Chambersburg HospitalSM
an affiliate of Summit Health

THE PEAK OF GOOD HEALTH

May 8, 2007

U.S. Nuclear Regulatory Commission
Material Licensing Branch
Region 1
475 Allendale Road
King of Prussia, PA 19406

030-03167

RE: Amendment to Radioactive License No. 37-12771-01
The Chambersburg Hospital

Gentlemen:

Please add Amir Batouli, M.D. as an authorized user. Included with this amendment request, is Dr. Batouli's ABR board certification, form NRC313A (Preceptor Attestation – 4 pages), and a copy of the New York City Radioactive Materials License under which Montefiore Medical Center is covered.

If you have questions, please do not hesitate to contact the undersigned.

Sincerely yours,

John Massimilla
Vice President
Administration

Enclosures

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NMSS/RGN1 MATERIALS-002

Chambersburg Hospital is a Not-for-Profit Organization

112 North Seventh Street • P.O. Box 6005 • Chambersburg, PA 17201-6005 • (717) 267-3000 • *www.summithealth.org*

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Amir R. Batouli, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this ninth day of June, 2004
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED
IN THE
DISTRICT
OF
COLUMBIA
1934

President

Secretary-Treasurer

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AMERICAN BOARD OF MEDICAL SPECIALTIES

Certificate No. 49696

Valid through 2014

NRC FORM 313A (AUD) (10-2006) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Amir Batouli, MD	

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 35.200 Imaging and localization studies
- [ ] 35.500 Sealed sources for diagnosis (specify device _____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

[ ] 1. **Board Certification**

a. Provide a copy of the board certification.

b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

[ ] 2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.

b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	Montefiore Med. Center 111 East 210 St Bronx, NY 10467	1000 Hours Total experience	7/00 - 6/30/04

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Leonard McLean MD	NY City # 75-2885-01

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*.

- [x] 35.290
- [x] 35.390 → generator experience in 32.290(c)(1)(ii)(G)

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3. **Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Montefiore Med. Center 111 E. 210 ST Bronx, NY 10467	200	7/1/00 - 6/30/04 DURING RESIDENCY
Radiation protection	"	150	"
Mathematics pertaining to the use and measurement of radioactivity	"	150	"
Chemistry of byproduct material for medical use *(not required for 35.690)*	"	100	"
Radiation biology	"	100	"
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.690).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Montefiore Med. Center Bronx, NY NYC Lic. # 75-2885-01	50	7/1/00 - 6/30/04
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	50	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	70	"

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3. **Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work Experience. (continued)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Montefiore Med. Center - Bronx, NY	50	7/1/00 - 6/30/04
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	10	"
Administering dosages of radioactive drugs to patients or human research subjects	"	150	"
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	"	10	"
Total Hours of Experience:		220	"

Supervising Individual: LEONARD M. FREEMAN, MD

License/Permit Number listing supervising individual as an authorized user: NY City - #-75-2885-01

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one)*.

☒ 35.190 ☒ 35.290 ☒ 35.390 ☒ 35.390 + generator experience in 35.290(a)(1)(ii)(G)

c. For 35.390 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

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PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.690)

First Section
Check one of the following for each use requested:

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☒ I attest that Amir BATOULI has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☒ I attest that Amir BATOULI has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section
Complete the following for preceptor attestation and signature:

☒ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☒ 35.190 ☒ 35.290 ☒ 35.390 ☒ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
LEONARD M. FREEMAN MD	Leonard M. Freeman	718-920 6060	4/25/07

License/Permit Number/Facility Name
N Y CITY - # 75-2885-01

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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 Application dated 24 March 2004 from Peter Semczuk, Vice President of Clinical Services, Montefiore Medical Center; License number 75-2885-01 is hereby amended in its entirety to read:

