



Hospital of Saint Raphael

A member of the Saint Raphael Healthcare System

1450 Chapel Street
New Haven, Connecticut 06511
(203) 789-3000

July 24, 2006

Br. 1

Licensing Assistance Section
Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

License Amendment Request
License No. 06-00200-03

03001238

Gentlemen:

The Hospital of Saint Raphael in New Haven, Connecticut requests an amendment to its current license to authorize Johnathan A. Haas, M.D., as an Authorized User for the following:

Material and Use: 35.300; 35.400; Iridium-192 for use in a High Dose Rate Remote Afterloader Unit

Dr. Haas has joined the Medical Staff of the Hospital of Saint Raphael as an attending Radiation Oncologist in the Radiation Therapy Department. Dr. Haas was Board-Certified by the American Board of Radiology in Radiation Oncology in 1998. His State of Connecticut License Number is 044390. He is currently on the Medical Staff at Winthrop University Hospital and is named as an Authorized User on their New York State Department of Health Radioactive Materials License #22-2 (a copy of this license is attached). Review of this license shows that Dr. Haas is currently approved for :

- 1) Any therapeutic procedure described in 10 NYCRR 16.123 (b) (4) , which states:
 - (4) Use of sources for radiation therapy by surface, intracavitary or interstitial application (brachytherapy).
 - (i) A licensee shall use the following sources in accordance with the manufacturer's radiation safety, handling and maintenance instructions:
 - (a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
 - (b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.;
 - (c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
 - (d) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;
 - (e) Iridium-192 as seeds encased in nylon ribbons for interstitial treatment of cancer;
 - (f) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and
 - (g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.

2006 JUL 31 PM 1:01
RECEIVED
REGION I

139210
NMSS/RGNI MATERIALS-002

(2)

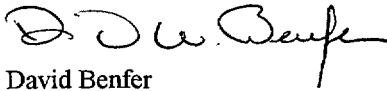
2) For treatment of superficial eye conditions

3) One source to be used in a Varian Varisource high dose rate remote afterloader unit for the treatment of humans.
One source in it's shipping container to be in possession of the licensee as necessary for the replacement of the source in the remote afterloader unit only.

The Hospital is also requesting that Robert Sinha , MD, be removed from the license effective July 21, 2006. Dr. Sinha will be joining a practice in California.

The Hospital also requests that David Choi, Ph.D. be removed from the license effective August 7, 2006. Dr. Choi has accepted a position in California.

Sincerely,



David Benfer
President and Chief Executive Officer
Hospital of Saint Raphael

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

License Number 22-2

Amendment Number 94

DH Number 05-053

Winthrop University Hospital
Department of Medical Physics
259 First Street
Mineola, New York 11501

Attention: David Gregorius, M.S.
Radiation Safety Officer

Dear Licensee:

In accordance with the request dated January 17, 2005, signed by Daniel Walsh and David Gregorius, M.S., New York State Department of Health Radioactive Materials License No. 22-2 is amended as follows:

RECEIVED
REGION 1
2005 JUL 31 PM 1:00

Change Condition Nos. 6 through 8 to Read:

- | | | | | | |
|----|--|----|---|----|---|
| 6. | Radioactive Materials
(element & mass no.) | 7. | Chemical and/or
Physical Form | 8. | Maximum quantity
licensee may possess
at one time |
| A. | Any radioactive material
as described in
10 NYCRR 16.123(b)(1),
except alpha or positron
emitting isotopes | A. | Any radiopharmaceutical
as described in
10 NYCRR 16.123(b)(1) | A. | As necessary for uses
in Subitem 9A |
| B. | Any radioactive material
as described in
10 NYCRR 16.123(b)(2),
except alpha or positron
emitting isotopes | B. | Any radiopharmaceutical
or reagent kit as
described in
10 NYCRR 16.123(b)(2) | B. | As necessary for uses
in Subitem 9B |

