary	3	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2008
Sm-153	unsealed; intravenous	5	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2008
Cs-137	manual brachytherapy	>30	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2008
Ir-192	manual brachytherapy and	>50	Dr. Selim and Dr. Rafia	NY Methodist Hospital, Br	6/2002-6/2008

NRG FORM 313A (10-2003)		U.S. NUCLEAR REGULATORY COMMISSION	
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.600(c)			
Training Element	Type of Training *	Location and Dates	
Remote Afterloaders	supervised and didactic	June 2002- June 2006	
Stereotactic Radiosurgery	supervised and didactic	June 2002- June 2006	
Use of Manual Brachytherapy sources; Use of unsealed byproduct material	supervised and didactic	June 2002- June 2006	
<p>* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.600(c)), didactic, or vendor training.</p>			
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)
Radiation Oncology MD	NY Methodist Hospital Brooklyn, NY  91-2842-01	June 2002- June 2006	ACGME
8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE			
<input type="checkbox"/> YES      Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.			
<input checked="" type="checkbox"/> N/A      of _____ the RSO for License No. _____			
9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE			
<input type="checkbox"/> YES      Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.861) or medical physics (35.51) under the supervision of _____			
<input checked="" type="checkbox"/> N/A      who is a medical physicist (35.861) or meets requirements for Authorized Medical Physicists (35.51);			
and			
<input type="checkbox"/> 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) _____			
<input checked="" type="checkbox"/> N/A      under the supervision of _____ who is a medical physicist (35.861) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____			

NRC FORM 313A  
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

**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

B. Supervisor is:

Hosny Selim, MD

☒ Authorized User

☐ Authorized Medical Physicist

☐ Radiation Safety Officer

☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.390 (a) and (b) (1) (II) (G)

for medical uses in Part 35, Section(s) (see attached license)

D. Address

NY Methodist Hospital  
506 6th Street  
Brooklyn, NY 11215

E. Materials License Number

91-2842-01

**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) 390; 490; 690  
as documented in section(s) 5 & 6 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 Authorized user



N/A types of use, as documented in section(s) 5 through 6 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 35.390; 35.490; 35.690 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 license; OR



N/A

11d.



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



I meet the requirements of Authorized User 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): (see attached license)

A. Address

506 6th Street  
Brooklyn, NY 11215

B. Materials License Number

91-2842-01

C. NAME OF PRECEPTOR (print clearly)

Hosny Selim, MD

D. SIGNATURE OF PRECEPTOR



E. DATE

9/11/06



Nucletron

8671 Robert Fulton Drive  
Columbia, MD 21046Telephone: 410-312-4100  
Toll Free: 800-336-2249  
Canada Toll Free: 800-445-2249  
FAX: 410-312-4196

## Nucletron Training Seminar

Institution: Trinitas HospitalCity, State/Province, Zip: Elizabeth, NJ 07201**1 Teaching Aids Used**

User's Manual ☒

Applicators and Accessories ☒

Source Container and Dummy Sources ☒

Other ☒

**2 Topics Covered**

Explanation of Remote Afterloading ☒

Explanation of Radiation Protection ☒

**3 Applications**

Bronchus ☐

Interstitial ☐

Intracavitary ☐

Intraoperative ☐

**4 Applicators/Accessories**

Bronchus ☐

GYN ☐

Esophagus ☐

Interstitial ☐

Other ☐

**5 Equipment Operation**

Treatment Unit ☒

Handling ☒

Power Requirements ☒

Console ☒

Treatment ☒

Start ☒

Interrupt ☒

Emergency Stop ☒

Alarm and Error Codes ☒

**Radioactive Source:**ir192**6 Receiving**

Unpacking ☐

Acceptance ☐

Calibration ☐

Installation ☐

**7 Shipping**

Release ☐

Packing ☐

Documents ☐

Measurements ☐

Emergency Procedures ☒

All areas marked were covered during training

Mon Aug 2006 08/28/06 13:58:42

Instructor

FSE

Title

Mon Aug 2006 08/28/06 13:35:20

Department Head

Phy

Title

\* List of all attendees accompanies this form


**Nucletron**

 8671 Robert Fulton Drive  
Columbia, MD 21046

 Telephone: 410-312-4100  
Toll Free: 800-336-2249  
Canada Toll Free: 800-445-2249  
FAX: 410-312-4196

