

December 4, 2017

Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406-1415
Attn: Medical Licensing

RE: Amendment Request to add AU (Lic. No. 06-00854-03)/03001246

Dear Medical Licensing Staff,

Saint Francis Hospital and Medical Center requests the addition of a physician, David James Grew MD, as an Authorized User for the following:

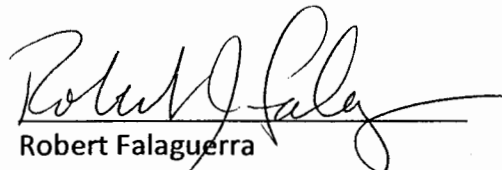
- 35.300 Parenteral administration of any beta emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required, and
- 35.300 Parenteral administration of any other radionuclide for which a written directive is required

Please find attached, a completed Form 313A(AUT), Administration Logs for Dr. Grew, and ABR documentation.

If you have any questions or require additional information, please do not hesitate to contact us.

Sincerely,


Gregory S. Hisel, CHP
Radiation Safety Officer
St Francis Hospital and Medical Center
114 Woodland Street
Hartford, CT 06105
Cell: 518-755-7465
Email: ghisel@stfranciscare.org


Robert Falaguerra
Vice President
Facilities, Support Services, and Construction
St Francis Hospital and Medical Center
114 Woodland Street
Hartford, CT 06105
Tel: 860-714-5400

REC PG 1 12 15 17 40745

602092

INTERNAL USE ONLY



**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

David James Grew MD

State or Territory Where Licensed

Connecticut

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 (continued)

b. Supervised Work Experience (continued)

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Kevin Du MD

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

- 35.390 With experience administering dosages of:
- 35.392 Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- 35.394 Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- 35.396 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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	5	NYU Dept of Radiation Oncology	2015
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	4	NYU Dept of Radiation Oncology	2015
Parenteral administration of any other radionuclide for which a written directive is required	1	NYU Dept of Radiation Oncology	2015
<div style="border: 1px solid black; padding: 2px;">Radium 223</div> <p>(Let radionuclides)</p>			

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)**:

- 35.390 With experience administering dosages of:
 - 35.392 Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
 - 35.394 Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
 - 35.386 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 David Grew MD 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 Grew MD 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 David Grew MD 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 35.398:

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 35.398 (d)(1), and the supervised work and clinical case experience required by 35.398(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 **David Grew MD** has satisfactorily completed the board certification

Name of Proposed Authorized User

requirements of 35.398(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.398 (d)(1) and the supervised work and clinical case experience required by 35.398(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

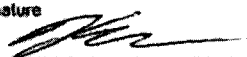
I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

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 KEVIN DU	Signature 	Telephone Number (212) 731-5003	Date 7/28/17
License/Permit Number/Facility Name NYS 261756 / NYU LANGONE MEDICAL CENTER			



5441 E. Williams Blvd. Suite 200 Tucson, Arizona 85711 Phone: (320) 799-2960 Fax: (320) 799-3300 Website: www.abr.org

June 25, 2015

Residency Program: 33-08-30-3

67900

Kevin Lee Du, MD

David James Grew, MD

Dear Dr. Du

The above named physician has indicated that training in your program will be completed prior to September 30. Since this candidate's admissibility to the board examination process is contingent upon having fulfilled the training requirements, please respond to the following and return this form to our office IMMEDIATELY.

Is this resident still in your department?

Yes No

If No...

What was the date of termination or completion?

6 30 2015
Month Day Year

How many months did the resident satisfactorily complete in your program?

48
Months

Has this resident resumed training in another program?

Yes No

If Yes...

If known, please indicate name and address of new institution.

