Holy Name Hospital

Member
NewYork-Presbyterian Healthcare System
Affiliate: Columbia University College of Physicians & Surgeons

718 Teaneck Road | Teaneck, New Jersey 07666
Tel: 201-833-3000 | www.holyname.org

March 27, 2007

NMSB1

Pamela J. Henderson, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

03002472

Re: Holy Name Hospital
License No. 29-03382-01

Dear Ms. Henderson:

We are requesting that the following authorized users be removed from our license:
Howard Berman, MD Elizabeth Greenstein, MD

We would like to add an additional authorized user to our license:
Joshua Gross, MD

He would be authorized for material and use in 35.100 and 35.200. Enclosed is a copy of his most recent Radioactive Materials License from Beth Israel Medical Center in New York, NY, his New Jersey medical license and ABR certificate.

We would also like to add material and use in 35.300 and 35.500 for Benjamin Rosenbluth, MD, presently on the existing license. Enclosed is another copy of his medical use training and experience and preceptor attestation submitted to add him as an authorized user.

If you need any additional information, please contact me 201-833-3675.

Sincerely,

Jacqueline C. Brunetti, MD
Radiation Safety Officer

Michael Maron
President and CEO

JCB/MM:md
Enclosures

140367

NMSS/RGN1 MATERIALS-002

MEM\LET\US REGULATORY.LTR

REC'D IN LAT APR 11 2007

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 letter dated 10 October 2006 from Fukiat Ongseng, M.D., Radiation Safety Officer, Beth Israel Medical Center; License number 91-2897-01 is amended to change Item 3b, Conditions 15, 26, and to read:

LICENSEE

1. Name: Beth Israel Medical Center

2. Address: First Avenue at 16th Street
New York, New York 10003

3a. License Number: 91-2897-01

3b. Amendment Number: 31

4. Expiration Date: 30 November 2008

5. Reference Number: 602-Series and 611-Series

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: 91-2897-01

Amendment Number: 31

Reference Number: 602-Series and 611-Series

6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(C)	Any radioactive material identified in §175.103(f)(1)(i), NYC Health Code	(C)	Any radiopharmaceutical or radiobiologic for therapy with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) accepted by FDA	(C)	As necessary for uses authorized in Subitem 9(C)
(D)	Any radioactive material identified in §175.103(h)(1), NYC Health Code	(D)	Any brachytherapy source identified in §175.103(h)(1), NYC Health Code	(D)	945 Gigabecquerels
(E)	Hydrogen-3	(E)	Any	(E)	4 Gigabecquerels
(F)	Carbon -14	(F)	Any	(F)	4 Gigabecquerels
(G)	Phosphorus-32	(G)	Any	(G)	4 Gigabecquerels
(H)	Cobalt-57	(H)	Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(H)	12 Sources, not to exceed 925 Megabecquerels per source
(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)	12 Sources, not to exceed 740 Megabecquerels per source
(J)	Cobalt-57	(J)	Any	(J)	4 Gigabecquerels
(K)	Phosphorus-32	(K)	Sealed Sources (Guidant Corporation, Model GDT P-32 Series)	(K)	66.6 Gigabecquerels total, no source to exceed 22.2 Gigabecquerels
(L)	Germanium-68	(L)	Photon Line Source (DuPont-Merck, Model #NER 8410)	(L)	450 Megabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-2897-01

Amendment Number: 31

Reference Number: 602-Series and 611-Series

6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(M)	Strontium-82/Strontium-85/Rubidium-82	(M)	Generator (Bracco Diagnostics Cardiogen-82 Strontium Sr-82-Rubidium Rb-82 Generator, NDA #19-414)	(M)	Strontium-82, 7.4 Gigabecquerels; Strontium-85, 28 Gigabecquerels
(N)	Strontium-90	(N)	Sealed Source (DuPont, Model NES # 2503-3)	(N)	370 Megabecquerels
(O)	Yttrium-90	(O)	Any	(O)	8 Gigabecquerels
(P)	Molybdenum-99	(P)	Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(P)	259 Gigabecquerels
(Q)	Technetium-99m	(Q)	Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(Q)	259 Gigabecquerels
(R)	Technetium-99m	(R)	DTPA Aerosol with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(R)	12 Gigabecquerels

