CHRISTIANA CARE
HEALTH SYSTEM

Office of Chief Operating Officer
Medical Group of Christiana Care
Michael S. Eppehimer, MHSA, FACHE
Suite 2100
200 Hygeia Drive
Newark, DE 19713
PH: (302) 623-0568; FAX: (302) 623-0117

January 5, 2018

G2
03001303

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Re: NRC License 07-12153-02

Dear Ms. Lanzisera:

This is a request for a license amendment for the following items.

- Please add Tony Francis, MD as an Authorized User for 35.100; 35.200; 35.300; Yttrium-90 TheraSpheres and Yttrium-90 SIR-spheres. Dr. Francis is currently approved on two agreement state licenses. The two licenses are attached for your review. The three patient hands-on cases for Yttrium-90 TheraSpheres and Yttrium-90 SIR-spheres will be performed at Christiana Care and supervised by our approved AUs once Dr. Francis comes on board in March 2018.
- Please remove Erin E. Grady, MD and Vinita Patanaphan, MD as AUs from our license.
- We would like to transition the senior management representative role from me to Kert Anzilotti, MD. Below is Dr. Anzilotti's contact information.

  Kert F. Anzilotti, MD, MBA
  Chief Medical Officer Acute Care
  Christiana Care Health System
  CH Management Suite 1218
  4755 Ogletown-Stanton Rd., Newark, DE 19718
  Office: (302)733-1323, Fax: (302)733-1267

If you have any questions, or need any additional information, please do not hesitate to contact me or Xiaoqian (Carol) Wen, RSO at (302) 623-3839.

Sincerely,

Michael S. Eppehimer, MHSA, FACHE
Chief Operating Officer, Medical Group of Christiana Care
Christiana Care Health System
Phone: (302) 623-0568

Cc: Hung Dam, MD (Chair of RSC); Xiaoqian (Carol) Wen, RSO

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REC'D IN LAT 1-10-18

NRC FORM 313 (10-2017) 10 CFR 30, 32, 33, 34, 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 06/30/2019**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-2 F43), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. **SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.**

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

IF YOU ARE LOCATED IN:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- ☐ A. NEW LICENSE
- ☑ B. AMENDMENT TO LICENSE NUMBER 07-12153-02
- ☐ C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include zip code)*

Christiana Care Health Services, Inc
Management Suite - Room 1218
4755 Ogletown-Stanton Road
Newark, Delaware 19718

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

No change

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Xiaoqian (Carol) Wen

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(302)623-3839	(484)633-0035

BUSINESS E-MAIL ADDRESS

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSE FEES. (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)
***Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.**

FEE CATEGORY: N/A AMOUNT ENCLOSED: $

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Xiaoqian (Carol) Wen		1/2/2018

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		
APPROVED BY				DATE	

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 10 January 2017 from Tony Francis, M.D., Radiation Safety Officer, Jacobi Medical Center; License number 91-3079-01 is hereby amended in Item 3b, Conditions 12, 22, and to read:

LICENSEE

1. Name: NYCHHC: Jacobi Medical Center

2. Address: 1400 Pelham Parkway South
Bronx, New York 10461

3a. License Number: 91-3079-01

3b. Amendment Number: 17

4. Expiration Date: 30 April 2018

5. Reference Number:

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), 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(d)(2), 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)
(C)	Molybdenum-99	(C)	Generators with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(C)	111Gigabecquerels
(D)	Technetium-99m	(D)	Generators with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(D)	111 Gigabecquerels

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6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may possess at any one time
(E)	Technetium-99m	(E)	DTPA Aerosol with an active (*i.e.* not withdrawn or terminated "New Drug Application" (NDA) approved by FDA	(E)	3.7 Gigabecquerels
(F)	Rubidium-81	(F)	Contained in a dispensing column within a krypton-81m gas generator with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(F)	925 Megabecquerels
(G)	Krypton-81m	(G)	Gas Generator with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(G)	925 Megabecquerels
(H)	Any radioactive material identified in §175.103(e), NYC Health Code	(H)	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	(H)	As necessary for uses authorized in Subitem 9(H)
(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)	5 Sources not to exceed 925 Megabecquerels per source
(J)	Cobalt-57	(J)	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"	(J)	5 Sources not to exceed 740 Megabecquerels per source
(K)	Barium-133	(K)	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"	(K)	5 Sources not to exceed 18.5 Megabecquerels per source
(L)	Cesium-137	(L)	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"	(L)	5 Sources not to exceed 18.5 Megabecquerels per source

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-3079-01

Amendment Number: 17

Reference Number:

6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may possess at any one time
(M)	Technetium-99m	(M)	Pertechnetate	(M)	Individual amounts not to exceed 1.85 Gigabecquerels
(N)	Chromium-51	(N)	Any	(N)	37 Megabecquerels
(O)	Cobalt-57	(O)	Any	(O)	37 Megabecquerels
(P)	Iodine-125	(P)	Any	(P)	12 Megabecquerels
(Q)	Carbon-14	(Q)	Urea (Tri Med Specialties Inc., NDA 20-617)	(Q)	18.5 Megabecquerels
(R)	Fluorine-18	(R)	Fluorodeoxyglucose F18 injection	(R)	18.5 Gigabecquerels
(S)	Germanium-68/Gallium-68	(S)	Line Source (CTI Services, Inc., Model LS-0.5)	(S)	37 Megabecquerels
(T)	Cesium-137	(T)	Calibration and Gauging Gamma Source (Isotope Products Labs, Model HEG-137)	(T)	4.44 Gigabecquerels total, not to exceed 1.11 Gigabecquerels per source
(U)	Depleted Uranium	(U)	Sealed Beam Shapers (Steel Cladding and Nickel Alloy Plating)	(U)	55 Kilograms
(V)	Gadolinium-153	(V)	Welded Line Source Housing (North American Scientific, Inc., Model MED3601; DuPont Merck, Model NLS-8112)	(V)	37 Gigabecquerels total per system, not to exceed 11.1 Gigabecquerels per housing
(W)	Carbon-14	(W)	Bactec 12B and 13A Mycobacteria Culture Vials	(W)	148 Megabecquerels
(X)	Xenon-133	(X)	Gas or Ventilation Study System with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(X)	3.7 Gigabecquerels
(Y)	Nickel-63	(Y)	Ring Sources (NEN, Model NER-004R)	(Y)	555 Megabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-3079-01

Amendment Number: 17

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) For producing technetium-99m.

(D) For use in reagent kits with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA for human-use diagnostic studies involving imaging and localization and as non-human use check, calibration and reference material.

(E) Pulmonary function studies administered using either a Mallinckrodt Sunaco, Inc., a Cadema System, Inc., a Medi-Nuclear Corporation Aero-Vent, or AMICI, Inc. Swirler aerosol delivery system.

(F) For producing krypton-81m gas.

(G) Pulmonary ventilation studies.

(H) Any radiopharmaceutical or radiobiologic therapy procedure authorized by applicable law.

(I) Flood calibration sources (Non-Human Use).

(J) through (L) Calibration sources (Non-Human Use).

(M) Calibration check and reference material (Non-Human Use).

(N) through (P), (Q) and (W) In-vitro laboratory studies (Non-Human Use).

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

(S) In an ADAC Laboratories MCD Attenuation Correction device.

(T) and (U) In an ADAC Laboratories MCD-AC Attenuation Correction device.

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

(X) Inhalation studies in the evaluation of pulmonary function, study of pulmonary ventilation, imaging the lungs or the assessment of cerebral blood flow.

(Y) Ion Mobility Spectrometer Cells (IMS Cells) and Model 2428800 (Hand Held CW Detector contained in Smiths Detection ADP 2000 Chemical Agent Monitor Devices) (Non-Human Use).

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-3079-01

Amendment Number: 17

Reference Number:

10. The licensee shall comply with the provisions of Article 175 of the New York City Health Code entitled "Radiation Control."

11. The radioactive material may be used only at the Jacobi Hospital Building, North Basement, Nuclear Medicine Department, in Rooms BN-13A, BN-19, BN-19A, BN-19B, BN-20, BN-20A, BN-20B, BN-21, BN-23, and in Radionuclide Treatment Rooms 4(A): Rooms 8, 9, 10, 11, 12, 5(A): Rooms 8, 9, 10, 11, 12, and 6A: Rooms 8, 9, 10, 11, 12, and in the PET trailer located outside building 1 South Basement, adjacent to parking lot "J", 1400 Pelham Parkway South, Bronx, New York 10461.

12. 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	Materials and Use
Tony Francis, M.D.	All
Arthur Karmen, M.D.	Subitems 6(W), 6(Y)
Syed Mahmood, M.D.	All
Surekha Patel, M.D.	Subitems 6(A) through 6(M), 6(R) through 6(V), and 6(X)
Lionel Zuckier, M.D.	All

13. The radiation safety officer for this license is Tony Francis, M.D.

14. The therapy physicist for this license is Thomas Petrone, D.A.B.R.

15. 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.

16. Radioactive material as a sealed source shall not be opened by the licensee.

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

18. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculation and steps to be taken if activities of molybdenum-99 in excess of the limits specified in Section 175.103(d)(3) of the New York City Health Code are detected.

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

20. 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 Gigabecquerels, 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.

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number:	91-3079-01
Amendment Number:	17
Reference Number:	

(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.

21. 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(e)(3) of the New York City Health Code.

22. 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 28 March 2013
(B) Letter dated 20 March 2015
(C) Letter dated 2 May 2016
(D) Letter dated 10 January 2017

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FOR THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Date: 01/20/2017

Hailu W. Tedla
Radioactive Materials Division
Office of Radiological Health

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 2 May 2016 from Christopher Rust, Associate Executive Director, North Central Bronx Hospital; License number 91-3211-01 is hereby amended in Item 3b, Conditions 13, 19, and to read:

LICENSEE

1. Name: N.Y.C.H.H.C.-
North Central Bronx Hospital

2. Address: 3424 Kossuth Avenue
Bronx, New York 10467

3a. License Number: 91-3211-01

3b. Amendment Number: 6

4. Expiration Date: 31 May 2018

5. Reference Number: 91-1641-01

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), 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(d)(2), 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: 91-3211-01

Amendment Number: 6

Reference Number: 91-1641-01

6.	Radioactive materials (element number	7.	Chemical and/or physical form	8.	Maximum quantity licensee may possess at any one time
(C)	Rubidium-81	(C)	Contained in a dispensing column within a krypton-81m gas generator with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(C)	925 Megabecquerels
(D)	Krypton-81m	(D)	Gas Generator with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(D)	925 Megabecquerels
(E)	Xenon-33	(E)	Gas or Ventilation Study System with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(E)	3.7 Gigabecquerels
(F)	Technetium-99m	(F)	DTPA Aerosol with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(F)	3.7 Gigabecquerels
(G)	Any radioactive material identified in §175.103(c), NYC Health Code	(G)	Any radiopharmaceutical/radiobiological for therapy 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	(G)	As necessary for uses authorized in Subitem 9(G)
(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)	5 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)	5 Sources not to exceed 740 Megabecquerels per source

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number: 91-3211-01

Amendment Number: 6

Reference Number: 91-1641-01

6. Radioactive materials (element number)		7. Chemical and/or physical form		8. Maximum quantity licensee may possess at any one time	
(J)	Barium-133	(J)	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"	(J)	5 Sources not to exceed 18.5 Megabecquerels per source
(K)	Cesium-137	(K)	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"	(K)	5 Sources not to exceed 18.5 Megabecquerels per source
(L)	Technetium-99m	(L)	Pertechnetate	(L)	Individual amounts not to exceed 1.85 Gigabecquerels
(M)	Technetium-99m	(M)	Any	(M)	Individual amounts not to exceed 3.7 Gigabecquerels
(N)	Nickel-63	(N)	Ring Sources (NEN Model NER-004R)	(N)	555 Megabecquerels
(O)	Molybdenum-99	(O)	Generators with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(O)	111Gigabecquerels
(P)	Technetium-99m	(P)	Generators with an active (i.e. not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA	(P)	111 Gigabecquerels

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number:	91-3211-01
Amendment Number:	6
Reference Number:	91-1641-01

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) For producing krypton-81m gas.

(D) Pulmonary ventilation studies.

(E) Inhalation studies in the evaluation of pulmonary function, study of pulmonary ventilation, imaging the lungs, or assessment of cerebral blood flow.

(F) Pulmonary function studies administered using either a Mallinckrodt Sunaco, Inc., a Cadema System, Inc., or a Medi-Nuclear Corporation Aero-Vent aerosol delivery system.

(G) Any radiopharmaceutical therapy procedure approved in Section 175.103(e) of the New York City Health Code.

(H) Flood calibration sources (Non-Human Use).

(I) through (K) Calibration sources (Non-Human Use).

(L) Calibration check and reference material (Non-Human Use).

(M) In-vitro labeling studies (Non-Human Use).

(N) Ion Mobility Spectrometer Cells (IMS Cells), Model 2428800 (Hand Held CW Detector contained in Smiths Detection ADP 2000 Chemical Agent Monitor Device) (Non-Human Use).

(O) For producing technetium-99m.

(P) For use in reagent kits with an active (*i.e.* not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA for human-use diagnostic studies involving imaging and localization and as non-human use check, calibration and reference material.

10. The radioactive materials may only be used in Rooms 2F26 Gamma Camera Room and Stress Testing Lab, 2G08F Hot Lab, North Central Bronx Hospital, 3424 Kossuth Avenue, Bronx, New York 10467.

11. The licensee shall comply with the provisions of Article 175 of the New York City Health Code entitled "Radiation Control."

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CITY OF NEW YORK RADIOACTIVE MATERIALS LICENSE

License Number:	91-3211-01
Amendment Number:	6
Reference Number:	91-1641-01

12. 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	Materials and Use
Tony Francis, M.D.	All
Sumina Goel, M.D.	All
Syed Mahmood, M.D.	All
Surekha Patel, M.D.	All
Salil Sarkar, M.D.	All

13. The radiation safety officer for this license is Tony Francis, M.D.

14. Radioactive material as sealed source shall not be opened by the licensee.

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

16. 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 Gigabecquerels, 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(c)(9) 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		
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17. 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(e)(3) of the New York City Health Code.

18. 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.

19. 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 28 March 2013
(B) Letter dated 2 May 2016

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FOR THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Date: 5/25/16

Erik Finkelstein
Radioactive Materials Division
Office of Radiological Health

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Christiana Care Health Services, Inc.
Attn: Michael S. Eppehimer, MHSA, FACHE
Chief Operating Officer
4755 Ogletown-Stanton Road
Newark, DE 19718

Date
01/23/2018

License Number(s)
07-12153-02

Mail Control Number(s)
602196

Licensing and/or Technical Reviewer or Branch
Medical Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 01/05/2018

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239