LICENSEE

1. **Name:** Montefiore Medical Center

2. **Address:** 111 East 210th Street
Bronx, New York 10467

3a. **License Number:** 75-2885-01

3b. **Amendment Number:** 19

4. **Expiration Date:** 31 December 2008

5. **Reference Number:** 188-7

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 with atomic number 3-83, inclusive, except as listed below	(A)	Any	(A)	3.7 Gigabecquerels each, except as listed below
(B)	Hydrogen-3	(B)	Any	(B)	7.4 Gigabecquerels
(C)	Strontium-90	(C)	Sealed Sources Mold (Atlantic Research, Model B)	(C)	7.4 Gigabecquerels
(D)	Molybdenum-99	(D)	Generators with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(D)	333 Gigabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 75-2885-01

Amendment Number: 19

Reference Number: 188-7

6.	Radioactive materials (element number)	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(E)	Technetium-99m	(E)	Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(E)	333 Gigabecquerels
(F)	Technetium-99m	(F)	DTPA Aerosol with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(F)	5.6 Gigabecquerels
(G)	Iodine-125	(G)	Sealed Sources (Nordion International Inc., Models C-235/C-236 and C-324/C-236; Amersham Corp. Model IMC.P2, Centichem, Model 6525)	(G)	22.2 Gigabecquerels, 2 sources of not more than 11.1 Gigabecquerels each.
(H)	Iodine-125	(H)	Sealed Source- Seeds (MediPhysics/Amersham, Models 6702, 6711, 6720; Source Tech Medical, LLC, Model STM1251)	(H)	11.1 Gigabecquerels
(I)	Iodine-131	(I)	Any	(I)	37.0 Gigabecquerels
(J)	Xenon-133	(J)	Gas or Ventilation Study System with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(J)	118.4 Gigabecquerels
(K)	Cesium-137	(K)	Sealed Sources (Minnesota Mining and Manufacturing, Nuclear Associates, and Amersham)	(K)	166.5 Gigabecquerels
(L)	Gadolinium-153	(L)	Sealed Sources (Amersham Corp., Model #GDC.CY1 or Lunar GD Series; New England Nuclear Corp., Model Nos. NER-430, NER-431; Gulf Nuclear, Model #GD-1; or Biosources, Model #OS-213A)	(L)	111 Gigabecquerels, 2 sources of not more than 55.5 Gigabecquerels each
(M)	Iridium-192	(M)	Sealed Source (Best Industries, Model 81-01)	(M)	26 Gigabecquerels
(N)	Iridium-192	(N)	Sealed Sources (Mallinckrodt Medical BV, Model DRN 07736) **********	(N)	1.78 Terabecquerels, 4 sources of not more than 444 Gigabecquerels each

CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 75-2885-01

Amendment Number: 19

Reference Number: 188-7

6.	Radioactive materials (element number)	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(O)	Cobalt-57	(O)	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"	(O)	5 Sources not to exceed 925 Megabecquerels per source
(P)	Cobalt-57	(P)	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"	(P)	5 Sources not to exceed 740 Megabecquerels per source
(Q)	Barium-133	(Q)	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"	(Q)	5 Sources not to exceed 18.5 Megabecquerels per source
(R)	Cesium-137	(R)	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"	(R)	5 Sources not to exceed 18.5 Megabecquerels per source
(S)	Technetium-99m	(S)	Pertechnetate	(S)	Individual amounts not to exceed 1.85 Gigabecquerels
(T)	Depleted Uranium	(T)	Titanium Alloy	(T)	323 Kilograms
(U)	Radium-226	(U)	Sealed Sources	(U)	25 Micrograms
(V)	Samarium-153	(V)	As a radiopharmaceutical with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug Application" (IND) accepted by FDA	(V)	11.1 Gigabecquerels
(W)	Fluorine-18	(W)	Fluorodeoxyglucose (FDG)	(W)	370 Gigabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 75-2885-01

