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JK MEDICAL CENTER

24-12611-01
03002555

RADIATION ONCOLOGY
732-321-7167
732-906-4915 FAX

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

136783
NMSS/RGNI MATERIALS-002

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

1.	Name:	Parkway Hospital	3a. License Number:	91-2932-01
			3b. Amendment Number:	8
2.	Address:	70-35 113th Street Queens, New York 11375	4. Expiration Date:	31 May 2006
			5. Reference Number:	155-1,3

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in §175.103(d) (1)(i), NYC Health Code	(A)	Any radiopharmaceutical or radiobiologic with an active(*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA;	(A)	As necessary for uses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in §175.103(d)(1)(ii), NYC Health Code	(B)	Any radiopharmaceutical or radiobiologic with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an application accepted by FDA (GELS, POWDERS, AEROSOLS AND LIQUIDS ONLY AS LISTED	(B)	As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 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)	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.* [illegible] withdrawn or terminated) [illegible] Evaluation of Device" [illegible] in NRC "Registry of [illegible] Sealed Sources and [illegible]	(H)	5 Sources not to exceed 18.5 Megabecquerels per source
(I)	Cesium-137	(I)	[illegible] with an active (i.e. [illegible] drawn or terminated) [illegible] Evaluation of Device" [illegible] in NRC "Registry of [illegible] Sealed Sources and [illegible]	(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 posses 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 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 St, 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 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
Warren Freitag, M.D.	Subitems 6(A), 6(B), 6(D) through [illegible]
Spyros Hiniadis, M.D.	Subitems 6(A), 6(B), 6(D) through [illegible]
Roberto Lipsztein, M.D.	Subitems 6(K) and 6(L)
Howard Pollack, M.D.	Subitems 6(A) through 6(J), and [illegible]
Michael Tarbell, M.D.	Subitems 6(A) through 6(J), and [illegible]

14. The radiation safety officer for the license is Michael [illegible], M.D.

15. The therapy [illegible] under this license is [illegible] R.A.B.R.S.

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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 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 dosimetric measurements including the specific survey instrument used and the name of the individual performing the survey.

17. Any [illegible] used in accordance with Title 21, Part [illegible] Code of Federal [illegible]

18. Tec[illegible] labeled sulfur colloid preparations [illegible] shall not be used in humans.

[illegible]

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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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