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 22-2
Amendment No. 94

6.	Radioactive Materials (element & mass no.)	7.	Chemical and/or Physical Form	8.	Maximum quantity licensee may possess at one time
C.	Any radioactive material as described in 10 NYCRR 16.123(b)(3), except alpha or positron emitting isotopes	C.	Any radiopharmaceutical as described in 10 NYCRR 16.123(b)(3) Iodine 131 restricted to capsule form only	C.	As necessary for uses in Subitem 9C
D.	Any radioactive material listed in 10 NYCRR 16.123(b)(4)	D.	Any radioactive source listed in 10 NYCRR 16.123(b)(4)	D.	1.2 curies total for all radioactive material authorized in Subitem 6D
E.	Cobalt 57	E.	Sealed source	E.	30 millicuries per source
F.	Molybdenum 99/ Technetium 99m	F.	Generator	F.	4 curies
G.	Technetium 99m	G.	Diethylenetriamine- pentaacetic acid (DTPA)	G.	200 millicuries
H.	Xenon 133	H.	Gas	H.	500 millicuries
I.	Technetium 99m	I.	Any	I.	1 curie
J.	Thallium 201	J.	Thallos chloride	J.	50 millicuries
K.	Hydrogen 3	K.	Any, except gas	K.	25 millicuries
L.	Carbon 14	L.	Any	L.	5 millicuries
M.	Phosphorus 32	M.	Any	M.	50 millicuries
N.	Phosphorus 33	N.	Any	N.	25 millicuries

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 22-2
Amendment No. 94

6.	Radioactive Materials (element & mass no.)	7.	Chemical and/or Physical Form	8.	Maximum quantity licensee may possess at one time
O.	Sulfur 35	O.	Any	O.	25 millicuries
P.	Calcium 45	P.	Calcium chloride	P.	1 millicurie
Q.	Calcium 45	Q.	Calcium chloride	Q.	1 millicurie
R.	Calcium 47	R.	Calcium chloride	R.	100 microcuries
S.	Calcium 47	S.	Any	S.	1 millicurie
T.	Chromium 51	T.	Any	T.	10 millicuries
U.	Rubidium 86	U.	Any	U.	2 millicuries
V.	Technetium 99m	V.	Diethylenetriamine- pentaacetic acid (DTPA)	V.	10 millicuries
W.	Iodine 125	W.	Any	W.	25 millicuries
X.	Cesium 137	X.	Sealed source (J.L. Shepherd Series 10 Portable Beam Calibrator Model 10A-1)	X.	50 millicuries
Y.	Depleted Uranium	Y.	Metal alloy	Y.	250 pounds
Z.	Strontium 90	Z.	Sealed source (ARC Model B-1)	Z.	50 millicuries
AA.	Germanium 68	AA.	Sealed sources (CTI Services, Inc., Models CS and LS)	AA.	28 millicuries (not to exceed 4.06 millicuries per source)
BB.	Fluorine 18	BB.	Fluorodeoxyglucose (FDG)	BB.	As necessary for uses in Subitem 9BB

**NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE**

CONDITIONS

License No. 22-2
Amendment No. 94

6.	Radioactive Materials (element & mass no.)	7.	Chemical and/or Physical Form	8.	Maximum quantity licensee may possess at one time
CC.	Technetium 99m	CC.	Sulfur Colloid	CC.	6 millicuries
DD.	Reserved	DD.	Reserved	DD.	Reserved
EE.	Iodine 131	EE.	Tositumomab (Bexxar)	EE.	500 millicuries
FF.	Iridium 192	FF.	Sealed source (Omnitron Model No. SL-777V or Varian Medical Systems, Inc., Model No. VS2000)	FF.	19.5 curies total. Two sources, not to exceed 11 curies per installed source, and 12 curies per source in its shipping container.

Change Condition No. 9 to Read:

9. Authorized use (unless otherwise described, the authorized place of use is the licensee's address stated in Item 2, above).
- A. and F. Any diagnostic procedure involving measurement of uptake, dilution, or excretion, as described in 10 NYCRR 16.123 (b) (1).
- B. and F. Any diagnostic procedure involving imaging and localization studies, as described in 10 NYCRR 16.123 (b) (2).
- C. Any therapeutic procedure described in 10 NYCRR 16.123 (b) (3).
- D. Any therapeutic procedure described in 10 NYCRR 16.123 (b) (4).
- E. Calibration/reference source.
- F. and G. Evaluation of pulmonary ventilation.
- H. Evaluation of pulmonary function, blood pool, and/or cerebral blood flow studies.