Amendment Number: 19

Reference Number: 188-7

6.	Radioactive materials (element number)	7.	Chemical and/or physical form	8.	Maximum quantity licensee may posses at any one time
(X)	Strontium-82/Strontium-85/Rubiduim-82	(X)	Generator (Bracco Diagnostics Cardiogen-82 Strontium Sr-82-Rubidium RB-82 Generator, NDA #19-414)	(X)	Strontium-82, 7.4 Gigabecquerels; Strontium-85, 28 Gigabecquerels
(Y)	Cesium-137	(Y)	Sealed Sources (Amersham Corp., Model CDC.SP1)	(Y)	426.24 Gigabecquerels total not to exceed 1.48 Gigabecquerels per source.
(Z)	Cesium-137	(Z)	Sealed Source (Isotope Products Laboratories Model HEG-137)	(Z)	185 Megabecquerels
(AA)	Iridium-192	(AA)	Sealed Source (Mallinckrodt Medical BV, Model DRN 07736)	(AA)	888 Gigabecquerels, 2 sources of not more than 444 Gigabecquerels each.
(BB)	Cesium-137	(BB)	Sealed Sources (CIS -US, Inc., Model Number CEA-ORIS-LAP1B Model 437C)	(BB)	3 Sources not to exceed 207.6 Terabecquerels
(CC)	Palladium-103	(CC)	Sealed Sources-Seeds (Theragenics Corp., Model 200; North American Scientific, Inc., Model MED3633)	(CC)	18.5 Gigabecquerels
(DD)	Technetium-99m	(DD)	Pertechnetate with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) Approved by FDA	(DD)	37 Gigabecquerels
(EE)	Gadolinium-153	(EE)	Welded Line Source Housing (North American Scientific, Inc., Model MED3601; DuPont Merck, Model NES-8412; Isotope Products Laboratories, Model A310)	(EE)	148 Gigabecquerels total not to exceed 11.1 Gigabecquerels per housing
(FF)	Strontium-90/Yttrium-90	(FF)	Brachytherapy Seed Sources (Novoste Corporation, BEBIG Model Sr0.S03, AEAT SICW Series (SICW.1 and SICW.2))	(FF)	29.6 Gigabecquerels, with no source to exceed 185 Megabecquerels
(GG)	Yttrium-90	(GG)	Liquid	(GG)	4.1 Gigabecquerels
(HH)	Sodium-22	(HH)	Sealed Sources (Isotope Products Laboratories, Model GF-0227)	(HH)	37 Megabecquerels
(II)	Cesium-137	(II)	Sealed Sources (Isotope Products Laboratories, Model HEG-0111)	(II)	1.48 Gigabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
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THE TOTAL POSSESSION LIMIT FOR (A) THROUGH (II) SHALL NOT EXCEED 213 TERABECQUERELS

CONDITIONS

9. Authorized Use:

(A) through (N) (X), and through (Y) Medical research, diagnosis and therapy (Broad Human Use).

(N) In a Nucletron Model 105.999 Remote Afterloader Brachytherapy Unit for the interstial, intracavitary, intraluminal, and gynecological radiotherapy (Human Use) in Weiler Hospital, Room I-79. No source greater than 370 Gigabecquerels shall be installed in the Unit.

(O) Flood calibration source (Non-Human Use).

(P) through (R) Calibration sources (Non-Human Use).

(S), (GG) Calibration check and reference material (Non-Human Use).

(T) In three (3) Varian Clinac 600C radiotherapy linear accelerators (Non-Human Use).

(U) Storage awaiting proper disposal.

(W) As listed under a "New Drug Application" (NDA) approved by FDA or an "Investigational New Drug" (IND) application accepted by FDA

(V) For the treatment of painful bone metastases in humans.

(Y) In a Nucletron Engineering B.V. Selectron Low Dose Rate Remote After Loading Brachytherapy Unit.

(Z), (HH) Calibration sources (Non-Human Use).

(AA) In a Nucletron Model 105.999 Remote Afterloading Brachytherapy Unit for interstial, intracavitary, intraluminal, and gynecological radiotherapy (Human Use) in Moses Division, Room 29. No source greater than 370 Gigabecquerels shall be installed in the Unit.

(BB) In a Compagnie ORIS Model 1BL-437C Irradiator for Biological materials for the irradiation of blood products.

(CC) Radiotherapy implanation (Human Use).

(DD) Medical research and diagnosis (Human Use).

(EE) In an ADAC Laboratories Model Vantage Attenuation Correction System.

