

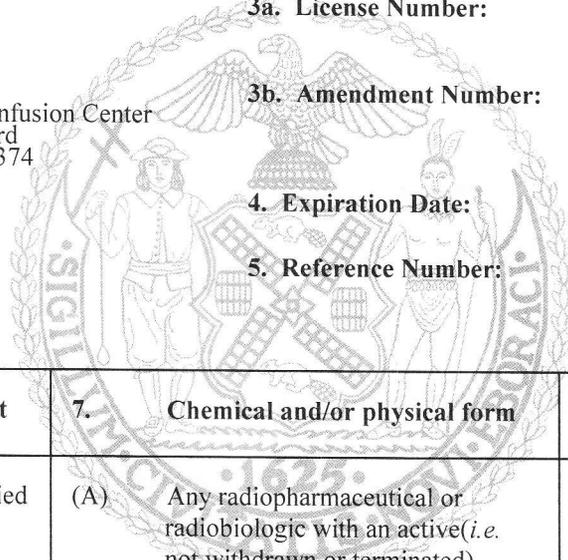
## CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

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 3 April 2011 from Kent Friedman, M.D. ; License number 91-3381-01 is amended to change Item 3b, Condition 13, 18, to add Item 6 (J), Condition 9 (J) , and to read:

### LICENSEE

<b>1. Name:</b>	Kent Friedman, M.D.	<b>3a. License Number:</b>	91-3381-01
<b>2. Address:</b>	NYU Hospitals Center Columbus Imaging & Infusion Center 97-77 Queens Boulevard Queens, New York 11374	<b>3b. Amendment Number:</b>	3
		<b>4. Expiration Date:</b>	30 April 2013
		<b>5. Reference Number:</b>	



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>i.e.</i> not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA.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>i.e.</i> not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA (EXCEPT GENERATORS, AEROSOLS AND GASES) *****	(B) As necessary for uses authorized in Subitem 9(B)

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

**License Number:** 91-3381-01

**Amendment Number:** 3

**Reference Number:**

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(C) Cobalt-57	(C) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(C) 1 Source not to exceed 925 Megabecquerels
(D) Cobalt-57	(D) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(D) 1 Source not to exceed 740 Megabecquerels
(E) Barium-133	(E) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(E) 1 Source not to exceed 18.5 Megabecquerels
(F) Cesium-137	(F) Sealed Sources with an active ( <i>i.e.</i> not withdrawn or terminated) "Safety Evaluation of Device" published in NRC "Registry of Radioactive Sealed Sources and Devices"	(F) 1 Source not to exceed 18.5 Megabecquerels
(G) Technetium-99m	(G) Pertechnetate	(G) Individual amounts not to exceed 1.85 Gigabecquerels
(H) Fluorine-18	(H) Fluorodeoxyglucose Injection	(H) 37 Gigabecquerels
(I) Ge/Ga-68	(I) Cylinder Sealed Source (CTI Service, Model CS)	(I) 56 Megabecquerels
(J) Ge/Ga-68	(J) Line Sealed Sources (CTI Services, Model LS)	(J) 92.5 Megabecquerels total
(K) Indium - 111 / Yttrium-90	(K) IDEC Zevalin (Ibritumomab Tiuxetan) *****	(K) 3.7 Gigabecquerels

**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

**License Number:** 91-3381-01

**Amendment Number:** 3

**Reference Number:**

**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) Flood calibration sources (Non-Human Use).
- (D) through (F) Calibration sources (Non-Human Use).
- (G) Calibration check and reference material (Non-Human Use).
- (H) As listed under a "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA.
- (I) Instrument calibration and transmission determination.
- (J) Instrument calibration and transmission determination.
- (K) Preparation as described in Package Insert for ZEVALIN (#595398)

**10.** The radioactive material may be used only at the office of Kent Friedman, M.D., NYU Hospitals Center Columbus Imaging & Infusion Center, 97-77 Queens Boulevard, Queens, New York 11374.

**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 only by the following individuals for the materials and uses indicated:

Authorized User

Materials and Use

Gary Golduber, M.D.	Subitems 6 (A) through 6 (J)
Ponzo Fabia, M.D.	Subitems 6 (A) through 6 (J)
Kent Friedman, M.D.	All
Karen Mourtzikos, M.D.	Subitems 6 (A) through 6 (J)
Joseph Sanger, M.D.	Subitems 6 (A) through 6 (J)
Alexandra Seltzer, M.D.	Subitems 6 (A) through 6 (J)
Serafin Tiu, M.D.	Subitems 6 (A) through 6 (J)

**14.** The radiation safety officer for this license is Kent Friedman, M.D..

\*\*\*\*\*

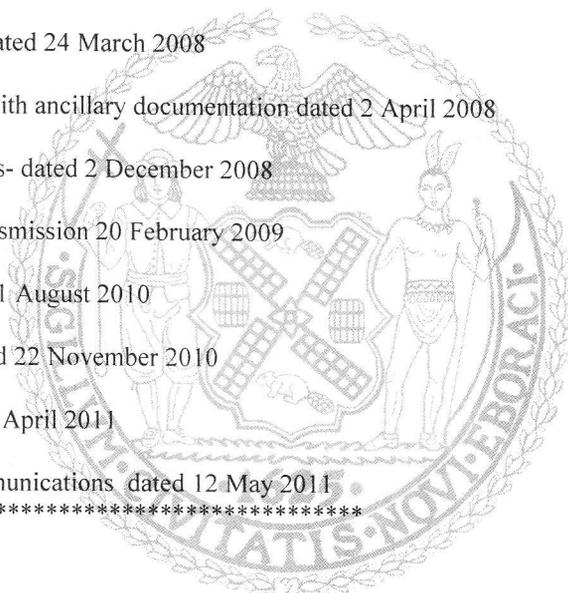
**CITY OF NEW YORK  
RADIOACTIVE MATERIALS  
LICENSE**

**License Number:** 91-3381-01

**Amendment Number:** 3

**Reference Number:**

15. Radioactive material as a sealed source shall not be opened by the licensee.
16. Technetium-99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.
17. 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.
18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations and procedures contained in the documents including any enclosures listed below. Article 175 of the New York City Health Code shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- (A) Letter dated 21 March 2008
- (B) Application dated 24 March 2008
- (C) Letter dated with ancillary documentation dated 2 April 2008
- (D) Two (2) letters- dated 2 December 2008
- (E) Facsimile transmission 20 February 2009
- (F) Letter dated 11 August 2010
- (G) Letter received 22 November 2010
- (H) Letter dated 3 April 2011
- (I) Two (2) communications dated 12 May 2011
- \*\*\*\*\*



**FOR THE NEW YORK CITY DEPARTMENT  
OF HEALTH AND MENTAL HYGIENE**

Date:

10 June 2011

DPH/rm

Daniel P. Hayes

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