Cardinal Health
Medical & Health Physics Services
9668 Marion Ridge
Kansas City, MO 64137
816.965.0330 tel
816.966.2040 fax

www.cardinal.com

CardinalHealth

January 14, 2010

Nuclear Regulatory Commission
Medical Licensing Division, Region III
2443 Warrenville Road
Lisle, IL 60532-4351

To Whom It May Concern:

Please amend the Radioactive Materials License #24-25816-01 (Truman Medical Center, 2301 Holmes Street, Kansas City, MO 64108) to include the following change:

They would like to have the following physician added to thier license as an authorized user for 35.200 specific to nuclear cardiology only:

Paramdeep S Baweja, M.D.

Please see the attached preceptor attestation and additional paperwork. Should you have any questions, please contact me, Marcia West, the health physicist at 816-807-8090 or by fax at 816-974-1443.

Your attention in this matter is greatly appreciated.

Sincerely,

Marcia R. West
Health Physics Specialist

RECEIVED JAN 2 0 2010

SUNY
DOWNSTATE
Medical Center

Radiation Physics Laboratory – box 1209
Radiation Safety Office
450 Clarkson Avenue
Brooklyn, N.Y. 11203-2098
Tel. 718- 270-1424 , Fax. 718-270-1376

Fax

To:	Marcy West - Cardinal Health	**From:**	Arthur Olson
Fax:		**Pages:**	11
Phone:		**Date:**	1/13/10
Re:	License requested	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Attached please find a copy of the requested license.

Please contact me (Ellen Berger 718 270-1424) for furhter assistance.

Thanks.

THIS FACSIMILE MESSAGE ACCOMPANYING THIS TRANSMITTAL FORM CONTAINS PRIVILEGED AND CONFIDENTIAL INFORMATION INTENDED SOLELY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHOM IT IS ADDRESSED. IF THE READER OF THIS NOTICE IS NOT THE INTENDED ADDRESSEE, OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU RECEIVED THIS FACSIMILE IN ERROR, PLEASE NOTIFY US BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL AT THE ADDRESS ABOVE. THANK YOU

Jan 13 2010 13:30 RAD.PHYSICS SUNY DOWNSTAT 7182701376 p.1

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 19 November 2009 from Ivan Lisnitzer, Executive Vice President for Administration, SUNY-Downstate Medical Center; License number 75-2934-01 is hereby amended in its entirety:

LICENSEE

1. Name: SUNY – Downstate Medical Center

2. Address: 450 Clarkson Avenue, Box 1209
Brooklyn, NY 11203-2098

3a. License Number: 75-2934-01

3b. Amendment Number: 17

4. Expiration Date: 30 November 2014

5. Reference Number: 82-Series; 148-Series

6.	Radioactive materials (element number)	7.	Chemical and/or physical form	8.	Maximum quantity licensee possess at any one time
(A)	Any radioactive material with atomic number 3-83, except as listed below	(A)	Any	(A)	3.7 Gigabecquerels each, except as listed below
(B)	Hydrogen-3	(B)	Labeled glucose	(B)	740 Megabecquerels
(C)	Fluorine-18	(C)	Fluorodeoxyglucose	(C)	44.8 Gigabecquerels
(D)	Cobalt-57	(D)	Sealed Sources with an active (*i.e* not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices" **********	(D)	5 Sources not to exceed 925 Megabecquerels per source

Jan 13 2010 13:30 RAD.PHYSICS SUNY DOWNSTAT 7182701376 P.2

CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 75-2934-01

Amendment Number: 17

Reference Number: 82-Series; 148-Series

6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(E)	Cobalt-57	(E)	Sealed Sources with an active (*i.e.* not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(E)	5 Sources not to exceed 740 Megabecquerels per source
(F)	Rubidium-81	(F)	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	(F)	4.63 Gigabecquerels
(G)	Krypton-81m	(G)	Gas Generator with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(G)	4.63 Gigabecquerels
(H)	Strontium-90	(H)	Sealed Source (Tracer Lab, Model # RA-1)	(H)	1.85 Gigabecquerels
(I)	Molybdenum-99	(I)	Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(I)	185 Gigabecquerels
(J)	Technetium-99m	(J)	Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(J)	185 Gigabecquerels
(K)	Technetium-99m	(K)	DTPA Aerosol with an active (*i.e.* not withdrawn or terminated "New Drug Application" (NDA) approved by FDA	(K)	3.7 Gigabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 75-2934-01