### Nucletron Training Seminar Attendance Registration

 Hospital: Trinitas Hospital Date: Monday, August 28, 2006

 Course: Inservice

 Instructor: Robert Ticknor

	Name	Department	Title	Signature
1	Eli Finkelstein	Rad Onc	MD	<i>Eli Finkelstein</i> <small>Mon Aug 28 2006 19:50:05</small>
2	Marco Naguib	Rad Onc	MD	<i>Marco Naguib</i> <small>Mon Aug 28 2006 19:50:05</small>
3	Sandra Chin	Rad Onc	Dosimetrist	<i>S. A. Chin</i> <small>Mon Aug 28 2006 19:50:05</small>
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

I certify that the above individuals have been instructed in Equipment Operation, Safety Precautions and Emergency Procedures in accordance with Nucletron Corporation Training Standards.

 Instructor Signature: *Robert Ticknor*  
Mon Aug 28 2006 19:50:05

 Instructor Title: Engineer



DEPARTMENT OF RADIATION ONCOLOGY

506 SIXTH STREET, BROOKLYN N.Y. 11215-9008 TEL 718/780-3677 FAX 718/780-3688

S. RAFLA, M.D., Ph.D., F.R.C.R.  
H. SELIM, M.D., F.R.C.R.  
K. PARIKH, M.D.  
M. TCHELEBI, M.D.  
H. ASHAMALLA, M.D., F.C.C.P.  
B. MOKHTAR, M.D.

August 18, 2006

To Whom It May Concern:

**RE: Marco Naguib, M.D.**

This letter is to indicate that Marco Naguib, M.D. completed four years of training in Radiation Oncology. He started on July 1<sup>st</sup>, 2002 and completed training on June 30<sup>th</sup>, 2006.

If you need further information, please do not hesitate to contact us at the above telephone number.

Sincerely,

A handwritten signature in black ink, appearing to read 'H. Selim'.

Hosny Selim, M.D.  
Director, Residency Program

HS/ga



## 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 letters dated 3 January 2006 and 31 January 2006 from Steven Garner, M.D., Chairman, Radiation Safety Committee, The New York Methodist Hospital; License number 91-2842-01 is hereby amended to change Item 3b, Conditions 12, 13, 24, to add Items 6(GG), 7(GG), 8(GG) through 6(JJ), 7(JJ), 8(JJ), Conditions 9(GG) through 9(JJ), and to read:

### LICENSEE

	3a. License Number:	91-2842-01
1. Name: The New York Methodist Hospital	3b. Amendment Number:	15
2. Address: 506 Sixth Street Brooklyn, New York 11215	4. Expiration Date:	31 October 2009
	5. Reference Number:	

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 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) *****	(B) As necessary for uses authorized in Subitem 9(B)

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

License Number: 91-2842-01

Amendment Number: 15

Reference Number:

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(C) Rubidium-81	(C) Contained in a dispensing column within a krypton-81m gas generator with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(C) 925 Megabecquerels
(D) Krypton-81m	(D) Gas Generator with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(D) 925 Megabecquerels
(E) Molybdenum-99	(E) Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(E) 148 Gigabecquerels
(F) Technetium-99m	(F) Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(F) 148 Gigabecquerels
(G) Technetium-99m	(G) DTPA Aerosol with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(G) 3.7 Gigabecquerels
(H) Xenon-133	(H) Gas Generator with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(H) 3.7 Gigabecquerels
(I) Cobalt-57	(I) 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"	(I) 5 Sources not to exceed 925 Megabecquerels per source
(J) Cobalt-57	(J) 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" *****	(J) 5 Sources not to exceed 740 Megabecquerels per source

