



ST MARY'S
MEDICAL CENTER

PUBLIC
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PDR

030-02031

830 SOUTH JEFFERSON AVENUE
SAGINAW, MICHIGAN 48601
(517) 776-8000

January 27, 1997

B. J. Holt, Chief
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Ms. Holt,

Letter of notification, License No. 21-03646-03, to reflect the following change.

1. Authorized Users

Please add Michael Cappelli, M.D. to the license. He will be joining the St. Mary's staff under License No. 21-03646-03. He was an Authorized User on City of New York Radioactive Materials License 91-2897-01. Please see the copy of the New York Radioactive Materials licence which lists Michael Cappelli, M.D. as an authorized user. He is to be authorized to use any byproduct material identified in 10 CFR 35.300 and 35.400.

Please remove Roberto Cordoba, M.D. from License No. 2103646-03.

If you have any questions please contact me at (517)776-8073. Thank you for your attention in this matter.

Sincerely,

Terrence J. Dillon

Terrence J. Dillon, M.S.
Radiation Safety Officer

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Member of DAUGHTERS OF CHARITY NATIONAL HEALTH SYSTEM

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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 5 February 1996 from Peter Kelly, Chief Operating Officer, Beth Israel Medical Center, License number 91-2897-01 is hereby amended to read:

LICENSEE

	3a. License Number:	91-2897-01
1. Name:	3b. Amendment Number:	9
	4. Expiration Date:	30 November 1998
2. Address:	5. Reference Number:	602-Series and 611-Series
First Avenue at 16th Street New York, New York 10003		

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(e)(1)(i), 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 (GENERATORS, AEROSOLS AND GASES ONLY AS LISTED BELOW)	(B) As necessary for uses authorized in Subitem 9(B)

**CITY OF NEW YORK
RADIOACTIVE MATERIALS
LICENSE**

License Number:

-2897-01

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Amendment Number:

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Reference Number:

602-Series and 611-Series

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) Any radioactive material identified in §175.103(h)(1), NYC Health Code	(D) Any brachytherapy source identified in §175.103(h)(1), NYC Health Code	(D) 945 Gigabecquerels
(E) Hydrogen-3	(E) Any	(E) 4 Gigabecquerels
(F) Carbon -14	(F) Any	(F) 4 Gigabecquerels
(G) Phosphorus-32	(G) Any	(G) 4 Gigabecquerels
(H) Cobalt-57	(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) 10 Sources, not to exceed 925 Megabecquerels per source
(I) Cobalt-57	(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) 10 Sources, not to exceed 740 Megabecquerels per source
(J) Cobalt-57	(J) Any	(J) 4 Gigabecquerels
(K) Germanium-68/ Gallium-68	(K) Generator (DuPont-Merck Model # IGG-099)	(K) 2 Gigabecquerels
(L) Germanium-68	(L) Photon Line Source (DuPont-Merck, Model #NER 8410) *****	(L) 148 Megabecquerels

CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number:

91-2897-01

Amendment Number:

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Reference Number:

602-Series and 611-Series

6. Radioactive materials (element number)	7. Chemical and/or physical form	8. Maximum quantity licensee may possess at any one time
(GG) Cesium-137	(GG) 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"	(GG) 10 Sources, not to exceed 18.5 Megabecquerels per source
(HH) Rhenium-186	(HH) Any	(HH) 4 Gigabecquerels
(II) Iridium-192	(II) Sealed Source (Byk Mallinckrodt Model #CIL BV, Petten, Holland)	(II) 888 Gigabecquerels, 2 sources not to exceed 444 Gigabecquerels per source
(JJ) Iridium-192	(JJ) Sealed Source- Seeds in nylon ribbons (Best Industries, Inc. Model 81-01)	(JJ) 19 Gigabecquerels
(KK) Thallium-201	(KK) Thallous Chloride (DuPont-Merck, NDA 17-806, Mallinckrodt, NDA 18-150; Medi-Physics, NDA 18-110)	(KK) 1.9 Gigabecquerels
(LL) Depleted Uranium	(LL) Metal Alloy	(LL) 32 Kilograms
(MM) Fluorine-18	(MM) Fluorodeoxyglucose F-18 Injection *****	(MM) 7.4 Gigabecquerels

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) Any radiopharmaceutical therapy procedure approved in Section 175.103(f)(1)(i) of the New York City Health Code.