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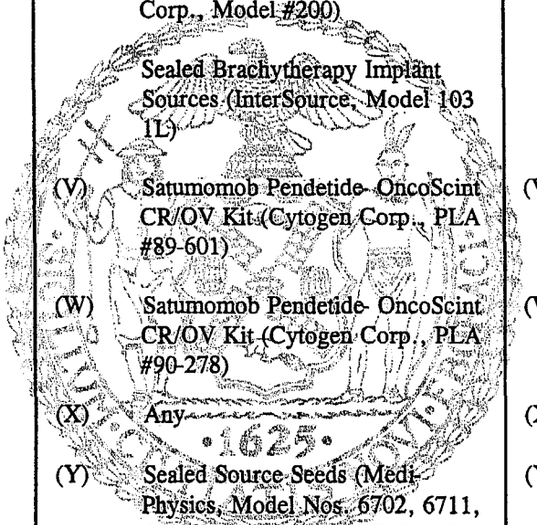
CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-2897-01

Amendment Number: 31

Reference Number: 602-Series and 611-Series

6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(S)	Technetium-99m	(S)	Sodium Pertechnetate (Medi-Physics, NDA 17-267 and 17-471; CIS-US, NDA 17-321; Mallinckrodt, NDA 17-725)	(S)	18.5 Gigabecquerels
(T)	Technetium-99m	(T)	Pertechnetate	(T)	Individual amounts not to exceed 1.85 Gigabecquerels
(U)	Palladium-103	(U)	Sealed Source Titanium Encapsulated Seeds (Theragenics Corp., Model #200)	(U)	33 Gigabecquerels, not to exceed 4 Gigabecquerels per seed
			Sealed Brachytherapy Implant Sources (InterSource, Model 103 1L)		33 Gigabecquerels, not to exceed 410 Megabecquerels per seed
(V)	Indium-111	(V)	Satumomob Pendetide- OncoScint CR/OV Kit (Cytogen Corp., PLA #89-601)	(V)	925Megabecquerels
(W)	Indium-111	(W)	Satumomob Pendetide- OncoScint CR/OV Kit (Cytogen Corp., PLA #90-278)	(W)	925 Megabecquerels
(X)	Iodine-125	(X)	Any	(X)	8 Gigabecquerel
(Y)	Iodine-125	(Y)	Sealed Source Seeds (Medi-Physics, Model Nos. 6702, 6711, 6720, North American Scientific Model MED 3631)	(Y)	8 Gigabecquerels,not to exceed 4 Gigabecquerels per seed
(Z)	Barium-133	(Z)	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" **********	(Z)	12 Sources, not to exceed 18.5 Megabecquerels per source



CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-2897-01

Amendment Number: 31

Reference Number: 602-Series and 611-Series

6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(AA)	Cesium-137	(AA)	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"	(AA)	12 Sources, not to exceed 18.5 Megabecquerels per source
(BB)	Iridium-192	(BB)	Sealed Sources Seeds in Nylon Ribbons (Best Industries, Inc.,Model 81-01)	(BB)	19 Gigabecquerels
(CC)	Thallium-201	(CC)	Thallous Chloride (DuPont-Merck, NDA 17-806, Mallinckrodt, NDA 18-150; Medi-Physics, NDA 18-110)	(CC)	3.4 Gigabecquerels
(DD)	Depleted Uranium	(DD)	Metal Alloy	(DD)	32 Kilograms
(EE)	Fluorine-18	(EE)	Fluorodeoxyglucose F-18 Injection	(EE)	37 Gigabecquerels
(FF)	Iridium-192	(FF)	Sealed Source (RAD S.L., Inc., Model #SL-77HS)	(FF)	111 Gigabecquerels
(GG)	Iodine-125	(GG)	Sealed Source (North American Scientific, Model MED 3631); Medi Physics, Models 6702, 6711, 6720)	(GG)	8 Gigabecquerels
(HH)	Iridium-192	(HH)	Sealed Source (Mallinckrodt Medical BV, Westerdiumweg 3, NL-1755 LE Petten, Product Code DRN 07736, or AEA Technology)	(HH)	888 Gigabecquerels, 2 sources of not more than 444 Gigabecquerels each
(II)	Fluorine-18	(II)	Fluorodeoxyglucose F-18 Injection	(II)	37 Gigabecquerels
(JJ)	Iridium-192	(JJ)	Sealed Sources- Seeds in nylon ribbons (Best Industries, Inc., Model 81-01)	(JJ)	111 Gigabecquerels
(KK)	Gadolinium-153	(KK)	Sealed Source-Transmission Line Sources	(KK)	37 Gigabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	91-2897-01
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	Reference Number:	602-Series and 611-Series

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) Any radiopharmaceutical therapy procedure approved in Section 175.103(f)(1)(i) of the New YorkCity Health Code.

