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JK MEDICAL CENTER
RADIATION ONCOLOGY
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24-12611-01
03002555

TO: NRC attn: Shirley Xu
Fax #: 73 (610) 337-5269
From: Trent Hall
Date: 5-16-05 Pages: 8
(including cover sheet)

Here is the license you requested.

mail control # 136783

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 14 March 2001 from Frank Mazzagatti, Ph.D., Senior Vice President-Administration, Parkway Hospital; License number 91-2932-01 is hereby amended in its entirety to read:

LICENSEE

<p>1. Name: Parkway Hospital</p> <p>2. Address: 70-35 113th Street Queens, New York 11375</p>	<p>3a. License Number: 91-2932-01</p> <hr/> <p>3b. Amendment Number: 8</p> <hr/> <p>4. Expiration Date: 31 May 2006</p> <hr/> <p>5. Reference Number: 155-1,3</p>
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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identified in §175.103(d) (1)(i), NYC Health Code	(A) Any radiopharmaceutical or radiobiologic with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA	(A) As necessary for uses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in §175.103(d) (1)(ii), NYC Health Code	(B) Any radiopharmaceutical or radiobiologic with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA (GENERAL PURPOSES, AEROSOLS AND GASES ONLY AS LISTED)	(B) As necessary for uses authorized in Subitem 9(B)

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6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess 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) Technetium-99m	(D) DTPA Aerosol with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(D) 7.4 Gigabecquerels
(E) Xenon-133	(E) Gas or Ventilation Study System with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(E) 18.5 Gigabecquerels
(F) Cobalt-57	(F) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(F) 5 Sources not to exceed 925 Megabecquerels per source
(G) Cobalt-57	(G) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(G) 5 Sources not to exceed 740 Megabecquerels per source
(H) Barium-133	(H) Sealed Sources with an active (i.e. not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(H) 5 Sources not to exceed 18.5 Megabecquerels per source
(I) Cesium-137	(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 18.5 Megabecquerels per source

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6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(J) Technetium-99m	(J) Pertechnetate	(J) Individual amounts not to exceed 1.85 Gigabecquerels
(K) Iodine-125	(K) Sealed Source Seeds (Medi-Physics, Model Nos. 6702, 6711, 6720, North American Scientific, Inc., Model No. MED 3631)	(K) 37 Gigabecquerels
(L) Palladium-103	(L) Sealed Sources (Theragenics Corp., Model #200) North American Scientific, Inc., Model No. MED 3633)	(L) 37 Gigabecquerels
(M) Iodine-131	(M) Sodium Iodide Capsules with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA *****	(M) 1.07 Gigabecquerels per capsule

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.

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- (C) Any radiopharmaceutical or radiobiologic therapy procedure authorized by application.
- (D) Pulmonary function studies administered using either a Mallinckrodt Sunaco, Inc., ~~System, Inc.~~, a Biodex Venti-Scan II, or a Medi-Nuclear Corporation Aero-Vent aerosol delivery system.
- (E) Inhalation studies in the evaluation of pulmonary function, study of pulmonary ~~ventilation~~ imaging the lungs or the assessment of cerebral blood flow.
- (F) Flood calibration sources (Non-Human Use).
- (G) through (I) Calibration sources (Non-Human Use).
- (J) Calibration check and reference material (Non-Human Use).
- (K) As a sealed source for the interstitial treatment of prostrate cancer as a permanent ~~implant~~.
- (L) As sealed source for the interstitial treatment of prostrate cancer as a permanent ~~implant~~.
- (M) Treatment of hyperthyroidism.

10. The radioactive material may be used and stored only at Parkway Hospital, 70-35 113th ~~Street~~, New York 11375.

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

Failure to pay the fee for inspection of a radioactive material site, upon notification from ~~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~~ individual(s) for the materials and uses indicated:

Authorized User

Materials and Use

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Warren Freitag, M.D.
Spyros Hatzinadis, M.D.
Roberto Lipstein, M.D.
Richard Pollack, M.D.
Michael Tarrell, M.D.

Subitems 6(A), 6(B), 6(D) through ~~6(F)~~
Subitems 6(A), 6(B), 6(D) through ~~6(F)~~
Subitems 6(K) and 6(L)
Subitems 6(A) through 6(J), and ~~6(K)~~
Subitems 6(A) through 6(J), and ~~6(K)~~

14. The radiation safety officer for this license is Michael ~~Tarrell~~, M.D.

15. The ~~therapy~~ ~~responsible~~ for this license is Thomas ~~R.A.B.R.~~

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16. 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.

(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 unriated 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 information for patient release, patient's dose rate measurements including the specific survey instrument used and the name of the individual performing the survey.

17. Any radioactive material or radioactive waste shall be used in accordance with Title 21, Part 21.1 of the Code of Federal Regulations.

18. Technetium-99m labeled sulfur colloid preparations with a particle size greater than 1000 nm shall not be used in humans.

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21. 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 12 March 1996
- (B) Letter dated 22 April 1996
- (C) Letter dated 3 September 1996
- (D) Letter dated 27 September 1996
- (E) Letter dated 2 October 1996
- (F) Letter dated 5 February 1997
- (G) Letter dated 12 June 1997
- (H) Letter dated 4 August 1997
- (I) Letter dated 10 August 1997
- (J) Letter dated 15 September 1997
- (K) Letter with attachments dated 28 October 1999
- (L) Letter with attachments dated 6 December 1999
- (M) Letter with attachments dated 6 February 2000
- (N) Letter dated 28 February 2000
- (O) Letter dated 3 October 2000
- (P) Letter dated 14 March 2001
- (Q) Letter with attachments dated 9 April 2001

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