(FF) Percutaneous Coronary Intervention (PCI) for the treatment of in-stent restenosis using the Novoste Corporation Beta-Cath System A1000 Series (A1732, A1733, A1730, and A1767), subject to the strictures contained in FDA premarket approval application (PMA #P000018/S18) dated 25 March 2002, and subsequent FDA premarket approvals.

(II) Transmission sources (Human Use).

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
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10. The radioactive materials shall only be used at the following facilities and addresses of the Montefiore Medical Center: Moses Division, bounded by East 210th Street, Wayne Avenue, East Gun Hill Road, Dekalb Avenue and Kossuth Street (except North Central Bronx Hospital, 3424 Kossuth Avenue); WHAECOM (Jack Weiler Hospital of the Albert Einstein College of Medicine) Division, 1825 Eastchester Road; Montefiore Medical Park at 1695-A Eastchester Road (Rooms 110, 111, 120 and 251), 1525 Blondell Avenue (Room 103); Medical Arts Pavillion at 3400 Bainbridge Avenue (7th Floor Nuclear Cardiology Suite); and Room 8-51 of Blood Bank, Montefiore Medical Center, 111 East 210th Street, all of the Bronx, New York.

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 shall be used by or under the supervision of individuals designated by the Human Use Radiation Safety Committee, Montefiore Medical Center, Paul Goodwin, Ph.D., Chairman.

14. The radiation safety officer for this license is Sherman Heller, Ph.D.

15. The radiation therapy physicists for this license are Rafael Yankelevich, D.A.B.R., and Ravindra Yaparpalvi, D.A.B.R.

16. The use of radioactive material in or on humans shall be by or under the supervision of physicians.

17. The possession limit, when specified in Subitem 8, includes all radioactive material possessed by the licensee under this license whether in storage, implanted and/or inserted in hospitalized patients or otherwise in use.

18. Technetium-99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.

19. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Section 175.103(e)(2)(i) of the New York City Health Code are detected.

    (a) Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

    (b) The licensee shall maintain, for inspection by the Bureau of Radiological Health, results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests. These records shall be maintained for three (3) years following the performance of these tests and the training of personnel.

20. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to, or in the leaflet or brochure that accompanies, the generator or reagent kit.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
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21. The following conditions apply for iodine-131 radiopharmaceutical therapy:

(a) Patient 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 1.2 Gigabecquerel, or the measured maximum dose rate at a distance 1 meter from the patient is less than 0.07 mSv/hr.

(2) Measured and documented patient-specific parameters which otherwise result in compliance with the requirements of Section 175.103(c)(9) of the New York City Health Code.

(b) The radiation safety guidance required by Section 175.103(f)(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 written 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 problems or questions.

(2) Information regarding the type of treatment given.

(3) Precautions regarding distances that should be maintained from other individuals, including separate sleeping arrangements.

(4) Precautions regarding minimizing time in public places.

(5) Precautions to reduce the spread of radioactive contamination (including, but not limited to, vomitus and urine).

(6) The length of time each of the precautions should be in effect.

(c) A "Record of Release" shall be maintained for each patient and shall contain at least the following items: activity at administration, any required decay calculations, date and time of patient release, copy of the patient's written instructions, and if required for patient release either patient's dose rate measurements (including the specific survey instrument used and the name of the individual performing the survey), or patient-specific parameters.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
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22. For individuals who open and/or prepare oral solutions of iodine-131 for therapeutic doses, surveys (*e.g.* measurement of iodine-131 in the thyroid gland of laboratory personnel and contamination surveys of personnel, equipment and facilities) shall be performed to determine compliance with Section 175.103(f)(3) of the New York City Health Code.

23. Conditions for use of tritium (more than 3.7 gigabecquerels in noncontained form):

A) Individuals involved in operations which utilize, at any one time, more than 3.7 gigabecquerels of hydrogen-3 in a noncontained form (other than metallic foil) shall have bioassays performed within one (1) week following a single operation, and at weekly intervals for continuing operations.

B) Tritium shall not be used in such a manner as to cause any individual to receive a radiation exposure such that urinary excretion rates exceed 740 kilobecquerels of tritium per liter when averaged over a calendar quarter.

