Yale
NewHaven
Health
Bridgeport
Hospital

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NRC License No.: 06-01060-01
Docket No.: 030-01247
Mail Control No.: 588254 amy

July 5, 2016

U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

RE: Bridgeport Hospital Amendment Request to Remove Indukala Doddamane, M.D. and Michael Meszaros, M.D. as Authorized Users and to Add Sabinus Ekeh, MS as an Authorized Medical Physicist, on the License.

Gentlemen & women of the NRC:

Bridgeport Hospital would like to amend its license to remove Indukala Doddamane, M.D. and Michael Meszaros, M.D. as Authorized Users from the license and add Sabinus Ekeh, M.S. as an Authorized Medical Physicist (AMP). Mr. Ekeh has been previously listed as an HDR AMP on California State Radioactive Materials License No.: 7809-34. We have attached a copy of the license with his name listed as an HDR AMP for your review. He has been hired as a locum tenens physicist and is expected to begin service on or before August 15th and will serve as a Medical Physicist at least through December 2, 2016.

If you have any further questions, please feel free to contact Mr. Bohan at (203) 688-2950, or mike.bohan@yale.edu.

Regards,

Michael R Tatta

Michael R. Tatta
Director, Imaging, Laboratory & Radiation Oncology

Attachments: CA State RML License 7809-34

Radiation Safety Office
Radiological Physics
20 York St. – WWW 229
New Haven, CT 06510
Phone: (203) 688-2950
(203) 336-7814
Fax: (203) 688-4135

REC'D IN LAT 07/08/2016

591458
REGION I MATERIALS-002

# RADIOACTIVE MATERIAL LICENSE

*Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the California Department of Public Health now or hereafter in effect and to any standard or specific condition specified in this license.*

| | | | |
|---|---|---|---|
| 1.Licensee: | CHW Medical Foundation<br>dba: Mercy Imaging Centers | 3. License Number: 7809-34 | Amendment Number: 6 |
| 2. Address: | 6305 Coyle Ave.<br>Carmichael, CA 95608 | 4. Expiration date: February 16, 2020 | (2) |
| Attention: | John Micheels<br>Operations Manager, CEO | 5. Inspection agency: | Radiologic Health Branch<br>North |

**In response to the letter dated April 12, 2012, signed by Sabinus Ekhe [*sic*], M.S., Radiation Safety Officer, License Number 7809-34 is hereby amended as follows:**

| 6. Nuclide | 7. Form | 8. Possession Limit |
|---|---|---|
| A. Any radioactive material permitted by 10 CFR 35.200. | A. Any<br>Excluding Xenon | A. Total possession limit not to exceed 1.85 Ci. |
| **B. Radioactive material permitted by 10 CFR 35.600 as specified below:**<br><br>**1. Iridium-192** | **B.**<br><br>**1. Sealed source (Varian Medical Systems, Model VS2000).** | **B.**<br><br>**1. Total 21 Ci in 2 sources. No single source to exceed 11 Ci.** |
| C. Any radionuclide with atomic numbers 3-83, inclusive, except: Strontium-90 and Lead-210. | C. Sealed, solid or liquid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission, an Agreement State or a Licensing State. | C. Total not to exceed 50 mCi. Each source not to exceed 20 mCi. |

9. Authorized Use

A. Any imaging and localization study permitted by 10 CFR 35.200.

**B. 1. To be used in a Varian Medical Systems, Inc., Model VariSource iX HDR remote afterloader for physical measurements only.**

C. Marker and calibration sources.

## *LICENSE CONDITIONS*

10. Radioactive material shall be used only at the following locations:

(a) 6305 Coyle Avenue, Carmichael, CA. **(excluding HDR)**

(b) 3301 C. Street, Building 500, Sacramento, CA.

RPS 7\30\12

**RADIOACTIVE MATERIAL LICENSE**

License Number: 7809-34

Amendment Number: 6

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Items 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 100425 of the California Health and Safety Code.

12. (a) The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8, and 9 of this license as follows:

| | |
|---|---|
| (1) Raghav Raman, M.D. | 35.200 and 9.C. |
| (2) Rajiv K. Chopra, M.D. | 35.200 and 9.C. |
| (3) Gregory Rogalski, M.D. | 35.200 and 9.C. |
| (4) Gordon K. Arakawa, M.D. | 35.200 and 9.C. |
| (5) **Nataraj Shanmugam, M.D.** | **35.200 and 9.C.** |
| (6) **John M. Stevenson, M.D.** | **35.600** |

(b) **The following individuals are Authorized Medical Physicists and are approved for physical measurements and for the material and uses indicated below:**

| | |
|---|---|
| (1) **Sabinus Ekeh, M.S.** | **(HDR)** |

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with the statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(a) The new license application, with attachments, dated September 24, 2009, signed by Sigrid Owyang, Executive Director, supplemented by the letters, with attachments, dated February 1, 2010, and February 5, 2010, both signed by John Micheels, Operations Manager and CEO.

(b) The letter dated March 21, 2011, signed by Sigrid Owyang, Executive Director, supplemented by the letter dated July 1, 2011, signed by John Micheels, Operations Manager, regarding the addition of a Sr-82/Rb-82 generator, with associated commitments and procedures.

(c) The letters, with attachments, dated October 31, 2011 and November 7, 2011, both signed by John Micheels, Clinical Operations Manager, regarding the new use location at 3301 C. Street, Building 500, Sacramento, CA, and the Philips Gemini TF PET/CT camera, with associated commitments and procedures.

