U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 81

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, 37, 39, 40, 70 and 71, 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	In accordance with letter dated September 26, 2019.	4. Expiration Date: March 31, 2025
1. Kaiser Foundation Hospital Diagnostic Imaging Department		5. Docket No.: 030-03546 Reference No.:
2. 3288 Moanalua Road Honolulu, HI 96819	3. License number: 53-05379-01 is amended in its entirety to read as follows:	

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 6 curies total	C. For any use permitted by 10 CFR 35.300.
D. Yttrium-90 permitted by 10 CFR 35.1000	D. Microspheres (manufacturer as listed in Sealed Source and Device Registry NR-0220-D-131-S, TheraSphere,)	D. 540 millicuries per vial and 3 curies total	D. TheraSphere for permanent brachytherapy using delivery system as listed in Sealed Source and Device Registry NR-0220-D-131-S

CONDITIONS

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10. Licensed material may be used or stored at the licensee's facilities located at 3288 Moanalua Road, Honolulu, Hawaii, 96819 (Island of Oahu).

11. The Radiation Safety Officer (RSO) for this license is Harry F. Palmer, M.C.E.

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

A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists in accordance with 10 CFR 35.13 and 10 CFR 35.14.

B. The following individuals are authorized users for the material and medical uses as indicated:

Authorized Users	Material and Use
Peter Abcarian, M.D.	35.100; 35.200
Bradford S. Burton, M.D.	35.100; 35.200
Daniel C. Henshaw, M.D.	35.100; 35.200; 35.300
Steven W. Hong, M.D.	35.100; 35.200; 35.300
Shane Inoue, M.D.	35.100; 35.200; 35.300
Taylor L. McDonald, M.D.	35.100; 35.200; oral administration of sodium iodide I-131
Lex Mitchell, M.D.	35.100; 35.200
Mitchell A. Moy, M.D.	35.100; 35.200; oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries; Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
Felix Lee Song, M.D.	35.100; 35.200

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Authorized Users	Material and Use
Jayme M. Takahashi, M.D.	35.100; 35.200; oral administration of sodium iodide I-131; Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
Kristi S.M. Takaki, M.D.	35.100; 35.200; oral administration of sodium iodide I-131; Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required.
John T. Watabe, M.D.	35.100; 35.200
Samuel M.H. Wu, M.D.	35.100; 35.200; 35.300; 35.1000 Y-90 TheraSphere use

13. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

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 the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

C. 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 the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

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E. 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.

F. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) 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.

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.

14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

15. The licensee shall conduct a physical inventory every 6 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 3 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.

16. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

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17. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 December 10, 2014 (ML15016A208)

B. Letter dated June 1, 2018 (ML18177A159)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: December 12, 2019

By: /RA/

Michelle R. Simmons
Region 4