C) Urinalysis shall be performed at weekly intervals on all individuals who work in the restricted areas of facilities in which tritium is used. If the average concentration of tritium in urine for any single individual during a calendar quarter is less than 370 kilobecquerels per liter, urinalysis shall be performed on that individual at monthly intervals for the following calendar quarter and may continue at monthly intervals so long as the average concentration in the calendar quarter remains below 370 kilobecquerels per liter. The urine specimen shall be collected on the same day of the week insofar as possible.

D) A report of an average concentration in excess of the limits specified in subitem C above for any individual shall be filed, in writing, within thirty (30) days of the end of the calendar quarter with the Radioactive Materials Division, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007. The report shall contain the results of all urinalyses for the individual during the calendar quarter, the cause of the excessive concentration and the corrective steps, taken or planned, to assure against recurrence.

E) Any single urinalysis which discloses a concentration greater than 1.85 megabecquerels per liter shall be reported in writing, within seven (7) days of the licensee's receipt of the results, to the Radioactive Materials Division, Office of Radiological Health, 11th Floor, 2 Lafayette Street, New York, New York 10007.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
	Amendment Number:	19
	Reference Number:	188-7

24. 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 dose rate measurements including the specific survey instrument used and the name of the individual performing the survey.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	75-2885-01
	Amendment Number:	19
	Reference Number:	188-7

25. The following subitems refer to the high dose rate remote afterloader brachytherapy units possessed by the licensee, (which presently are Nucletron Model 105.999 Remote Afterloader Brachytherapy Units), each of which is henceforth referred to as the "Unit":

(a) All operators of the Unit other than authorized physician users must be New York State licensed radiation therapy technologists.

(b) When treatments are performed with the Unit, only the patient shall be in the treatment room.

(c) The Unit shall be labeled with the radiation symbol and the appropriate wording, "Caution" or "Danger" and "Radioactive Material".

(d) The written instruction for operation and safety contained in the manufacturer's Instruction Manual shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of the Unit.

(e) The Unit facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation. The patient shall be visually monitored during treatment.

(f) Daily (or on each day of use) checks of the Unit shall be performed to ascertain:

(1) Guide tubes are free of kinks or other imperfections.

(2) Reproducibility of source positioning within catheter to within ± 1mm.

(3) Proper functioning of room interlocks.

(4) Proper functioning of source position indicators (e.g., lights, alarms, room monitor).

(g) Written emergency instructions shall be posted at the Unit console. These instructions shall inform the Unit operator of the procedure to be followed should he/she be unable to return the source(s) to the shielded position with controls outside the treatment room. These instructions shall caution individuals to avoid exposure to the unshielded source(s) when in the treatment room and shall include specific instructions for:

(1) Locating and using the device for manually returning the source(s) to the shielded position.

(2) Removing the patient from the treatment room.

(3) Securing the room against unauthorized entry.

(4) Notifying the responsible physician or radiation safety officer.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
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	Reference Number:	188-7

(h) Prior to initiation of a treatment program using the Unit and subsequent to each installation of iridium-192 source, radiation surveys and tests shall be performed in accordance with the following:

(1) A radiation survey shall be made of:

(i) The Unit's source housing with the iridium-192 source in the shielded position. The dose rate at a distance of 1 meter around the surface of the Unit is less than 0.1μSv/hr.

(ii) All areas adjacent to the treatment room with the Unit's source in the treatment position. The survey shall be performed with a phantom and clearly establish:

(A) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 175.03(c) of the New York City Health Code.

(B) That radiation levels in unrestricted areas do not exceed the limits specified in Section 175.03(d) of the New York City Health Code.

(2) Tests shall be made to determine proper operation of:

(i) Electrical interlocks on entrance doors to the Unit treatment room.

(ii) The Unit's source shielded/unshielded indicators both at the source housing and on the control panel outside the treatment room.

(iii) The Unit's treatment timing device.

(3) A report of the results of the above surveys and tests shall be sent to the Radioactive Materials Section, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007, not later than thirty (30) days following each installation of the Unit's source.