(D) Any brachytherapy procedure approved in Section 175.103(h)(1) of the New York City Health Code.

(E) (F), (G), (J), (O), (X), (BB) In-vitro laboratory studies and studies in lower animals (Non-Human Use).

(H) Flood calibration sources (Non-Human Use).

(I), (Z), (AA) Calibration sources (Non-Human Use).

(K) In a Guidant Corporation GALILEO series Intravascular Brachytherapy (IVB) High Dose Rate Afterloader (HDR) Device for human use under the auspices of an IDE or PMA issued by the FDA for clinical research or general clinical use respectively.

(L) Quality control for position emission tomography (PET) studies.

(M) Myocardial perfusion agent to distinguish normal from abnormal myocardium in patients with suspected myocardial infarction. The licensee shall comply with the package insert instructions of Bracco Diagnostics Cardiogen82 Strontium Sr-82-Rubidium Rb-82 Generator.

(N) To be held in storage awaiting proper disposal.

(P) For producing technetium-99m.

(Q) 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 nonhuman use check, calibration and reference material.

(R) Pulmonary function studies administered using either a Mallinckrodt Sunaco, Inc., a Cadema System, Inc., or a Medi-Nuclear Corporation Aero-Vent aerosol delivery system.

(S) Blood pool imaging (Human-Use).

(T) Calibration check and reference material (Non-Human Use).

(U) In ophthalmic plaques for the treatment of ocular tumors in humans.

(V) Imaging and localization of ovarian carcinomas.

(W) Imaging and localization of colorectal carcinomas.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	91-2897-01
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(Y) In ophthalmic plaques for the treatment of ocular tumors in humans.

(CC) Myocardial perfusion imaging, the diagnosis and localization of myocardial infarction and prognosis regarding survival after onset of symptoms of acute MI to assess site and size of perfusion defect.

(DD) Internal shielding for molybdenum-99/technetium-99m generators.

(EE) In accordance with protocols submitted 4 November 1994 entitled "Positron Emission Tomography with Rubidium-82 Compared with F-18-fluorodeoxyglucose for Measuring Myocardial Viability and Potential for Recovery of Left Ventricular Function" and "Remote Metabolic Effects and Neuropsychiatric Consequences of Discrete Striatal Infarction: A Positron Emission Tomographic Study."

(FF) Clinical trials in the following investigational device exemptions (IDEs) sponsored by Interventional Therapies, LLC: IDE number G970195/S18, S19, S20, and any later supplements; and IDE Number G970268/S12, S13, S14, and any later supplements.

(GG) Any brachytherapy procedure approved in Section 175.103(h)(1) of the New York City Health Code.

(HH) In a Nucletron Corporation MicroSelectron-HDR Model 105.999 Remote Afterloading Brachytherapy Unit for interstitial, intracavitary and gynecological radiotherapy (Human Use). No source greater than 370 gigabecquerels shall be installed in the Unit.

(II) As listed under a "New Drug Application" (NDA) approved by FDA, or an "Investigational New Drug" (IND) application accepted by FDA.

(JJ) As specified in Section 175.103(h)(1)(v) of the New York City Health Code, and in accordance with "A Multicenter Trial of Localized Radiation Therapy to Inhibit Restenosis," Cordis, Protocol #POO-5001-Gamma V, IDE Number G960127/S65, and any later supplements.

To reduce in-stent restenosis using the Cordis Checkmate System subject to the "Conditions of Approval" contained in FDA premarket approval application (PMA #P990036) dated 3 November 2000.

(KK) Sealed line sources with an active (i.e., not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" and authorized for human use.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number:	91-2897-01
Amendment Number:	31
Reference Number:	602-Series and 611-Series

10. The radioactive materials may be used only at the following facilities of Beth Israel Medical Center: Petrie Campus (First Avenue at 16th Street) - BS25 and adjacent Radioactive Storage Room, 2S75; Karpas Building- OR#3; Dazian Building - Cath Labs 1, 2, A and B; 2S60, 2S71, 2S74, 2S75, 6S46-48, 8D62-8D68, 12D05, 12D44; Phillips Ambulatory Care Center (10 Union Square East) - Rooms L68, 3P25, 3P23A, 3P23B, 3P21, 4L-01, 4L-03.

