

Hill, Carol

From: Hirata, Emily <ehirata@queens.org>
Sent: Tuesday, May 12, 2015 3:11 PM
To: Hill, Carol
Cc: CHADWICK, DARLENA
Subject: Notification of Temporary RSO -- part 1/3
Attachments: QMCletter-TempRSO-2015May.pdf

Dear Ms. Hill,

In accordance with the requirements of 35.14(b), we are notifying the Commission of the appointment of Blaine T. Ikeda as temporary Radiation Safety Officer at the Queen's Medical Center for the following licenses:

- 53-16533-02
- 53-16533-04MD
- 53-29377-03

Attached to this email is the signed letter of this notification and that authority and responsibility for ensuring the safe use of radiation at The Queen's Medical Center has been delegated to Blaine Ikeda. I'm also enclosing copies of the licenses on which Blaine Ikeda is listed as an authorized nuclear pharmacist (53-16533-04MD) and Radiation Safety Officer (53-29217-01MD.)

(Due to file size limits with email, I'll be sending copies of the NRC licenses separately.)

If you have any questions or require additional information, please don't hesitate to contact me.

Best regards,
Emily

Emily Hirata, MS DABR
Chief Medical Physicist
The Queen's Medical Center
Office: (808) 691-7346
Fax: (808) 691-4507

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: PHL Date: 6-2-15



THE QUEEN'S MEDICAL CENTER

1301 Punchbowl Street ▪ Honolulu, Hawaii 96813 ▪ Phone (808) 538-9011 ▪ FAX: (808) 691-4646 ▪ www.queens.org

May 7, 2015

United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-4005

RE: Notification Pursuant to 35.14(b)(2)
Appointment of Temporary RSO
The Queen's Medical Center
NRC License No. **53-16533-02,**
53-16533-04MD, and
53-29377-03

Dear Sir/Madam:

Pursuant to requirements of 35.14(b), we hereby notify the Commission of appointment of Blaine T. Ikeda as temporary Radiation Safety Officer for the above referenced licenses.

Blaine T. Ikeda is currently listed as:

- Authorized nuclear pharmacist and radiation safety officer on NRC license **53-29217-01MD**, and
- Authorized nuclear pharmacist on NRC license **53-16533-04MD**

We have enclosed copies of the above licenses (53-29217-01MD and 53-16533-04MD).

Blaine T. Ikeda has been delegated the authority and responsibility for ensuring the safe use of radiation at The Queen's Medical Center ("QMC"), which includes identifying radiation safety problems; initiating, recommending, or providing corrective actions; stopping unsafe operations; verifying implementation of corrective actions; and ensuring compliance with procedures approved by QMC and applicable governmental regulations.

Blaine T. Ikeda is delegated the authority necessary to meet these responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety protocols.

Thank you for your cooperation. If you have any questions or require additional information, please contact our Chief Medical Physicist, Emily Hirata at 808-691-7346 or Darlena Chadwick at 808-691-4742.

Sincerely,

Darlena Chadwick, MSN, MBA, FACHE
Vice President, Patient Care
Oncology/Neuroscience/Pharmacy/Gastroenterology/Pathology/Professional Services

Hill, Carol

From: Hirata, Emily <ehirata@queens.org>
Sent: Tuesday, May 12, 2015 3:12 PM
To: Hill, Carol
Subject: Notification of Temporary RSO -- part 2/3
Attachments: NRC-RML-53-29217-01MD-Amd03-PharmaRx-exp2015.pdf

Dear Ms. Hill,

Enclosed is a copy of the license on which Blaine Ikeda is listed as Radiation Safety Officer (53-29217-01MD.)

If you have any questions or require additional information, please don't hesitate to contact me.

Best regards,
Emily

Emily Hirata, MS DABR
Chief Medical Physicist
The Queen's Medical Center
Office: (808) 691-7346
Fax: (808) 691-4507

Hill, Carol

From: Hirata, Emily <ehirata@queens.org>
Sent: Tuesday, May 12, 2015 3:13 PM
To: Hill, Carol
Subject: Notification of Temporary RSO -- part 3/3
Attachments: NRC-RML-53-16533-04MD-exp2020.pdf

Dear Ms. Hill,

Enclosed is a copy of the license on which Blaine Ikeda is listed as an authorized nuclear pharmacist (53-16533-04MD).

If you have any questions or require additional information, please don't hesitate to contact me.

Best regards,
Emily

Emily Hirata, MS DABR
Chief Medical Physicist
The Queen's Medical Center
Office: (808) 691-7346
Fax: (808) 691-4507

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. The Queen's Medical Center	3. License number 53-16533-04MD
2. 1301 Punchbowl Street Honolulu, Hawaii 96813	4. Expiration date June 30, 2020
	5. Docket No. 030-38265 Reference No.

6. Byproduct, source, and/or special nuclear material

Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

A. Fluorine-18

A. Any

20 curies

B. Any byproduct material authorized under 10 CFR 35.65

B. Sealed Source

B. 10 millicuries

9. Authorized use:

A. Preparation and distribution of radioactive drugs and radiopharmaceuticals for medical use in accordance with 10 CFR 32.72.

B. Calibration and checking of the licensee's instruments.

★ ★ ★ CONDITIONS ★ ★ ★

10. Licensed material shall be used or stored only at the licensee's facilities located at 1301 Punchbowl Street, Honolulu, Hawaii

11. Licensed material shall be used by, or under the supervision of:

A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) and (4), or

B. Authorized Nuclear Pharmacist(s): Blaine T. Ikeda, PharmD.

12. The Radiation Safety Officer for this license is Brian Oyadomari.

13. This license does not authorize distribution to persons exempt from licensing.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
53-16533-04MDDocket or Reference Number
030-38265

14. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 Becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 612 East Lamar Boulevard, Suite 400, Arlington, Texas 76011-4125, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.
15. Sealed sources containing licensed materials shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
16. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 31.210 or by an Agreement State.
17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days from decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
53-16533-04MDDocket or Reference Number
030-38265

- B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee;
- C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
19. The licensee is authorized to retrieve, receive, and dispose of radioactive waste from its customers limited to radiopharmacy-supplied syringes and vials and their contents.
20. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
21. 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. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated March 11, 2010 [ML100840679]
B. Letter dated April 9, 2010 [ML101536068]
C. Letter dated May 25, 2010 [ML101530081]



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date June 3, 2010

By

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4125

16 586952



DATE

06/02/2015

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Blaine T. Ikeda
Radiation Safety Officer
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, Hawaii 96813

LICENSE NUMBER

53-16533-04MD

MAIL CONTROL NUMBER

586952

LICENSING AND/OR TECHNICAL REVIEWER

CH

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION DATED: 05/07/2015

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 fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

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 IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

✓ 6/2

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02500
Status Code: Pending Amendment
Fee Category: 3C
Exp. Date:
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: QUEEN'S MEDICAL CENTER, THE
Received Date: 05/12/2015
Docket Number: 3038265
Mail Control Number: 586952
License Number: 53-16533-04MD
Action Type: Notifications

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____