



WAYNE MEMORIAL
HOSPITAL

NMSB 1

March 20, 2006

03013285

RE: Amendment to NRC License Number: 37-17755-01

U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pa. 19406

2006 MAR 23 AM 10:33

RECEIVED
REGION I

2006 MAR 23 AM 10:33

Dear Sir or Madam:


We would like to amend our Materials License to reflect the following change:

- Add the following Authorized User to our NRC license

	Individual	Previous experience, license number, etc.	Requested Uses
Authorized User	Nicholas F. Sapienza, M.D.	New York State Department of Health Radioactive Materials License No.: 3049 (July 9, 2004)	35.100, 35.200
We have enclosed a copy of NYS Dept. of Health Radioactive Materials License No. 3049 for your review.			

If you require any additional information concerning this amendment request, please contact our consultant physicists, Sam Payne (570) 477-3925 or Doug Heim (570) 473-1726.

Sincerely,


David L. Hoff, CEO

138623

NMCS/RGN MATERIALS-032

601 PARK STREET, HONESDALE, PA 18431 570 253-8100 FAX 570 253-7312



STATE OF NEW YORK
DEPARTMENT OF HEALTH

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

The Hospital
43 Pearl Street West
Sidney, New York 13838

JUL - 9 2004

Attention: Nicholas F. Sapienza, M.D.
Radiation Safety Officer

Re: NYS Dept. of Health Radioactive
Materials License No. 3049
DH No. 04-097

RECEIVED
JUL 14 2004

Dear Dr. Sapienza:

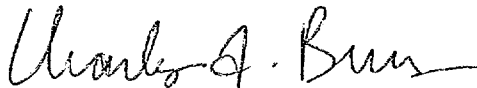
Enclosed is Amendment No. 8 to New York State Department of Health Radioactive Materials License No. 3049, which names you as Radiation Safety Officer and an authorized user for diagnostic nuclear medicine. Also, Drs. McChesney, Sacks and Wagner have been removed from the list of authorized users.

As Radiation Safety Officer, you should become familiar with Part 16 of the New York State Sanitary Code (copy enclosed) and with the conditions of the license, including documents incorporated by reference in Condition No. 11.

If I may be of assistance, please contact this office at (518) 402-7590 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
Flanigan Square – Room 530
547 River Street
Troy, New York 12180-2216

Sincerely,


Charles J. Burns
Associate Radiological Health Specialist

RD/CJB:crs

Enclosure: Amendment No. 8
Part 16

cc: George Innes, M.D., CEO

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

License Number 3049

Amendment Number 8

DH Number 04-097

The Hospital
43 Pearl Street West
Sidney, New York 13838

Attention: Nicholas F. Sapienza, M.D.
Radiation Safety Officer

Dear Licensee:

In accordance with the request dated March 11, 2004, signed by George Innes, M.D., and Christine C. Kennedy, New York State Department of Health Radioactive Materials License No. 3049 is amended as follows:

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:
- | | |
|---------------------------|------------------|
| Nicolas F. Sapienza, M.D. | All subitems |
| James J. Vincens, M.D. | Subitems D and E |
- B. Radioactive material listed in Item 6 shall be used by Nicolas F. Sapienza, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: **JUL - 9 2004**
RD/CJB:crs

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

cc: George Innes, M.D., CEO

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

License Number 3049

Amendment Number 4

DH Number 01-504

The Hospital
43 Pearl Street West
Sidney, New York 13838

Attention: Lawrence J. Rosenblum, M.D.
Radiation Safety Officer

Dear Licensee:

In accordance with the request dated October 19, 2001, signed by Russell Test and Lawrence Rosenblum, M.D., New York State Department of Health Radioactive Materials License No. 3049 is amended as follows:

Change Condition No. 6, 7 and 8 to Read:

6. Radioactive Materials (element & mass no.)	7. Chemical and/or Physical Form	8. Maximum quantity licensee may
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) (Restricted from molybdenum 99/ technetium 99m generators)	B. As necessary for uses in Subitem 9B
C. Technetium 99m	C. Diethylenetriamine- pentaacetic acid (DTPA)	C. 100 millicuries
D. Technetium 99m	D. Any	D. 400 millicuries
E. Thallium 201	E. Thallous Chloride	E. 50 millicuries