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

12. Failure to pay the fee for inspection of a radioactive material site, upon notification from the Department, will result in termination of this license.

13. Radioactive materials listed in Item 6 are authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Authorized User	Materials and Use
Steven Begman, M.D.	Subitems 6(H), 6(I), 6(L), 6(M), 6(S), 6(T), 6(Z), 6(AA), 6(CC), 6(KK)
Manjeet Chadha, M.D.	Subitems 6(C), 6(D), 6(K), 6(O), 6(X), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)
Ilona Cohen, M.D.	Subitems 6(A), 6(B), 6(C), 6(H), 6(I), 6(L), 6(M), 6(P), 6(Q), 6(R), 6(T), 6(V), 6(W), 6(Z), 6(AA), 6(II), 6(KK)
Ronald Ennis, M.D.	6(C), 6(D), 6(K), 6(O), 6(X), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)
Andrew Evans, M.D.	Subitems 6(C), 6(D), 6(K), 6(O), 6(X), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-2897-01

Amendment Number: 31

Reference Number: 602-Series and 611-Series

Paul Gliedman, M.D.	Subitems 6(C), 6(D), 6(K), 6(O), 6(X), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)
Charles Goldfarb, M.D.	Subitems 6(A), 6(B), 6(C), 6(H), 6(I), 6(L), 6(M), 6(P), 6(Q), 6(R), 6(T), 6(V), 6(W), 6(Z), 6(AA), 6(II), 6(KK)
Joshua Gross, M.D.	Subitems 6(A), 6(B), 6(H), 6(I), 6(L), 6(M), 6(P), 6(Q), 6(R), 6(T), 6(V), 6(W), 6(Z), 6(AA), 6(II), 6(KK)
Peter Han, M.D.	Subitems 6(C), 6(D), 6(K), 6(O), 6(X), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)
Louis Harrison, M.D.	Subitems 6(C), 6(D), 6(K), 6(O), 6(X), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)
Harvey Hecht, M.D.	Subitems 6(H), 6(I), 6(L), 6(M), 6(S), 6(T), 6(Z), 6(AA), 6(CC), 6(KK)
Kenneth Hu, M.D.	Subitems 6(C), 6(D), 6(K), 6(O), 6(X), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)
Fukiat Ongseng, M.D.	Subitems 6(A), 6(B), 6(C), 6(D), 6(H), 6(I), 6(K), 6(L), 6(M), 6(P), 6(Q), 6(R), 6(T), 6(V), 6(W), 6(Z) 6(AA), 6(BB), 6(EE), 6(II), 6(KK)
Leonid Poretsky, M.D.	Subitems 6(G), 6(X)
John Protic, M.D.	Subitems 6(E), 6(F), 6(G), 6(J)
Donna Seto-Young, Ph.D.	Subitems 6(G), 6(X)
Daniel Shasha, M.D.	Subitems 6(C), 6(D), 6(K), 6(O), 6(X), 6(U), 6(Y), 6(AA), 6(BB), 6(FF), 6(GG), 6(HH), 6(JJ)
Andrew Van Tosh, M.D.	Subitems 6(H), 6(I), 6(L), 6(M), 6(S), 6(T), 6(Z), 6(AA), 6(CC), 6(KK)

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	91-2897-01
	Amendment Number:	31
	Reference Number:	602-Series and 611-Series

14. The radiation safety officer for this license is Fukiat Ongseng, M.D.

15. The therapy physicists for this license are Svetlana Denissova, D.C.C.P.M., Eli Furhang, D.A.B.M.P., Rob Mooij, D.A.B.R., Raymond Ross, D.A.B.R., J. Allen Shih, D.A.B.R., Jussi Sillanpaa, D.A.B.R., and Edward Soundentas, D.A.B.M.P.

16. Radioactive material as a sealed source shall not be opened by the licensee.

17. Experimental animals administered radioactive materials or their products shall not be used for human consumption.

18. Any radiopharmaceutical or radiobiologic with a current and active IND issued by FDA shall be used in accordance with Title 21, Part 312 of The Code of Federal Regulations or any successor regulation.