**CITY OF NEW YORK
RADIOACTIVE MATERIALS
LICENSE**

License Number: 91-289
Amendment Number: 9
Reference Number: 602-Series and 611-Series

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- (CC) In ophthalmic plaques for the treatment of ocular tumors in humans
- (FF) Inhalation studies in the evaluation of pulmonary function, study of pulmonary ventilation, imaging the lungs or the assessment of cerebral blood flow.
- (II) In a Nucletron MicroSelectron -HDR Remote Afterloader Brachytherapy Unit for the interstitial, intracavitary and bronchial radiation treatment of cancer in humans. No source greater than 370 gigabecquerels shall be installed in this Afterloader Brachytherapy Unit.
- (KK) Myocardial perfusion imaging, the diagnosis and localization of myocardial infarction and prognosis regarding survival after onset of symptoms of acute MI to assess site and size of perfusion defect.
- (LL) Internal shielding for molybdenum-99/technetium-99m generators.
- (MM) In accordance with protocols submitted 4 November 1994 entitled "Positron Emission Tomography with Rubidium-82 Compared with F-18-fluorodeoxyglucose for Measuring Myocardial Viability and Potential for Recovery of Left Ventricular Function" and "Remote Metabolic Effects and Neuropsychiatric Consequences of Discrete Striatal Infarction: A Positron Emission Tomographic Study".

10. The radioactive material may be used only at the Silver Building (Rooms 2S60, 2S72, 2S74, BS25 and adjacent Radioactive Materials Storage Room), the Dazian Building (Rooms 12D05A, 12D87 and 8th Floor Nuclear Cardiology and PET Facility) and the Bernstein Building (Rooms 10B31 and 10B39), all of Beth Israel Medical Center, First Avenue at 16th Street, New York, New York 10003; Rooms 100, 123, 647 and 649, Beth Israel Medical Center North, East End Avenue at 87th Street, New York, New York 10128. The following radioactive materials may be used in Rooms 3W30, 3W31, 3W47, 3W48 and 3W49, Beth Israel Medical Center Extension Clinic (a.k.a., Phillips Ambulatory Care Center), 10 Union Square East, New York, New York 10003: subitems 6(A), 6(B), 6(C), 6(H), 6(I), 6(L), 6(M), 6(N), 6(R), 6(S), 6(T), 6(V), 6(Y), 6(Z), 6(EE), 6(FF), 6(GG) and 6(MM). The following radioactive materials may be used in the Beth Israel Medical Center Nuclear Cardiology Suite, 425 East 61st Street, Sixth Floor, New York, New York 10021: subitems 6(H), 6(I), 6(U), 6(V), 6(EE), 6(GG) and 6(KK).
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 by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Authorized User

Michael Cappelli, M.D.

Materials and Use

Subitems 6(O), 6(W), 6(AA), 6(DD), 6(HH)

Subitems 6(E), 6(F), 6(G), 6(J), 6(BB)

Subitems 6(C), 6(D), 6(II), 6(JJ)

Subitems 6(C), (D), 6(II), 6(JJ)

In-vitro usage of Subitems 6(H), 6(I), 6(K), 6(L), 6(O), 6(V), 6(EE), 6(GG), 6(MM)

DATE: 2-3-97

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: BJ HOLT
LICENSEE: ST. MARYS
LICENSE NUMBER: 21-03646-03

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

- ☐ Additional Information to Control No. _____
Process in as a new action, additional information, and no fee required.
- ☐ Process as new licensing action. Review has already been started on Control No. _____ and this information cannot be combined with current in-house action.
- ☐ Can be combined with Control No. _____. Review has not started.
- ☐ Appears to be information for the license file - file it.
- ☐ Licensee is adding Nuclear Pharmacists.
- ☐ Amendment is necessary _____. Amendment is not necessary _____.
(Information for license file)
- ☒ Licensee is adding authorized users.
- ☒ A check is included _____. No check is included ✓.
- Amendment is necessary _____. Amendment is not necessary ✓.
(This is a Notification)
- ☐ Process in as a new licensing action:
- A. Amendment _____
B. Renewal _____
C. New License Application _____
- ☐ Other: _____

Thank You For Your Help!!!

10/16/96