(i) Any changes made in treatment room shielding, location, or use of the Unit which could result in an increase in radiation levels in unrestricted areas outside of the treatment room and made subsequent to the completion of the initial radiation survey performed in accordance with Subitem (h) shall be evaluated by a radiation survey made in accordance with the requirements of Subitem (h)(1)(ii). A report describing the change(s) and giving the results of the survey(s), shall be sent to the Radioactive Materials Section, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007, not later than thirty (30) days following completion of the change(s).

(j) Each Unit shall be fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism. This inspection and servicing shall be performed by Nucletron Corporation or by persons specifically authorized to do so by the U.S. Nuclear Regulatory Commission or an Agreement State.

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FROM :MONTEFIORE FAX NO. :17189204854 May. 08 2007 09:40AM P16
May-08-2007 06:11 PM 17189204854 16/20

CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
	Amendment Number:	19
	Reference Number:	188-7

(k) The following shall be performed by Nucletron Corporation or by persons specifically authorized to do so by the U.S. Nuclear Regulatory Commission or an Agreement State:

(1) Installation, relocation or removal of the Unit containing sources.

(2) Source exchange.

(3) Any maintenance or repair operations on the Unit involving work on any mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the Unit and result in increased radiation levels.

(l) Following source exchange and/or any source repairs and before its medical use, the licensee shall calibrate each iridium-192 sealed source in the Unit. The source output shall be determined to within an accuracy of ± 3 percent.

(m) The entrance to the room where the Unit is located shall be equipped with an electrical interlock system that will return the device's source to the shielded position immediately upon opening the entrance door. The interlock system shall be connected in such a manner that the device's source cannot be moved into the irradiation position until the treatment room entrance door is closed and the source "on-off" control is reset at the control panel.

(n) The Unit room shall be equipped with a radiation monitoring device which continuously monitors the source condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make the operator continuously aware of source condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor.

Whenever the continuous radiation monitoring device is not operational, any person entering the treatment room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the source condition.

(o) Relocation of the Unit to a new location is not permitted without a license amendment from the New York City Department of Health. Following such amendment and relocation, a radiation survey shall be made and reported to the Office of Radiological Health within thirty (30) days after completion of the move.

(p) Immediately after completing patient treatment with the Unit, the licensee shall conduct a radiation survey to ensure that the source has been removed from the patient. The area of use shall also be surveyed to ensure proper return of the source to the shielded position. The licensee shall make a record of each survey and retain the results for at least three (3) years.

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FROM :MONTEFIORE FAX NO. :17189204854 May. 08 2007 09:41AM P17

CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	75-2885-01
	Amendment Number:	19
	Reference Number:	188-7

26. The following conditions apply to the Nucletron Selectron SEL 103 Low Dose Rate (LDR) Remote Afterloading Brachytherapy Unit, henceforth referred to as the "LDR Unit".

(a) All operators of the LDR Unit other than authorized physician users shall be New York State licensed radiation therapy technologists.

(b) When treatments are performed with the LDR Unit, only the patient shall be in the treatment room.

(c) The LDR Unit shall be used in the Weiler Hospital, Floor 5 South, Room 516.

(d) The LDR Unit shall be labeled with the radiation symbol and the appropriate wording "Caution" or "Danger" and "Radioactive Material".

(e) The entrance to the room where the LDR Unit is located shall be equipped with an electrical interlock system that will return the sources to the shielded position immediately upon opening the entrance door. The interlock system shall be connected in such a manner that treatment cannot be recontinued until the entrance door is closed and the source "on/off" control is reset at the control panel.

(f) The room where the LDR Unit is located shall be equipped with a radiation monitoring device which continuously monitors the source condition and is equipped with a back-up power supply for emergency operation. This device shall energize a visible and/or audio signal to ensure that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. This device shall be operationally tested on each day of the LDR Unit's use. Whenever this device is not operational, any person entering the room following or during an irradiation shall enter with an operational radiation survey meter and shall determine the source status.

