



March 12, 2020

Carol Hill, Licensing Assistant
Nuclear Materials Safety Branch B
United States Nuclear Regulatory Commission Region IV
(Attn: Michelle Simmons, Health Physicist)
1600 East Lamar Blvd.
Arlington, Texas 76011-4511
817-200-1590

Re: Kaiser Foundation Hospitals, NRC License No. 53-05379-01 ("NRC License")
Kaiser Foundation Hospitals, State of Hawaii Facility License H0026 ("DOH License")
Supplemental information for authorization of Dr. Lex Mitchell for 10CFR35.300

Dear Ms. Simmons,

I'm enclosing the additional information you asked for on the phone on March 2, 2020, after our letter of 12/19/19 which requested amendment of the above license to add Dr. Lex Mitchell as an Authorized User under 10CFR35.300 for I-131 therapies and parenteral administrations.


I am attaching three Written Directives for mentored I-131 therapies > 33mCi and three for mentored parenteral administrations (six in all), with patient identification redacted. For ease I am attaching a copy of the above license showing the mentoring physicians as appropriately authorized.

The three cases for I-131 > 33mCi were mentored by Dr. Kristi Takaki.
One Xofigo case was also mentored by Dr. Takaki.
One Xofigo case and the Lutathera case were mentored by Dr. Daniel Henshaw.

I'm enclosing a copy of the above NRC license showing them to be Authorized Users for the uses for the cases in which they were mentors.

If you need any additional information, please let me know at the above address or saddhu809@gmail.com (808-226-1961cell).

Sincerely,


Harry Palmer M.C.E., R.S.O.
DI Administration
Kaiser Permanente
3288 Moanalua Rd.
Honolulu, HI 96819

cc: Lex Mitchell M.D., Daniel Henshaw M.D., Kristi Takaki M.D., Robert Diaz, Jeff Eckerd, State of Hawaii

Enclosures: Six redacted Written Directives, Copy of NRC License

Kaiser Permanente
3288 Moanalua Road
Honolulu, Hawaii 96819
Phone: (808) 432-0000

QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

This form is required for these specific radiopharmaceuticals:

- a. Sodium Iodide-125 > 30 microcuries (uCi)
- b. Sodium Iodide-131 > 30 microcuries (uCi)
- c. All Therapy Doses

****This form must be completed before administering the dosage!**

I.

Radiopharmaceutical:
Chemical Form:

Administration Route:

I-131
Sodium
Iodide
Oral

P-32
Sodium
Phosphate
I.V.

Sm-153
Samarium
Lexidronam
I.V.

Sr-89
Strontium
Chloride
I.V.

Y-90
Ibritumomate
Tiuxetan(Zevalin)
I.V.

Radiopharmaceutical:
Chemical Form:
Administration Route:

Y-90
Theraspheres
I.A.

Lu-177
Lutetium
I.V.

Ra223
Dichloride (Xofigo)
I.V.

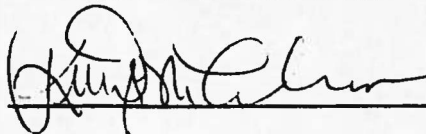
Prescribed Dose:

150 mCi

Date

3-4-2020

Authorized User:



**QUALITY MANAGEMENT PROGRAM
 WRITTEN DIRECTIVE**

This form is required for these specific radiopharmaceuticals:

- a. Sodium Iodide-125 > 30 microcuries (uCi)
- b. Sodium Iodide-131 > 30 microcuries (uCi)
- c. All Therapy Doses

****This form must be completed before administering the dosage!**

I. Written Directive

MR#: _____

Radiopharmaceutical:	I-131	P-32	Sm-153	Sr-89	Y-90
Chemical Form:	Sodium Iodide	Sodium Phosphate	Samarium Lexidronam	Strontium Chloride	Ibritumomate Tiuxetan(Zevalin)
Administration Route:	Oral	I.V.	I.V.	I.V.	I.V.

Radiopharmaceutical:	Y-90	Lu-177	Ra223
Chemical Form:	Theraspheres	Lutetetium	Dichloride (Xofigo)
Administration Route:	I.A.	I.V.	I.V.

Prescribed Dose: _____

150 mCi

Date

2/21/2020

Authorized User: _____

[Signature]

QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

This form is required for these specific radiopharmaceuticals:

- a. Sodium Iodide-125 > 30 microcuries (uCi)
- b. Sodium Iodide-131 > 30 microcuries (uCi)
- c. All Therapy Doses

****This form must be completed before administering the dosage!**

I. Written Directive

MR#:

Radiopharmaceutical:	I-131	P-32	Sm-153	Sr-89	Y-90
Chemical Form:	Sodium Iodide	Sodium Phosphate	Samarium Lexidronam	Strontium Chloride	Ibritumomate Tiuxetan(Zevalin)
Administration Route:	Oral	I.V.	I.V.	I.V.	I.V.