For those applicants who have completed the essential training requirements:

I verify the initiation and completion dates noted above and verify that the applicant has completed 48 months of training in radiation oncology, including at least 36 months in clinical radiation oncology (except Holman Pathway residents who require only 27 months in clinical radiation oncology) with adequate exposure to medical oncology, diagnostic radiology and pathology through multidisciplinary tumor board attendance and/or formal rotations

Program Director Signature

[Signature]
Printed name Kevin Du, MD, PhD

Date

9/1/15

I have reviewed the case logs of the applicant and verify that they have completed the essential training requirements defined by the RRC in Radiation Oncology in (Please initial each line or submit the indicated log):

External beam irradiation (at least 450 simulations)

KD

Interstitial radiation (at least 6 cases)

KD

Intracavitary radiation (at least 15 insertions)

KD

Unsealed sources (3 oral I131 and 3 Perlonera) Submit log

Program Director

[Signature]

Date

9/1/15

For those applicants who have NOT completed the essential training requirements:

I have reviewed the case logs of the applicant and verify that they have completed all of the essential training requirements in external beam radiation, interstitial, intracavitary radiation and unsealed sources except the following: (Please list specific procedures and the deficient quantity, e.g., 10 External Beam Radiation Therapy Cases)

Arrangements have been made for the applicant to complete these procedures before September 30 and he/she will submit documentation of completion for review prior to the scheduled oral examination.

Program Director

Date

**Radiation Oncology
Oral I-131 & Parenteral Administration Log**

DAVID GREW NYU 4303521067
Resident Name Program Program #

Date	Disorder	Radionuclide	Dose Administered	Preceptor Name/Signature
<u>Oral I-131</u> (>33 mCi)				
1. <u>6/24/15</u>	<u>Thyroid Ca</u>	<u>I-131</u>	<u>150mCi</u>	<u>M. Ales</u>
2. <u>6/25/15</u>	<u>Thyroid Ca</u>	<u>I-131</u>	<u>100 mCi</u>	<u>Fabio Ponzo</u>
3. _____	_____	<u>I-131</u>	_____	_____
<u>Parenteral</u>				
1. <u>6/23/15</u>	<u>Liver Met. (Melanoma)</u>	<u>Y90</u>	<u>30mCi</u>	<u>DNYA SRIDHAR</u>
2. <u>6/23/15</u>	<u>HCC</u>	<u>Y90</u>	<u>17mCi</u>	<u>Fabio Ponzo</u>
3. _____	_____	_____	_____	_____

**Radiation Oncology
Oral I-131 & Parenteral Administration Log**

DAVID GREW NYU 4303521067
 Resident Name Program Program #
 4303521067

Date	Disorder	Radionuclide	Dose Administered	Preceptor Name/Signature
Oral I-131 (>33 mCi)				
1. 4/23/15	Thyroid Cancer	I-131	450 mCi	F. Panzo
2. 5/6/15	Thyroid Cancer	I-131	130 mCi	panzo
3. 5/28/15	Thyroid Cancer	I-131	248 mCi	KFTZ
Parenteral				
1. 5/6/15	Prostate Ca.	Ra223	130 ^{µCi} mCi	KFTZ
2. 5/12/15	Hepatocellular Ca.	Y-90	27 mCi	Y/ma
3. 6/11/15	HCC	Y-90	5 mCi	Y/ma

Case Log

Carcinoma
Ermelinin

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Radiation Oncology, the Association of University Radiologists,
the American Association of Physicists in Medicine, and the Society of Interventional Radiology,
the American Board of Radiology hereby certifies that

David James Grew, MD

Has pursued an accepted course of graduate study and clinical work, has met certain standards
and qualifications, including passing the examinations conducted under the authority of
the American Board of Radiology, demonstrating to the satisfaction of the Board qualification
to practice, and is therefore awarded the Board's certification in

Radiation Oncology

All Eligible



Certificate No. 67900

Ongoing validity of this certificate is contingent upon
meeting the requirements of Maintenance of Certification

This diplomate of the American Board of Radiology
is permitted to use the **DAOR** mark to signify this certification.

DAOR



Milton J. Sobotca, MD
President

S. P. ...
Secretary-Treasurer

Valerie B. Johnson, MD
Executive Director

Effective: May 17, 2016



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

St. Francis Hospital and Medical Center
ATTN: Robert J. Falaguerra, VP, Facilities,
Support Services and Construction
114 Woodland Street
Hartford, CT 06105-1299

Date

January 5, 2018

License Number(s)

06-00854-03

Mail Control Number(s)

602092

Licensing and/or Technical Reviewer or Branch

Medical Branch (Branch 1)

This is to acknowledge receipt of your: Letter and/or Application Dated: 12/04/2017

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 complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

The following administrative omissions have been identified:

[Empty box for administrative omissions]

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 I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239