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

License No. 22-2
Amendment No. 94

9. I. and J. For determination of cardiac function.
- K. through P., S. through W., and CC. For in vitro and/or non-human in vivo research.
- Q. and R. To be used for calcium absorption studies by dual isotope technique and utilizing neutron activation analysis.
- X. To perform survey meter calibrations.
- Y. For use as shielding for a Varian Clinac 600c linear accelerator.
- Z. For treatment of superficial eye conditions.
- AA. For attenuation correction in a CTI ECAT EXACT PET system.
- BB. Any diagnostic procedure as its described in 10 NYCRR 16.123 (b) (1) and (2). The licensee shall limit is use of fluorine-18 FDG to administration of no more than 400 millicuries per week for diagnostic studies. Records indicating the number of PET scans performed per week, including activity injected per patient, must be maintained for inspection by the Department.
- DD. Reserved.
- EE. For treatment of non-Hodgkin's lymphoma.
- FF. One source to be used in a Varian Varisource high dose rate remote afterloader unit for the treatment of humans. One source in its shipping container to be in possession of the licensee as necessary for the replacement of the source in the remote afterloader unit only.

Change Condition No. 10 to Read:

10. A. Radioactive material listed in Item 6 shall be used by, or under the tutelage of the following individuals, with the specified limitations:
- | | |
|---------------------------------|---|
| John F. Aloia, M.D. | Iodine-131 for the treatment of hyperthyroidism |
| Joseph E. Gardella, M.D., Ph.D. | Subitems I and J |
| Jonathan A. Haas, M.D. | Subitems D, Z and FF |

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

License No. 22-2
Amendment No. 94

10. A. (Continued)

Gerald A. Irwin, M.D.	Subitems A through J, and EE
Alan J. Katz, M.D.	Subitems D and Z
Todd C. Kerwin, M.D.	Subitems I and J
Betty Motroni, M.D.	Subitems A, B, C, E through J, AA, BB, and EE
Wei Wen Sung, M.D.	Subitems A, B, C, E through J, AA, BB, and EE
Elizabeth Ying-Kou Yung, M.D.	Subitems A, B, C, E through J, AA, BB, and EE

B. Radioactive material listed in Item 6 shall be used by, or under the supervision of the following individuals, with the specified limitations:

John F. Aloia, M.D.	Subitems K through W
Gerald A. Irwin, M.D.	Subitems N, P, S, T, and V
Jeffrey A. Kazzaz, Ph.D.	Subitems K through W
Louis Ragolia, Ph.D.	Subitems K through W, and CC

C. Radioactive material listed in Item 6 shall be used by David R. Gregorius, M.S., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.

D. The Radiation Therapy Physicists for this license are James Avanzanto, M.S. and Raymond Bcers, M.S.

Change Condition No. 11 to Read:

11. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license, in accordance with statements, representations, and procedures contained in the documents (including any enclosures) listed below:

A. Letter dated March 20, 2001, signed by David Gregorius, M.S., and Daniel P. Walsh.

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

License No. 22-2
Amendment No. 94

11. B. Application for New York State Department of Health Radioactive Materials License dated May 8, 2001, signed by Daniel P. Walsh.
- C. Letter dated June 14, 2001, signed by David Gregorius, M.S.
- D. Letter dated August 19, 2001, signed by David Gregorius, M.S.
- E. Letter dated February 13, 2002, signed by David Gregorius, M.S., and Daniel P. Walsh.
- F. Letter dated June 21, 2002, signed by Barbara Kohart and David Gregorius, M.S.
- G. Letter dated October 24, 2002, signed by David Gregorius, M.S., and Daniel P. Walsh.
- H. Letter dated July 22, 2003, signed by David Gregorius, M.S., and Daniel P. Walsh.
- I. Letter dated May 26, 2004, signed by David Gregorius, M.S.
- J. Letter received January 26, 2005, signed by David Gregorius, M.S. and Daniel Walsh.

The New York State Department of Health's regulations shall govern the licensee's statements in applications or letters unless the statements are more restrictive than the regulations.

Change Condition No. 51 to Read:

51. The licensee shall not use the high dose rate remote control brachytherapy unit if the source has exceeded its useful life of 1000 wire extensions or as listed in the Sealed Source and Device Registry, whichever is less. The licensee shall document each wire extension to ensure that the 1000 wire extension limit is not exceeded.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: **MAR 10 2005**
RD/AD

By Robert E. Dansereau
Robert E. Dansereau, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

cc: Daniel P. Walsh, President/CEO

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

7/24/2004, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 06-00200-03 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.

Please provide to this office within 30 days of your receipt of this card

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** 139210.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.