Amendment Number: 17

Reference Number: 82-Series; 148-Series

6. Radioactive materials (element number		7. Chemical and/or physical form		8. Maximum quantity licensee may posses at any one time	
(L)	Technetium-99m	(L)	Pertechnetate	(L)	Individual amounts not to exceed 1.85 Gigabecquerels
(M)	Palladium-103	(M)	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"	(M)	10 Gigabecquerels
(N)	Iodine-125	(N)	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"	(N)	10 Gigabecquerels
(O)	Barium-133	(O)	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"	(O)	5 Sources not to exceed 18.5 Megabecquerels per source
(P)	Cesium-137	(P)	Sealed Sources (Minnesota Mining & Manufacturing, Model Series 6500, 6520 (Formerly 6D6C))	(P)	206 Sources not to exceed 37 Gigabecquerels total
(Q)	Cesium-137	(Q)	Sealed Source (Victoreen Nuclear Associates-Technical Operations, Model 773)	(Q)	6.29 Gigabecquerels
(R)	Cesium-137	(R)	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"	(R)	5 Sources not to exceed 18.5 Megabecquerels per source
(S)	Radium-226	(S)	Sealed Source **********	(S)	0.74 Megabecquerels

CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 75-2934-01

Amendment Number: 17

Reference Number: 82-Series; 148-Series

6. Radioactive materials (element number	7. Chemical and/or physical form	8. Maximum quantity licensee may posses at any one time
(T) Iridium-192	(T) Sealed Sources, Seeds in ribbons with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" Published in NRC "Registry of Radioactive Sealed Sources and Devices."	(T) 7.4 Gigabecquerels
(U) Iodine-131	(U) Any	(U) 22.2 Gigabecquerels
(V) Yttrium-90	(V) Ibritumomab Tiuxetan (IDEC Pharmaceuticals Corp., STN: BL 125019/0)	(V) 7.4 Gigabecquerels
(W) Yttrium-90	(W) Liquid	(W) 4.1 Gigabecquerels
(X) Indium-111	(X) Ibritumomab Tiuxetan (IDEC Pharmaceuticals Corp., STN: BL125019/0)	(X) 740 Megabecquerels
(Y) Iridium-192	(Y) Brachytherapy Seed Sources (Best Industries, Model 81-01)	(Y) 148 Gigabecquerels total, no single seed to exceed 1.3 Gigabecquerels; in a three - ribbon set containing 6, 10. or seeds per ribbon, 40.7 Gigabecquerels total (per set)
(Z) Germanium-68/ Gallium-68	(Z) Sealed Sources (Siemens Medical Solutions USA, Model LS-LA)	(Z) 1.11 Gigabecquerels (not to exceed 555 Megabecquerels per source)
(AA) Germanium-68/ Gallium-68	(AA) Sealed Source (Siemens Medical Solutions USA, Models CS-HT)	(AA) 1.11 Gigabecquerels (not to exceed 555 Megabecquerels per source)
(BB) Germanium-68/Gallium-68	(BB) Sealed Source (Isotope Products Laboratories, Model HEGL-Series)	(BB) 1.11 Gigabecquerels (not to exceed 555 Megabecquerels per source)
(CC) Strontium-90/Yttrium-90	(CC) Brachytherapy Seed Sources (Novoste Corporation, Models Bebig Sr0.S03 and AEAT SICW.2)	(CC) 29.6 Gigabecquerels total, 4.44 Gigabecquerels per device, no seed source to exceed 185 Megabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 75-2934-01

Amendment Number: 17

Reference Number: 82-Series; 148-Series

6. Radioactive materials (element number	7. Chemical and/or physical form	8. Maximum quantity licensee may posses at any one time
(DD) Cobalt-57	(DD) Gamma Reference Source (North American Scientific, Model MED3550)	(DD) 518 Megabecquerels
(EE) Gadolinium-153	(EE) Sealed Sources (Isotope Products Laboratories, Model No. IPL: NES-8412	(EE) 74 Gigabecquerels
(FF) Germanium-68/Gallium-68	(FF) Sealed Source (Isotope Products Laboratories, Model HEGL-0132)	(FF) 55.1 Gigabecquerels

****

THE TOTAL POSSESSION LIMIT FOR (A) THROUGH (FF) SHALL NOT EXCEED 890.32 GIGABECQUERELS

CONDITIONS

9. Authorized Use:

(A), (B), (F) through (K), (M), (N), (P), (T), (U) medical diagnosis, therapy, and research (Broad Human-Use).

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

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

(E), (O), (Q), (R), and (S), and (FF) Calibration sources (Non-Human Use).

(H) As a beta ophthalmic therapy applicator (Human-Use).

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

(V) For treatment of patient with relapsed, or refractory low grade, follicular or transformed B-cell Non-Hodgkin's Lymphoma.

(W) Calibration and reference material.

(X) For diagnostic imaging of Non-Hodgkin's Lymphoma.

(Y) To reduce In-stent re-stenosis using the Cordis Checkmate System.