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

License No. 3049
Amendment No. 4

Change Condition No. 9 to Read:

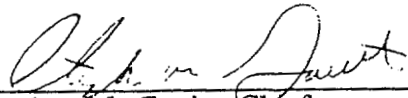
9. Authorized use (unless otherwise described, the authorized place of use is the licensee's address stated in Item 2, above).
- A. Any diagnostic procedure involving measurement of uptake, dilution, or excretion, as described in 10 NYCRR 16.123 (b) (1).
 - B. Any diagnostic procedure involving imaging and localization studies, as described in 10 NYCRR 16.123 (b) (2).
 - C. Evaluation of pulmonary ventilation.
 - E. and D. Determination of cardiac function.

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:
- | | |
|-----------------------------|---------------------|
| Lawrence J. Rosenblum, M.D. | Subitems A, B and C |
| James J. Vincens, M.D. | Subitems E and D |
- B. Radioactive material listed in Item 6 shall be used by Lawrence J. Rosenblum, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: NOV - 5 2001
SG/OAO:cer

By 
Stephen M. Gavitt, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

cc: Russell Test, Chief Executive Officer

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

License Number 3049

Amendment Number 3

DH Number 99-198

The Hospital
43 Pearl Street West
Sidney, New York 13838

Attention: Lawrence J. Rosenblum, M.D.
Radiation Safety Officer

Dear Licensee:

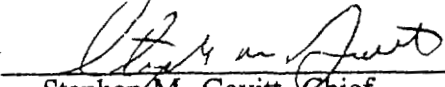
In accordance with the request dated May 13, 1999, signed by Russell Test, New York State Department of Health Radioactive Materials License No. 3049 is amended as follows:

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:
- Janet Cummings Martin, M.D.
- Lawrence J. Rosenblum, M.D.
- B. Radioactive material listed in Item 6 shall be used by, Lawrence J. Rosenblum, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: JUN 15 1999
SG/RD:

By 
Stephen M. Gavitt, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection

cc: Administrator

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

Amendment No. 2

Pursuant to the Public Health Law and Part 16 of the New York State Sanitary Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The 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.

-
- | | |
|--------------------------------|------------------------------------------------|
| 1. Name | 3. License Number 3049 |
| The Hospital | is amended in its entirety to read as follows: |
| 2. Address | 4. a. Effective Date |
| 43 Pearl Street West | <u>March 18, 1999</u> |
| Sidney, New York 13838 | b. Expiration Date |
| Attention: Jamil Sarfraz, M.D. | <u>March 31, 2009</u> |
| Radiation Safety Officer | |
| | 5. Reference Number |
| | DH No. 98-329 |
-
- | | | |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|
| 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)
(Restricted from molybdenum
99/ technetium 99m
generators) | B. As necessary for
uses in Subitem 9B |

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

License No. 3049
Amendment No. 2

- | | | | | | |
|----|-----------------------------------------------|----|------------------------------------------------|----|---------------------------------------------------------|
| 6. | Radioactive Materials
(element & mass no.) | 7. | Chemical and/or
Physical Form | 8. | Maximum quantity
licensee may
possess at one time |
| C. | Technetium 99m | C. | Diethylenetriamine-
pentaacetic acid (DTPA) | C. | 100 millicuries |
9. Authorized use (unless otherwise described, the authorized place of use is the licensee's address stated in Item 2, above).
- A. Any diagnostic procedure involving measurement of uptake, dilution, or excretion, as described in 10 NYCRR 16.123 (b) (1).
 - B. Any diagnostic procedure involving imaging and localization studies, as described in 10 NYCRR 16.123 (b) (2).
 - C. Evaluation of pulmonary ventilation.
10. A. Radioactive material listed in Item 6 shall be used by, or under the tutelage of the following individuals:
- Lewis Dosik, M.D.
 - Jamil Sarfraz, M.D.
 - Merrill Thallinger, M.D.
 - Guy Tufau, M.D.
- B. Radioactive material listed in Item 6 shall be used by Jamil Sarfraz, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.
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. Application for New York State Department of Health Radioactive Materials License dated January 13, 1993, signed by Gregg Voss.