Radiopharmaceutical:	Y-90	Lu-177	Ra223
Chemical Form:	Theraspheres	Lutetetium	Dichloride (Xofigo)
Administration Route:	I.A.	I.V.	I.V.

Prescribed Dose:

2.00 mCi Date 3/12/2020

Authorized User:

[Signature]

QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

This form is required for these specific radiopharmaceuticals:

- a. Sodium Iodide-125 > 30 microcuries (uCi)
- b. Sodium Iodide-131 > 30 microcuries (uCi)
- c. All Therapy Doses

****This form must be completed before administering the dosage!**

Patient: _____

Radiopharmaceutical:	I-131	P-32	Sm-153	Sr-89	Y-90
Chemical Form:	Sodium Iodide	Sodium Phosphate	Samarium Lexidronam	Strontium Chloride	Ibritumomate Tiuxetan(Zevalin)
Administration Route:	Oral	I.V.	I.V.	I.V.	I.V.

Radiopharmaceutical:	Y-90	Lu-177	Ra223
Chemical Form:	Theraspheres	Lutetetium	Dichloride (Xofigo)
Administration Route:	I.A.	I.V.	I.V.

Prescribed Dose: 96.7 micro Ci Date 1/14/2020

Authorized User: _____

[Signature]
Dr C New M.D.

QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

This form is required for these specific radiopharmaceuticals:

- a. Sodium Iodide-125 > 30 microcuries (uCi)
- b. Sodium Iodide-131 > 30 microcuries (uCi)
- c. All Therapy Doses

****This form must be completed before administering the dosage!**

I. Written Directive

MR#: _____

Radiopharmaceutical:	I-131	P-32	Sm-153	Sr-89	Y-90
Chemical Form:	Sodium Iodide	Sodium Phosphate	Samarium Lexidronam	Strontium Chloride	Ibritumomate Tiuxetan(Zevalin)
Administration Route:	Oral	I.V.	I.V.	I.V.	I.V.

Radiopharmaceutical:	Y-90	Lu-177	Ra223
Chemical Form:	Theraspheres	Lutetium	Dichloride (Xofigo)
Administration Route:	I.A.	I.V.	I.V.

Prescribed Dose: _____

71.5 microCi Date 12/12/19

Authorized User: _____

the C/M

QUALITY MANAGEMENT PROGRAM
WRITTEN DIRECTIVE

This form is required for these specific radiopharmaceuticals:

- a. Sodium Iodide-125 > 30 microcuries (uCi)
- ☒ b. Sodium Iodide-131 > 30 microcuries (uCi)
- c. All Therapy Doses

****This form must be completed before administering the dosage!**

I. Written Directive

Patient:

Radiopharmaceutical:	I-131	P-32	Sm-153	Sr-89	Y-90
Chemical Form:	Sodium Iodide	Sodium Phosphate	Samarium Lexidronam	Strontium Chloride	Ibritumomate Tiuxetan (Zevalin)
Administration Route:	Oral	I.V.	I.V.	I.V.	I.V.

Radiopharmaceutical:	Y-90	Lu-177	Ra223
Chemical Form:	Theraspheres	Lutetium	Dichloride (Xofigo)
Administration Route:	I.A.	I.V.	I.V.

Prescribed Dose:

200 mCi

Date

1/30/20

Authorized User:

[Signature]

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 1. Kaiser Foundation Hospital Diagnostic Imaging Department 2. 3288 Moanalua Road Honolulu, HI 96819		In accordance with letter dated September 26, 2019.	4. Expiration Date: March 31, 2025
			5. Docket No.: 030-03546 Reference No.:
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

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

53-05379-01

Amendment No. 81

Docket or Reference Number

030-03546

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:
- | <u>Authorized Users</u> | <u>Material and Use</u> |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

53-05379-01

Docket or Reference Number

030-03546

Amendment No. 81

Authorized Users

Jayme M. Takahashi, M.D.

Kristi S.M. Takaki, M.D.

John T. Watabe, M.D.

Samuel M.H. Wu, M.D.

Material and Use

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.

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.

35.100; 35.200

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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

53-05379-01

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Amendment No. 81

- 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

53-05379-01

Amendment No. 81

Docket or Reference Number

030-03546

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)

Date: December 12, 2019

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

By: 

Michelle R. Simmons
Region 4