(CC) In Novoste Beta-Cath System A 1000 Series Transfer Devices for intravascular brachytherapy

(Z), (AA), (BB), and (DD) to provide necessary calibration and correction factors for position emission tomography (PET) systems.

(EE) Attenuation measurements in a Philips FORTE Spec 5/8 Gamma Camera (Human Use).

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number:	75-2934-01
Amendment Number:	17
Reference Number:	82-Series; 148-Series

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

11. The radioactive material shall be used only at the buildings on the campus of SUNY Health Science Center at 450 Clarkson Avenue and bounded by New York Avenue, Lenox Road, East 37th Street and Clarkson Avenue.

12. Radioactive materials shall be used by or under the supervision of individuals designated by the Human Use Radiation Safety Committee, SUNY Health Science Health Center at Brooklyn, Arnold Strashun, M.D., Chairman.

13. The radiation safety officer for this license is Arthur Olson, D.A.B.R.

14. The therapy physicists for this license are Irene Alexandropoulos, and Andrew Lukban, D.A.B.R.

15. 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.

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

17. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination of technetium-99m. 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.

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

    (b) The licensee shall maintain, for inspection by the Bureau of Radiological Health, results of each test performed to de 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.

18. 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.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	75-2934-01
	Amendment Number:	17
	Reference Number:	82-Series; 148-Series

(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.

19. The following conditions apply for permanent brachytherapy implants:

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

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

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

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

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

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

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	75-2934-01
	Amendment Number:	17
	Reference Number:	82-Series; 148-Series

(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.

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

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	75-2934-01
	Amendment Number:	17
	Reference Number:	82-Series; 148-Series

21. The licensee is authorized to hold radioactive materials with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

(a) Radioactive waste to be disposed of in this manner shall be held for decay for a minimum of ten (10) half-lives.

(b) Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with appropriate low-level laboratory survey instruments. All radiation labels shall be removed or obliterated.

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.

23. Conditions for use of tritium (more than 3.6 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 wh tritium is used. If the average concentration of tritium in urine for any single individual during a calendar quarter is 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.

(D) A report of an average concentration in excess of the limit specified in Subitem B 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.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number:	75-2934-01
Amendment Number:	17
Reference Number:	82-Series: 148-Series

24. In addition to the possession limits in Item 8 and THE TOTAL POSSESSION LIMIT, the licensee shall further restrict the possession of licensed materials to quantities below the minimum limits specified in Section 175.101(n) of the New York City Health Code for establishing decommissioning financial assurance.

25. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source of Category I or Category II level as defined in 10 CFR §20.1003 shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (a) through (e) of 10 CFR §20.2207 for each type of transaction. Initial inventory reports must be submitted as described in paragraph (h). The reports must include information, be submitted in the time frame and in the manner specified, and be corrected as applicable as described in 10 CFR 20 §20.2207. The National Source Tracking System requirements - 10 CFR §20.1003 ([Nationally tracked source]Definitions), 10 CFR §20.2207 (Reports of transactions involving nationally tracked sources) and 10 CFR §20 Appendix E (Nationally Tracked Source Thresholds) - have been provided to each affected licensee, and are a document incorporated by reference as part of this license.

26. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations and procedures contained in the documents including any enclosures listed below. Article 175 of the New York City Health Code shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(A) Application dated 19 October 2009

(B) Letter dated 30 October 2009

(C) Letter dated 24 November 2009

****

FOR THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Date: DEC 17 2009

DPH/ih

Daniel P. Hayes

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

Jan 13 2010 13:32 RAD.PHYSICS SUNY DOWNSTAT 7182701376 p.11

Not sending out license

718-270-2136

- Call Emette Truman

- 913 492-8563

→ All on the license

Inst. license

→ Art. Olsen (Diane)

718-270-2121

718-270-1423 →

Arthur Olsen → Left a message

Ellen

Paramdeep Baweja

Dr. Lugar

DOWNSTATE MEDICAL CENTER

HUMAN USE 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 the licensee designated below, a license is hereby issued by the HUMAN USE RADIATION SAFETY COMMITTEE authorizing THE "AUTHORIZED USER" to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(B) 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. This License is for use at the Health Science Center at Brooklyn and Kings County Hospital Center as specified herein, and cannot be transferred.

