888 South King Street • Honolulu, HI 96813

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October 26, 2016

Nuclear Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region IV
1600 E. Lamar Blvd.
Arlington, TX 76011-4511

Subject: Notification
NRC License No. 53-18126-01
Docket No. 030-14529

Dear License Reviewer:

We have approved Kristi Takaki, M.D. for use of byproduct materials listed in 10 CFR 35.100, 35.200, and 35.300. Dr. Takaki is currently authorized for use of byproduct materials listed in 10 CFR 35.100 and 35.200 on NRC License #53-35181-01 issued to issued to InSight Imaging. A copy of this license is enclosed. Dr.. Takaki was certified in Nuclear Medicine by the American Board of Nuclear Medicine in 2010. A copy of her certification and completed 313A(AUT) form are enclosed.

If you require any additional information please contact our Radiation Safety Officer, Ronald Frick at 808-373-7009.

Sincerely,

Art Gladstone
Chief Executive Officer

Enclosures

NRC FORM 374 PAGE 1 OF 2 PAGES

U.S. NUCLEAR REGULATORY COMMISSION Amendment No. 02

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. Hawaii Pacific Imaging, LLC dba InSight Imaging	In accordance with letter dated April 13, 2016 3. License Number 53-35181-01 is amended in its entirety to read as follows:
2. 500 Ala Moana Boulevard, Suite #5B Honolulu, Hawaii 96813	4. Expiration date December 31, 2024
	5. Docket Number: 030-38778 Reference Number:

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
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 500 Ala Moana Boulevard, Suite #5B, Honolulu, Hawaii (Island of Oahu).

11. The Radiation Safety Officer for this license is Ronald Frick.

12. Licensed material is only authorized for use by, or under the supervision of:

A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
53-35181-01

Docket or Reference Number
030-38778

Amendment No. 02

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

Authorized Users	Material and Use
Kristi Takaki, M.D.	35.100; 35.200

13. 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 financial assurance for decommissioning.

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. 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 received September 24, 2014 (ML14287A712)
B. Email dated October 23, 2014 (ML14300A637)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date April 25, 2016

By _____
Roberto J. Torres, M.S., Senior Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4511

The American Board of Nuclear Medicine

Incorporated 1971

Certifies that

Kristi Sumie Michele Takaki, M.D.

has met the requirements of this Board and is qualified
during the period of 2010 through 2020 to practice as a Specialist
in all aspects of Clinical and Laboratory

Nuclear Medicine

Maintenance of this certificate requires full participation in the ABNM's
Maintenance of Certification program.

Barry L. Shulkin, M.D., MBA.
Chairman

Kirk A. Frey, M.D., Ph.D.,
Secretary-Treasurer

7959
Number

United States

NRC FORM 313A (AUT)
(06-2016)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.300)
[10 CFR 35.390, 35.392, 35.394, and 35.396]

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

Name of Proposed Authorized User	State or Territory Where Licensed
Kristi Takaki, M.D.	Hawaii

Requested Authorization(s) *(check all that apply)*:

☐ 35.300 Use of unsealed byproduct material for which a written directive is required

OR

☒ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☒ 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

☒ 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☒ 35.300 Parenteral administration of any other radionuclide for which a written directive is required

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☒ **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

☐ **2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.490 ☐ 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☒ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of Washington	30	7/1/2009 6/30/2010
Radiation protection	"	4	
Mathematics pertaining to the use and measurement of radioactivity	"	12	
Chemistry of byproduct material for medical use	"	29	
Radiation biology	"	4	
	Total Hours of Training: 322	Includes Nuclear Med Didactics	

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience	**Total Hours of Experience:** 1960 hours		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University of Washington WN-C001-1	☒ Yes ☐ No	7/1/2009 6/30/2010
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	"	☒ Yes ☐ No	"
Calculating, measuring, and safely preparing patient or human research subject dosages	"	☒ Yes ☐ No	"
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	"	☒ Yes ☐ No	"
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	"	☒ Yes ☐ No	"

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued).

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
David H. Lewis, MD	UW / WN-C001-1

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

- ☑ 35.390
- ☑ 35.392
- ☑ 35.394
- ☑ 35.396

With experience administering dosages of:

- ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☑ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	10	Univerisity of Washington	2009-2010
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	6	University of Washington	2009-2010
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	1		2010
Parenteral administration of any other radionuclide for which a written directive is required Yytrium 90 Zevalin (List radionuclides)	3	University of Washington	2009-2010

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
David H. Lewis MD	WN-C001-1

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☑ 35.390 ☑ 35.392 ☑ 35.394 ☑ 35.396	With experience administering dosages of: ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required ☑ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☑ I attest that Kristi Takaki, M.D. has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☑ I attest that Kristi Takaki, MD has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☑ I attest that Kristi Takaki, MD has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

☑ I attest that Kristi Takaki, M.D. has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

Third Section

☑ I attest that Kristi Takaki, M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☑ I attest that Kristi Takaki, MD is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☑ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☑ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☑ I attest that Kristi Takaki, MD has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☑ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☑ Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section
Complete the following for preceptor attestation and signature:

☑ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.390 ☑ 35.392 ☑ 35.394 ☐ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
David A. Lewis, MD	David A. Lewis, MD	2067443471	9/26/16
License/Permit Number/Facility Name			
WN-C001-1 University of Washington			

Hill, Carol

From: Ronald Frick <rfrick@gammacorp.com>
Sent: Tuesday, November 01, 2016 5:35 PM
To: Hill, Carol
Subject: [External_Sender] New Authorized User for Straub Clinic & Hospital
Attachments: NRC amendment ltr Dr Takaki.pdf

Hi Carol,
I have attached a notification letter from Straub Clinic & Hospital which adds a new Authorized User.
Please contact me if you need additional information.
Thank you,
Ron Frick
Gamma Corporation
rfrick@gammacorp.com
808-373-7009