(g) The written instructions for operation and safety contained in the instruction manual issued by the manufacturer shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of the LDR Unit.

(h) On each day of use, checks of the LDR Unit shall be performed to ascertain:

(1) Guide tubes are free of kinks or other imperfections.
(2) Reproducibility of source positioning to within ± 1mm.
(3) Proper functioning of source position indicators (*e.g.* lights, alarms, etc.) and
(4) Proper functioning of room interlocks.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE	License Number:	75-2885-01
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(i) An intercom shall be installed at the LDR Unit's remote control panel to enable communication with the patient without treatment interruption.

(j) The LDR Unit shall be leak tested at six (6) month intervals as required by §175.03(e) of the New York City Health Code.

(k) Following source exchange and/or any source repairs and before medical use, the licensee shall calibrate each source in the LDR Unit. The source output shall be determined to an accuracy of ± 3 percent.

(l) The following shall be performed by Nucletron Corporation , its parent company Nucletron Engineering BV, or by persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform service on such LDR Unit specified in their license:

(1) Installation, relocation or removal of the LDR Unit sources.

(2) Source exchange of the LDR Unit.

(3) Any maintenance or repair operations on the LDR Unit involving work on any mechanism that could expose the sources, reduce the shielding around the sources or compromise the safety of the LDR Unit and result in increased radiation levels.

(4) Upon completion of either Subitems l(1), l(2) or l(3), the LDR Unit shall be tested for proper operation of the source exposure mechanism, safety warning component labels, external radiation levels (with sources exposed and with sources shielded) and leak tested.

(m) Prior to initiation of a treatment program using the LDR Unit and subsequent to each installation of cesium-137 sources, radiation surveys and tests shall be performed in accordance with the following:

(1) A radiation survey shall be made of:

(i) The LDR Unit's source housings with the cesium-137 sources in the shielded position. The exposure rate within 100 cm of the surface of the treatment unit shall be less than 0.33 milliroentgens per hour.

(ii) All areas adjacent to the treatment rooms with the LDR Unit sources in the treatment position. The survey shall be performed with a phantom and clearly establish:

(A) that radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 175.03 of the New York City Health Code.

(B) that radiation levels in unrestricted areas do not exceed the limits specified in Section 175.03 of the New York City Health Code.

(2) A report of the results of the above surveys and tests shall be sent to the Radioactive Materials Section, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007, not later than thirty (30) days following each installation of the irradiator sources.

(n) Immediately after completing patient treatment, the licensee shall conduct a radiation survey to ensure that the sources have been removed from the patient. The area of use shall also be surveyed to ensure proper return of the sources to the shielded position. The licensee shall make a record of each survey and retain the results for at least three (3) years.

27. 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.

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FROM :MONTEFIORE FAX NO. :17189204854 May. 08 2007 09:41AM P19
May-08-2007 05:11 PM 17189204854 19/20

CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE		
	License Number:	75-2885-01
	Amendment Number:	19
	Reference Number:	188-7

28. The following subitems refer to the gamma irradiator, henceforth referred to as the irradiator (which presently is Compagnie ORIS Industry Model IBL-437C Irradiator for Biological Materials):

(A) The written instruction for operation and safety contained in the manufacturer's Instruction Manual shall be followed and a copy of these instructions shall be made available to each individual using or having responsibility for use of the irradiator.

(B) The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

(C) After installation of the irradiator and the (cesium-137) source and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report of the results of the survey shall be sent to the Radioactive Materials Division, Office of Radiological Health, 2 Lafayette Street, 11th Floor, New York, New York 10007, not later than thirty (30) days following installation of the source.

(D) The irradiator operators shall wear film badges at all times while on duty and an extremity radiation monitoring device (in the form of a ring dosimeter) when operating the irradiator.

29. 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 24 March 2004
(B) Letter dated 3 May 2004
(C) Letter and attachments dated 27 May 2004

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FOR THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Date: JUL 0 8 2004

RF/lh

Raymond Ford
Scientist
Radioactive Materials Division
Office of Radiological Health

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

5/8/2007, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 37-12771-01

☑ 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** 140515.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader