

JUN - 1 2012

DNMS

May 10, 2012

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

Docket: 030-03546
License: 53-05379-01

RE: Amendment for 35.394 Use for Current Authorized User

Greetings:

In accordance with 10 CFR 35.14(a), please amend our NRC License to add the category of use specified in 35.394 for the following current Authorized User:

Physician Name: David Kho, M.D.
Amendment request: Oral administration of sodium iodide I-131 greater than 33 mCi

Please find enclosed a copy of the completed form 313A(AUT) signed by a preceptor to document the additional case requirements to satisfy 10 CFR 35.394 requirement.

Please contact our Radiation Safety Officer, Brian Oyadomari, at 808-432-7328, or by email at Brian.T.Oyadomari@kp.org for any additional information to facilitate this amendment. Thank you very much.

Sincerely,



Robert Diaz
Director of Diagnostic Imaging
Kaiser Foundation Hospital-Hawaii

PUBLIC

- ☐ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A3 Sensitive-Security Related
☐ A7 Sensitive Internal
☐ Other: _____

Reviewer: *file* Date: 7/18/12

Attached:

1. Form 313A(AUT) for David Kho, MD

**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: 3/31/2012

Name of Proposed Authorized User

Dr. David Kho

State or Territory Where Licensed

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 53-05379-01 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.

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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
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input type="checkbox"/> 35.390 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input type="checkbox"/> 35.396	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required <input type="checkbox"/> 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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	1	Kaiser Foundation Hospital 3288 Moanalua Road Honolulu, HI 96819 Lic.No. 53-05379-01	11/01/2011
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			
(List radionuclides)			

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
Steven W. Hong, M.D.	53-05379-01
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input checked="" type="checkbox"/> 35.390	With experience administering dosages of:
<input checked="" type="checkbox"/> 35.392	<input checked="" type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input checked="" type="checkbox"/> 35.394	<input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input checked="" type="checkbox"/> 35.396	<input checked="" type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input type="checkbox"/> 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 David Kho, M.D. has satisfactorily completed the training and experience requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).
Name of Proposed Authorized User

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 _____ 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 _____ 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 David Kho, 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 Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☒ Oral Nal-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 David Kho, M.D. has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

- ☐ Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☒ Oral Nal-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 _____ 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 _____ 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

Steven W. Hong, M.D.

Signature

Steven W. Hong

Telephone Number

432-7342

Date

5/24/12

License/Permit Number/Facility Name

53-05379-01

**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. 3160-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

DR DAIMO KHO

State or Territory Where Licensed

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 160 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 (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Stephen Scharf, M.D.	NYC 91-2926-01
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input checked="" type="checkbox"/> 35.390	With experience administering dosages of:
<input checked="" type="checkbox"/> 35.392	<input checked="" type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input checked="" type="checkbox"/> 35.394	<input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input checked="" type="checkbox"/> 35.396	<input checked="" type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input checked="" type="checkbox"/> 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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	2	Lenox Hill Hospital New York City, NY 91-2926-01	09-2009
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			
(List radionuclides)			

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
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input type="checkbox"/> 35.390 : With experience administering dosages of:	
<input type="checkbox"/> 35.392	<input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394	<input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.398	<input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input type="checkbox"/> 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 DAVID KCHO has satisfactorily completed the training and experience requirements in 35.390(a)(1).

Name of Proposed Authorized User

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

Name of Proposed Authorized User

577620

Kaiser Foundation Hospital
3288 Moanalua Road
Honolulu, Hawaii 96819

Address Service Requested



Nuclear Materials Licensing Branch
U.S. NRC Region IV
1600 East Lamar Blvd
Arlington, TX 76011-4511



7601194511 C002





DATE

06/05/2012

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Kaiser Foundation Hospital
Diagnostic Imaging Department
ATTN: Brian Oyadomari RSO
3288 Moanalua Road
Honolulu, HI 96819

LICENSE NUMBER

53-05379-01

MAIL CONTROL NUMBER

577620

LICENSING AND/OR TECHNICAL REVIEWER

cmurnahan *CM*

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION DATED: 05/10/2012

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

*e-mailed to licensee
6-5-2012 CM*

Murnahan, Colleen

From: Murnahan, Colleen
Sent: Friday, June 08, 2012 2:47 PM
To: 'Brian.T.Oyadomari@kp.org'
Subject: Request for Additional Information - 53-05379-01

030-03546
53-05379-01
577620

Brian,

Please provide a copy of the New York City license 91-2926-01 where Dr. Stephen Scharf appears as an authorized user. **If the license is a broad scope, also provide a letter from the Chairperson stating Dr. Scharf's authorizations on the license.** It may be sent as a .pdf file attached to an e-mail addressed to me or faxed to my attention at the number below. **Please refer to Mail Control No. 577620 in your response.**

Thank you for your cooperation.

Colleen Murnahan, Licensing Assistant

Direct: 817-200-1103
Toll Free: 1-800-952-9677
Fax: 817-200-1263
E-mail: Colleen.Murnahan@nrc.gov

US Nuclear Regulatory Commission
1600 E. Lamar Blvd.
Arlington, TX 76011-4511



BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM LTS

Program Code: 02240
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 04/30/2015
Fee Comments: CODE 23
Decom Fin Assur Req: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: KAISER FOUNDATION HOSPITAL
Received Date: 06/01/2012
Docket Number: 3003546
Mail Control Number: 577620
License Number: 53-05379-01
Action Type: Amendment

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: _____