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

License No. 3049
Amendment No. 2

11. B. Letter dated March 2, 1993, signed by Jamil Sarfraz, M.D.
- C. Letter dated March 16, 1993, signed by Jamil Sarfraz, M.D.
- D. Letter dated March 26, 1993, signed by Jamil Sarfraz, M.D.
- E. Letter dated April 28, 1994, signed by Tom Graham, CEO.
- F. Letter dated July 29, 1994, signed by Jamil Sarfraz, M.D.
- G. Application for renewal of NYSDOH Radioactive Materials License No. 3049 dated April 29, 1998, signed by Jamil Sarfraz, M.D. and Russell Test, CEO.
- H. Letter dated September 1, 1998, signed by Jamil Sarfraz, M.D. and Russell Test, CEO.

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.

12. A. Radioactive material shall be stored in a locked facility in the original shipping container, or a container providing equivalent radiation protection. Such a facility may be a cabinet, a safe, or a room, providing the facility is locked at all times when no activities are in progress relating to the use of the radioactive material. This includes periods of brief absence of personnel from a nuclear medicine department, laboratory, etc., where radioactive materials are used or stored.
 - B. Radioactive materials shall not be stored in the same facilities with materials which might substantially increase the fire or explosion hazard of the storage space and its radioactive contents.
13. A. Transportation of licensed radioactive material shall be subject to all regulations of the U.S. Department of Transportation and other agencies of the United States having jurisdiction insofar as such regulations relate to the packaging of radioactive material, marking and labeling of the packages, loading and storage of packages, monitoring requirements, accident reporting, and shipping papers.
 - B. Transportation of low level radioactive waste shall be in accordance with the regulations of the New York State Department of Environmental Conservation as contained in 6 NYCRR Part 381.

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

License No. 3049
Amendment No. 2

14. All use of radioactive materials at this institution shall be coordinated with and approved by the Radiation Safety Committee of The Hospital.
15. The licensee shall have available an appropriate survey meter which shall be maintained operational and shall be calibrated before initial use and at subsequent intervals not exceeding twelve months by a person specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. Records of all calibrations shall be kept a minimum of five years.
16. For a period not to exceed sixty days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:
 - A. Has the prior written permission of the hospital's administrator and its Radiation Safety Committee;
 - B. Is specifically named as a user on a U.S. Nuclear Regulatory Commission or Agreement State license authorizing human use; and
 - C. Performs only those procedures for which he is specifically authorized by a U.S. Nuclear Regulatory Commission or Agreement State license.

The licensee shall maintain for inspection by the Department, copies of the written permission specified in subitem A above and of the license(s) specified in subitems B and C above. These records shall be maintained for five years from the time the licensee grants its permission under subitem A above.

17. Radioactive gases as free gas or in solution, 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.
18. The licensee shall not administer technetium-99m to patients if the technetium-99m contains more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

CONDITIONS

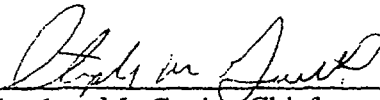
License No. 3049
Amendment No. 2

23. Plans of facilities which the licensee intends to dedicate to operations involving the use of radioactive material shall be submitted to the Department for review and approval prior to any such use.
24. The licensee shall maintain records of information important to safe and effective decommissioning at The Hospital, 43 Pearl Street West, Sidney, New York, and at other locations as the licensee chooses. The records shall be maintained until this license is terminated by the Department and shall include:
- A. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site;
 - B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and locations of possible inaccessible contamination such as buried pipes which may be subject to contamination;
 - C. Records of the cost estimate performed for the decommissioning funding plan or the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.
25. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator, provided it follows the procedures in the Calcorp, Inc. manual dated March 2, 1982.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: MAR 18 1999
SG/MV:ks

By


Stephen M. Gavitt, Chief

Radioactive Materials Section

Bureau of Environmental Radiation Protection

cc: Russell Test, CEO

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

3/20/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Approved. 37-17755-d 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** 138623.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.