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

License Number: 91-2842-01

Amendment Number: 15

Reference Number:

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(K) Barium-133	(K) 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"	(K) 5 Sources not to exceed 18.5 Megabecquerels per source
(L) Cesium-137	(L) 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"	(L) 5 Sources not to exceed 18.5 Megabecquerels per source
(M) Technetium-99m	(M) Pertechnetate	(M) Individual amounts not to exceed 1.85 Gigabecquerels
(N) Iridium-192	(N) Sealed Sources (Model GammaMed 232)	(N) 0.75 Terabecquerels, total no sources to exceed 375 Gigabecquerels
(O) Any radioactive material identified in §175.103(f)(1)(i), NYC Health Code	(O) Any radiopharmaceutical identified in §175.103(f)(1)(i), NYC Health Code	(O) As necessary for uses authorized in Subitem 9(O)
(P) Any radioactive material identified in §175.103(h)(1), NYC Health Code	(P) Any brachytherapy source identified in §175.103(h)(1), NYC Health Code	(P) 111 Gigabecquerels for all sources identified in Subitem 9(P)
(Q) Strontium-90/Yttrium-90	(Q) Sealed Source (Amersham Corp., Model #SIA.20)	(Q) 3.33 Gigabecquerels (Strontium-90)
(R) Iodine-125	(R) Sealed Sources-Seeds (Medi-Physics, Model Nos. 6701, 6702, 6711)	(R) 3.7 Gigabecquerels
(S) Cesium-137	(S) Sealed Sources (Minnesota Mining & Manufacturing, Model Series 6501, 6502, 6503 and Amersham Corp. Model Series CDCTI) *****	(S) Total activity not to exceed 31.8 Gigabecquerels and a maximum of 18 tube sources and 14 needle sources

# CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-2842-01

Amendment Number: 15

Reference Number:

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(T) Iridium-192	(T) Sealed Sources-Seeds in nylon ribbons (Best Industries, Inc. Model 81-01)	(T) 18.5 Gigabecquerels
(U) Depleted Uranium	(U) Metal Alloy	(U) 125 Kilograms
(V) Hydrogen-3	(V) Any	(V) 185 Megabecquerels
(W) Carbon-14	(W) Any	(W) 37 Megabecquerels
(X) Chromium-51	(X) Any	(X) 185 Megabecquerels
(Y) Cobalt-57	(Y) Any	(Y) 74 Megabecquerels
(Z) Iodine-125	(Z) Any	(Z) 185 Megabecquerels
(AA) Gold-198	(AA) Sealed Sources-Seeds (Best Industries, Inc., Model No. 81-02)	(AA) 22.2 Gigabecquerels
(BB) Phosphorous-32	(BB) Any	(BB) 185 Megabecquerels
(CC) Fluorine-18	(CC) Fluorodeoxyglucose Injection	(CC) 3.7 Gigabecquerels
(DD) Germanium-68/Gallium-68	(DD) Line Source (CTI Services, Inc. Model LS-0.5)	(DD) 37 Megabecquerels
(EE) Cesium-137	(EE) Calibration and Gauging Gamma Sources (Isotope Products Labs. Model HEG-137)	(EE) 4.44 Gigabecquerels total, not to exceed 1.11 Gigabecquerels per source
(FF) Depleted Uranium	(FF) Sealed Beam Shapers (Steel Cladding and Nickel Alloy Plating) *****	(FF) 55 Kilograms

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
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Amendment Number: 15

Reference Number:

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(GG) Technetium-99m	(GG) Sodium Pertechnetate (Medi-Physics, NDA 17-267 and NDA 17-471; CIS-US, NDA 17-321; Mallinckrodt, NDA 17-725)	(GG) 7.40 Gigabecquerels
(HH) Technetium-99m	(HH) Tetrofosmin Kit (Amersham, NDA 20-372)	(HH) 7.40 Gigabecquerels
(II) Thallium-201	(II) Thallous Chloride (DuPont Merck, NDA 17-806; Mallinckrodt, NDA 18-150; Medi-Physics, NDA 18-110; Bracco Diagnostics, NDA 18-548)	(II) 2.22 Gigabecquerels
(JJ) Cesium-131	(JJ) Brachytherapy Seeds (IsoRay Model CS-1, Lawrence CSEIRION Cs-131) *****	(JJ) 90 Gigabecquerels total, no seed to exceed 2.41 Gigabecquerels

**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) For producing krypton-81m gas.
- (D) Pulmonary ventilation studies.
- (E) For producing technetium-99m.
- (F) For use in reagent kits with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA for human-use diagnostic studies involving imaging and localization and as non-human use check, calibration and reference material.

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**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

Page 6 of 13 Pages

License Number: 91-2842-01

Amendment Number: 15

Reference Number:

- (G) Pulmonary function studies administered using either a Mallinckrodt Sunaco, Inc., a Cadema System, Inc., or a Medi-Nuclear Corporation Aero-Vent aerosol delivery system.
- (H) Inhalation studies in the evaluation of pulmonary function, study of pulmonary ventilation, imaging the lungs or the assessment of cerebral blood flow.
- (I) Flood calibration sources (Non-Human Use).
- (J) through (L) Calibration sources (Non-Human Use).
- (M) Calibration check and reference material (Non-Human Use).
- (N) In a GammaMed Plus HDR Remote Afterloader Brachytherapy Unit for the treatment of cancerous tumors. No source greater than 555 Gigabecquerels shall be installed into the HDR Remote Afterloader Brachytherapy Unit.
- (O) Any radiopharmaceutical or radiobiologic therapy procedure authorized by applicable law.
- (P) Any brachytherapy procedure approved in Section 175.108(h)(1) of the New York City Health Code.
- (Q) In an applicator for the treatment of superficial eye conditions.
- (R) As a sealed source in seeds for the interstitial treatment of cancer as a permanent implant.
- (S) As a sealed source in applicator cells for intracavitary treatment of cancer.
- (T) As seeds encased in nylon ribbon for the interstitial treatment of cancer.
- (U) As the beam definer and shielding in the Varian Model Clinac-4 Linear Accelerator (Non-Human Use).
- (V) through (Z) and (BB) *In-vitro* laboratory studies (Non-Human Use).
- (AA) For interstitial treatment of cancer.
- (CC) As listed under a "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA.
- (DD) In an ADAC Laboratories MCD Attenuation Correction device.
- (EE) and (FF) In an ADAC Laboratories MCD-AC Attenuation Correction device.
- (GG) Blood pool imaging.
- (HH) Imaging of the myocardium following separate administrations under exercise and resting conditions, and in the delineation of reversible myocardial ischemia in the presence or absence of infarcted myocardium.
- (II) 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.
- (JJ) For the treatment of malignant disease (e.g., head and neck, brain, breast, prostate, etc.) and may be used in topical, instilled, and intracavitary application for tumors of known radiosensitivity under FDA Premarket Approval K030162, dated 28 March 2003.

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**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

License Number: 91-2842-01

Amendment Number: 15

Reference Number:

10. The licensee shall comply with the provisions of Article 175 of the New York City Health Code entitled "Radiation Control."
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 at the Kirkwood Pavilion, Nuclear Cardiology Area; Buckley Pavilion, Ambulatory Surgery Area; Carrington Pavilion, Main Operating Area; Infill Pavilion, Nuclear Medicine Area; Miner Pavilion, Radioactive Material Storage Area; The New York Methodist Hospital, 506 Sixth Street, Brooklyn, New York 11215.
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

Hani Ashamalla, M.D.	Subitems 6(I) through 6(T), 6(AA), 6(JJ)
Leonard Berliner, M.D.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
Schawcz Bokhan, M.D.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
Ralph Carmel, M.D.	Subitems 6(V), 6(Y), 6(Z), 6(BB)
Steven Garner, M.D.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
Gabriel Gelves, D.O.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
Jeremy Green, M.D.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
Nnaemeka Ikoro, D.A.B.R.	Subitems 6(I) through 6(M), 6(U)
Claudia Lapidus, M.D.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
John Heitner, M.D.	Subitems 6(I) through 6(M), 6(GG) through 6(II)
Debra Kessler, M.D.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
Bahar Mokhtar, M.D.	Subitems 6(I) through 6(T), 6(AA), 6(JJ)
Kapilagauri Parikh, M.D.	Subitems 6(I) through 6(T), 6(AA), 6(JJ)
Surekha Patel, M.D.	Subitems 6(A) through 6(M), 6(O), 6(CC) through 6(FF)
Parashuram Pinnapureddy, M.D.	Subitems 6(A) through 6(M), 6(CC) through 6(FF)
Sameer Rafta, M.D.	Subitems 6(I) through 6(T), 6(AA), 6(JJ)
Hosny Selim, M.D.	Subitems 6(I) through 6(T), 6(AA), 6(JJ)
Hemant Shah, M.D.	Subitems 6(A) through 6(M), 6(O), 6(CC) through 6(FF)
Arun Tankhiwale, D.A.B.R.	Subitems 6(I) through 6(M), 6(U)
Mounzer Tchelchi, M.D.	Subitems 6(I) through 6(T), 6(AA), 6(JJ)
Lijun Weng, M.D.	Subitems 6(A) through 6(M), 6(O), 6(CC) through 6(FF)
Shung-Jun Yang, Ph.D.	Subitems 6(V), 6(W), 6(X), 6(Z)

14. The radiation safety officer for this license is Arun Tankhiwale, D.A.B.R.

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15. The therapy physicists for this license are Nnaemeka C. Ikoro, D.A.B.R. and Nokuleswar Panigrahi, D.A.B.R.
16. Radioactive material as a sealed source shall not be opened by the licensee.
17. Technetium-99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.
18. The following conditions apply for permanent brachytherapy implants:
  - (a) Iodine-125 implant patient's release shall be based on either of the following conditions:
    - A) The activity administered to the patient or the patient's calculated activity has decreased to less than 0.33 Gigabecquerel.
    - B) 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.
  - (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.

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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 Oligabecquerel, 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 licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculation 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.
21. 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.
22. 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.

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23. The following subitems refer to the high dose rate remote afterloader brachytherapy unit possessed by the licensee, henceforth referred to as the Unit (which presently is a Gamma Med Plus High Dose Rate (HDR) Remote Afterloader Unit):
- (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.
  - (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.

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- (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 be no more than 10 mR/hr at 5 cm from the surface, and no more than 1 mR/hr at 100 cm from the surface.
    - (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.
  - (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 (ii)(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 Gamma Med USA, Inc., or by persons specifically authorized to do so by the U.S. Nuclear Regulatory Commission or an Agreement State.

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- (k) The following shall be performed by Gamma Med USA, Inc., 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.
- (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

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24. 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) Letter dated 12 October 2004
- (B) Application dated 12 October 2004
- (C) Facsimile transmission dated 15 November 2004
- (D) Letter with attachments dated 8 December 2004
- (E) Facsimile transmission dated 21 December 2004
- (F) Letter dated 14 December 2005
- (G) Letter with attachments dated 3 January 2006
- (H) Letter with attachment dated 24 January 2006
- (I) Letter dated 31 January 2006
- (J) Facsimile transmission dated 1 February 2006
- (K) Letter dated 3 February 2006

FOR THE NEW YORK CITY DEPARTMENT  
OF HEALTH AND MENTAL HYGIENE

*Raymond Ford*

Raymond Ford  
Scientist  
Radioactive Materials Division  
Office of Radiological Health

Date: February 8, 2006  
RF/jh

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

9/5/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 29-04333-01 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

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** 139352.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.