19. For a period of sixty (60) days in any calendar year, a visiting physician is authorized to use licensed materialfor human use under the terms of this license, providing the visiting physician:

a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee;

b) Is specifically named as a user on a New York City Department of Health license authorizing human use; and

c) Performs only those procedures for which he is specifically authorized by the New York City Department of Health.

The license shall maintain for inspection by the Bureau copies of the written permission specifed in Subitem a) above and of the license(s) specified in Subitem b) and c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under Subitem a) above.

20. Technetium-99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.

21. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum99 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.

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The State Board of Medical Examiners of New Jersey

Certifies that

Joshua David Gross

having presented due evidence of Certification by the

National Board of Medical Examiners

is hereby licensed to practice Medicine and Surgery in the State of New Jersey.

No. 60936

Trenton, New Jersey,

July 26 1994

THE STATE BOARD OF MEDICAL EXAMINERS OF NEW JERSEY

President

Harvey L. Potter D.O.M

Secretary

The American Board of Radiology

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

Joshua David Gross, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this first day of June, 1984
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF MEDICAL SPECIALTIES

President

Secretary

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

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)

Benjamin Rosenbluth, Authorized User, 10 CFR 35.490, 10 CFR 35.690

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

NY, NJ

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	Memorial Sloan-Kettering Cancer Center (MSKCC), 1275 York Avenue, New York, NY 10021	100	Sep 2002 - Dec 2002 Sep 2003 - Dec 2003
Radiation Protection	MSKCC	10	Sep 2002 - Dec 2002 Sep 2003 - Dec 2003
Mathematics Pertaining to the Use and Measurement of Radioactivity	MSKCC	10	Sep 2002 - Dec 2002 Sep 2003 - Dec 2003
Radiation Biology	MSKCC/The Mount Sinai Hospital 1 Gustave L. Levy Place New York, New York 10029	100	Jan 2003 - Mar 2003 Jul 2004 - Jun 2005
Chemistry of Byproduct Material for Medical Use	MSKCC	5	Sep 2002 - Dec 2002 Sep 2003 - Dec 2003
OTHER			

NRC FORM 313A (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
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Michael Zelefsky	MSKCC 75-2968-01	Jan 2005 5 HRS
Checking survey meters for proper operation; Maintaining running inventories of material on hand	Michael Zelefsky	MSKCC 75-2968-01	Jan 2005 5 HRS
Preparing, implanting, and removing brachytherapy sources; Selecting the proper dose and how it is to be administered	Michael Zelefsky	MSKCC 75-2968-01	Jul 02 - Jun 06 500 HRS
Using administrative controls to prevent a medical event involving the use of byproduct material	Michael Zelefsky	MSKCC 75-2968-01	Jan 2005 5 HRS
Using emergency procedures to control byproduct material; Checking and using survey meters	Michael Zelefsky	MSKCC 75-2968-01	Jan 2005 5 HRS
Reviewing full calibration measurements and periodic spot-checks; Preparing treatment plans and calculating treatment doses and times	Michael Zelefsky	MSKCC 75-2968-01	Jan 2005 5 HRS
Using administrative controls to prevent a medical event involving the use of byproduct material	Michael Zelefsky	MSKCC 75-2968-01	Jan 2005 5 HRS
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Michael Zelefsky	MSKCC 75-2968-01	Jan 2005 5 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
I-125	LDR interstitial implant	30	Michael Zelefsky	MSKCC 75-2968-01	Jul 02 - Jun 06
Ir-192	HDR interstitial implant	20	Michael Zelefsky	MSKCC 75-2968-01	Jul 02 - Jun 06
I-125	LDR intracavitary implant	5	Michael Zelefsky	MSKCC 75-2968-01	Jul 02 - Jun 06
Ir-192	HDR intracavitary implant	25	Michael Zelefsky	MSKCC 75-2968-01	Jul 02 - Jun 06
I-131	Oral (unsealed source)	5	H. William Strauss	MSKCC 75-2968-01	Feb 06 - Mar 06
Y-90	IV (unsealed source)	1	H. William Strauss	MSKCC 75-2968-01	Feb 06 - Mar 06
MIBG-I-131	IV (unsealed source)	1	H. William Strauss	MSKCC 75-2968-01	Feb 06 - Mar 06
Sm-153	IV (unsealed source)	1	H. William Strauss	MSKCC 75-2968-01	Feb 06 - Mar 06