Licensee		License Number: 75-2934-01-202
1. Name: State University of New York Health Science Center at Brooklyn Downstate Medical Center Department of Cardiology 2. Address: 450 Clarkson Avenue Brooklyn, New York 11203 2A. Authorized User: Jason Lazar, M.D.		4. Expiration date: April 30, 2012 5. Reference Number: 82-202 5A. Radiation Safety Officer Arthur Olson
6. Radioactive Material (element and mass)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
A) Technetium 99m	Pyro and Trimeta Phospates prepared by Using kits: Mallinckrodt: TechneBcan Pyp N.D.A. # 17-528 Squibb: Phosphatec N.D.A. 17-680 New England Nuclear: Pyrolite N.D.A. 17-684	(A) 300 Millicuries
B) Thallium 201	Thallous Chloride supplied by: New England Nuclear N.D.A. 17-806 Mallinckrodt N.D.A. 18-150 Amersham N.D.A. 18-548 Medi Physics N.D.A. 18-110	(B) 100 Millicuries

DATE ISSUED: 6-3-2004

By

ARNOLD STRASHUN, M.D., Chairman
Human Use Radioisotope Committee

ARTHUR OLSON
Radiation Safety Officer

SEE CONDITIONS NEXT PAGE

CONDITIONS

Authorized User: Jason Lazar, M.D. License Number: 75-2934-01-202

9. Authorized use: (A) Cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction. (B) Myocardial imaging.

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

11. Radioactive material shall be used by, or under the direct supervision of, Jason Lazar M.D. Other physicians injecting radioactive materials into patients under the supervision of Dr. Lazar must be instructed by Dr. Lazar as the proper technique and emergency procedures in case of an accident.

12. Radioactive material to be administered to humans shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug and Cosmetic Act.

13. The radioactive material shall be used only at the Health Science Center at Brooklyn at the following location(s):

    Room: A2-349, A2-358, B2-318

14. Any Misadministrations must be reported immediately to the Chairman of the Human Use Radioisotope Committee and the Radiation Safety Officer.

15. A written consent form signed by the patient, describing the procedure using radioactive materials is required prior to each patient exam.

16. The authorized user is required to perform all safety test (wipe tests, surveys etc.) and maintain written records documenting results of such test. The authorized user is also required to maintain a current inventory of all radioactive materials on hand. Authorized user is required to insure that all safety precautions are implemented during the handling of injection of radioactive materials.

FAILURE TO COMPLY WITH THESE WRITTEN CONDITIONS MAY RESULT IN THE REVOCATION OF THIS LICENSE

SUNY
DOWNSTATE
Medical Center

Radiation Physics Laboratory – box 1209
Radiation Safety Office
450 Clarkson Avenue
Brooklyn, N.Y. 11203-2098
Tel. 718- 270-1424 , Fax. 718-270-1376

Fax

To:	Marcy West - Cardinal Health	**From:**	Arthur Olson
Fax:		**Pages:**	3
Phone:		**Date:**	1/13/10
Re:	License requested	**CC:**	

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

• **Comments:**

Attached please find a copy of the requested license.

Please contact me (Ellen Berger 718 270-1424) for furhter assistance.

Thanks.

THIS FACSIMILE MESSAGE ACCOMPANYING THIS TRANSMITTAL FORM CONTAINS PRIVILEGED AND CONFIDENTIAL INFORMATION INTENDED SOLELY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHOM IT IS ADDRESSED. IF THE READER OF THIS NOTICE IS NOT THE INTENDED ADDRESSEE, OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU RECEIVED THIS FACSIMILE IN ERROR, PLEASE NOTIFY US BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL AT THE ADDRESS ABOVE. THANK YOU

Jan 13 2010 15:11 RAD.PHYSICS SUNY DOWNSTAT 7182701376 p.1

NRC FORM 313A (AUD) (3-2009) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User	State or Territory Where Licensed
PARAMDEEP S BAWEJA	MISSOURI

Requested Authorization(s) *(check all that apply)*

- ☐ 35.100 Uptake, dilution, and excretion studies
- ☑ 35.200 Imaging and localization studies
- ☐ 35.500 Sealed sources for diagnosis (specify device _____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☑ 1. **Board Certification**

a. Provide a copy of the board certification.

b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

☐ 2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience:			

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*.

☐ 35.290 ☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G)

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ 3. **Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use *(not required for 35.590)*			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience		**Total Hours of Experience:**	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

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(3-2009)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. **Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		☐ Yes ☐ No	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

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(3-2009)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.690)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each use requested:

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☑ I attest that Paramdeep Bawejа has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190 ☑ 35.290 ☐ 35.390 ☐ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
JASON LAZAR, MD		(718) 270-2136	08/06/2009

License/Permit Number/Facility Name NRC LICENSE #: 75-2934-01-202
SUNY DOWNSTATE MEDICAL CENTER

PAGE 4

Certification Board of Nuclear Cardiology

Incorporated 1996

Certifies that

Paramdeep S. Baweja, MD

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD
FOR PHYSICIANS TRAINED 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 2007 - 2017

President

CBNC

Secretary

CERTIFICATE NUMBER: 5506

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