(d) The letter, with attachment, dated December 20, 2011, signed by Andrew Lloyd Holz, M.D., Radiation Safety Officer, regarding the appointment of the new Radiation Safety Officer.

(e) **The letter, with attachments, dated May 4, 2012, and the letter dated July 10, 2012, both signed by Sabinus Ekeh, M.S., Radiation Safety Officer, regarding the addition of the Varian Medical Systems, Inc., Model VariSource iX HDR remote afterloader for physical measurements only, with associated commitments and procedures.**

14. The Radiation Safety Officer in this program shall be Sabinus Ekeh, M.S.

**RADIOACTIVE MATERIAL LICENSE**

License Number: 7809-34
Amendment Number: 6

15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Title 17, California Code of Regulations, Section 30275 (c).

16. In lieu of the leak test intervals required by California Code of Regulations, Title 17, Section 30275 (c), sealed sources can be tested for leakage and/or contamination at longer intervals when they are specified in a certificate of registration issued by the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State. When a longer interval stipulated in a certificate of registration is used, the certificate must be maintained on file and available for inspection for as long as the associated leak test records are retained.

17. Quantitative analytical assays for the purpose of tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.

18. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Public Health:

    (a) The Radiation Safety Officer
    (b) Qualified individuals designated in writing by the Radiation Safety Officer

19. **The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.**

20. Where users or their assistants are engaged in elution from generators, the exposure to the fingers or hands shall be monitored as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (a).

21. The licensee is authorized to hold radioactive materials with a physical half-life of less than 65 days for decay in storage before disposal in ordinary trash provided:

    (a) Radioactive waste to be disposed of in this manner shall be held for decay in storage for at least 10 half-lives.

    (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    (c) Records shall be maintained of the disposal of licensed materials made by decay in storage. These records shall be sufficient to demonstrate compliance with this license condition and shall be retained for 3 years after the record is made.

    (d) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

22. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to Title 17, California Code of Regulations, Subchapter 4.6. Such procedures shall be performed under the supervision of authorized user physicians on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.

23. Release of patients containing radioactive materials or implants containing radioactive materials shall be in accordance with 10 CFR 35.75 (1-1-08 Edition).

24. **When performing written directive procedures for administration of Iodine-131 greater than 30 microcuries and/or therapeutic procedures of both sealed or unsealed radioactive material the licensee must comply with the requirements listed in 10 CFR 35.41 (1-1-08 Edition) including, but not limited to, the following:**

    (a) **Develop, implement and maintain written procedures that ensure the following:**

        (1) **The patient's or human research subject's identity is verified before each administration.**
        (2) **Each administration is in accordance with the treatment plan, if applicable, and written directive.**
        (3) **Both the manual and computer-generated dose calculations have been checked.**
        (4) **The computer-generated dose calculations have been correctly transferred into the consoles of therapeutic medical units authorized by 35.600.**

    (b) **Retain a copy of the written procedures for the duration of the license per 10 CFR 35.2041.**

25. **Remote afterloading units(s) authorized by this license shall be operated in accordance with 10 CFR 35.600, 35.604, 35.605, 35.610, 35.615, 35.630, 35.633, 35.643, 35.652, 35.657 and 35.690 (1-1-08 Edition).**

26. Production or processing of radiopharmaceuticals for the purpose of commercial distribution to other licensees is not authorized by this license.

27. For a period not to exceed 60 days in any calendar year, a physician is authorized to use licensed materials for human use under the terms of this license, provided the physician:

    (a) Has the prior written permission of the Licensee's Executive Management and its Radiation Safety Officer.

    (b) Is specifically named as an authorized user on a current and valid U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State license authorizing human use.

    (c) Performs only those procedures for which the physician is specifically authorized by the U.S. Nuclear Regulatory Commission, Agreement State or a Licensing State license.

    The licensee shall maintain for inspection copies of the written permission specified in (a) above and the license(s) specified in (b) and (c) above. These records shall be maintained for five years from the time the licensee grants its permission under (a) above.

28. The licensee will provide the Low Level Radioactive Waste (LLRW) reports specified in the California Health and Safety Code section 115000.1(h) to the California Department of Public Health (CDPH) on an annual basis for both shipped and stored LLRW. Alternatively, LLRW shipment information may be provided on a per shipment basis. LLRW shipment information and annual reports shall be mailed to:

    Attn: LLRW Tracking Program
    California Department of Public Health
    Radiologic Health Branch MS 7610
    P.O. Box 997414
    Sacramento, CA 95899-7414

29. At least 30 days prior to vacating any address of use listed in Condition 10 of this license, the licensee shall provide written notification thereof to the California Department of Public Health, in accordance with Title 17, California Code of Regulations, Section 30256 (b).

**RADIOACTIVE MATERIAL LICENSE**

License Number: 7809-34
Amendment Number: 6

30. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 6305 Coyle Ave., Carmichael, CA.

Issued for the State of California Department of Public Health

Date: July 16, 2012 By: _____

Radiologic Health Branch
MS 7610, P.O. Box 997414
Sacramento, CA 95899-7414

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

# ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

| Name and Address of Applicant and/or Licensee | Date |
|---|---|
| Bridgeport Hospital<br>ATTN: Michael R. Tatta, Admin. Dir.<br>267 Grant Street<br>Bridgeport, CT 06610-0120 | July 19, 2016 |
| | **License Number(s)**<br>06-01060-01 |
| | **Mail Control Number(s)**<br>591458 |
| | **Licensing and/or Technical Reviewer or Branch**<br>Medical Branch (Branch 1) |

**This is to acknowledge receipt of your:** ☑ **Letter and/or** ☐ **Application** **Dated:** 07/05/2016

**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**