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
HDR safety procedure training	GammaMed (i.e., vendor) HDR afterloader unit safety training	Memorial Sloan-Kettering Cancer Center (MSKCC), 1275 York Avenue, New York, NY 10021, June 15, 2006

* 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)
Radiation Oncology	Memorial Sloan-Kettering Cancer Center, 1275 York Avenue, New York, NY 10021 75-2968-01	July 2002 - June 2006	Accreditation Coucil for Graduate Medical Education 10 CFR 35.490, 10 CFR 35.690

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

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

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

☐ YES ☑ N/A 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 _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

☐ YES ☑ N/A 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) _____ under the supervision of _____ who is a medical physicist (35.961) 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: Michael Zelefsky, MD

B. Supervisor is:
- [x] Authorized User
- [ ] Authorized Medical Physicist
- [ ] Radiation Safety Officer
- [ ] Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 490 and 690

for medical uses in Part 35, Section(s) 490 and 690

D. Address
Memorial Sloan-Kettering Cancer Center
1275 York Avenue, New York, NY 10021

E. Materials License Number: 75-2968-01

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.
- [x] has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 490 and 690 as documented in section(s) 5 - 7 of this form.

11b. Select one
- [x] meets the requirements in [ ] 35.50(e) [ ] 35.51(c) [ ] 35.390(b)(1)(ii)(G) [x] 35.690(c) for all types of use, as documented in section(s) 5 - 7 of this form.
- [ ] N/A

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 _____ for _____ 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**
- [x] N/A

11d.
- [ ] I am an Authorized Nuclear Pharmacist; **or** [ ] I am a Radiation Safety Officer; **or**
- [x] I meet the requirements of 490 and 690 section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor [x] AU or [ ] AMP

for the following byproduct material uses (or units): remote afterloader, teletherapy, gamma SRS, brachytherapy

A. Address
Memorial Sloan-Kettering Cancer Center
1275 York Avenue, New York, NY 10021

B. Materials License Number: 75-2968-01

C. NAME OF PRECEPTOR *(print clearly)*	D. SIGNATURE – PRECEPTOR	E. DATE
Michael Zelefsky, MD		5/19/06

June 1, 2006

Sr. Patricia Lynch Regional Cancer Center Holy Name Hospital
Teaneck, New Jersey

RE: Benjamin Rosenbluth, MD

To Whom It May Concern:

Dr. Benjamin Rosenbluth has served as a resident in Department of Radiation Oncology for the past 4 years. Dr. Rosenbluth practiced under supervision of radiation oncology physicians authorized as users under the Memorial Sloan-Kettering Cancer Center Committee on Radiation, including Drs. Beryl McCormick and Michael Zeletsky, both certified in radiation oncology by the American Board of Radiology. These physicians practice under the aegis of the radiation protection program authorized by the NYDOH/MH broad scope human use license number 75-2968-01. Dr. Rosenbluth has received extensive experience with manual brachytherapy applications as well as treatments utilizing remote afterloader instrumentation.

Sincerely,

Jean St. Germain, MS, CHP, DABMP
Radiation Safety Officer
Attending Physicist

This Certifies that

Benjamin Rosenbluth

Completed Gammamed HDR Afterloader Safety Training on 6/15/06.

Douglas Boyles,
Field Service Rep. Varian Medical Systems

Benjamin Rosenbluth
Resident Name

Memorial Sloan-Kettering Cancer Center
Program

Date	Disorder	Dose Administered	Preceptor Name/Signature
Oral I-131			H. William Strauss
1. 2/9/06	Thyroid Cancer	201.6 mCi	
2. 2/15/06	Thyroid Cancer	207.3 mCi	
3. 2/15/06	Thyroid Cancer	450 mCi	
Parenteral			
1. 2/8/06	Stage IV Prostate	94 mCi (Samarium)	
2. 2/23/06	Met. Pheochrom.	125.6 mCi (MIBG)	
3. 3/1/06	Non-Hodgkin's	26 mCi (Zevalin)	

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

3/27/2007, and to inform you that the initial processing which includes an administrative review has been performed.

☑ 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. AMEND. 29-03382-01

☐ 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** 140367.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader