

THE
University of Vermont
MEDICAL CENTER

November 21, 2018

Nuclear Materials Safety Section
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard
King of Prussia, PA 19406

Br.1

RE: University of Vermont Medical Center
License # 44-10187-03 / 03003289

REC'D 11/29/18 PM 02:02

We request that our license be amended as follows:

- 1) Please remove the following Authorized Users (AU) from our radioactive materials license:
 - a. Daniel K. Fram, M.D. has discontinued his AU status for brachytherapy procedures (35.400) performed at The University of Vermont Medical Center.
 - b. Deborah Rubin, M.D. has discontinued her AU status for brachytherapy procedures (35.400) and HDR procedures (35.600) performed at The University of Vermont Medical Center.
 - c. Sean Reynolds, M.D. has discontinued his AU status for nuclear medicine procedures (35.100, 35.200, and oral administration of sodium iodide I-131) at The University of Vermont Medical Center.
- 2) Please add Naiim Ali, M.D. as an AU for nuclear medicine procedures, specifically 35.100, 35.200, and oral administration of sodium iodide I-131, performed at The University of Vermont Medical Center. Please find enclosed supporting documents demonstrating that Dr. Ali has met all regulatory requirements for training and clinical experience.
- 3) Please remove the following Authorized Medical Physicists (AMP) from our radioactive materials license:
 - a. Marleen Moore, M.S.
 - b. Christopher Muraski, M.S.
- 4) Please add Matthew Wojtecki, M.S. as an AMP for Iridium-192 in a HDR Remote Afterloader Unit for calibrations, spot-checks, and training at The University of Vermont Medical Center. Please find enclosed the supporting documents demonstrating that Mr. Wojtecki meets regulatory requirements for this material use.
- 5) Please remove the four Cobalt-57 custom sources for use in alignment calibration of a patient motion tracking system for SPECT imaging (License items 6.G. and 9.G.). These sources have been removed from our inventory. A copy of the depleted source disposal acknowledgement from Eckert & Ziegler for these four sources (Model# BM00-99) has been enclosed.

610700

UNSCHEM MATERIALS

Thank you for your attention to these items. If you have questions please contact Brian Oyadomari, M.S., Radiation Safety Officer, at (802) 847-4897. All correspondence should be copied to Brian Oyadomari, M.S., Garden Pavilion, ACC 2, The University of Vermont Medical Center.

Sincerely,

A handwritten signature in black ink, appearing to read "Eileen Whalen", followed by a long horizontal flourish.

Eileen Whalen, R.N.
President and Chief Operating Officer
University of Vermont Medical Center

A handwritten signature in black ink, appearing to read "Brian Oyadomari", followed by a long horizontal flourish.

Brian Oyadomari, M.S.
Radiation Safety Officer and Medical Physicist
University of Vermont Medical Center

Attachments:

1. Naiim Ali, M.D., Authorized User Forms 313aud and 313aut
2. Matthew Wojtecki, M.S, Authorized Medical Physicist NY Materials License
3. Depleted Source Disposal Acknowledgement from Eckert & Ziegler

**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

Naiim Ali, M.D.

State or Territory Where Licensed

Vermont

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 Usera. 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 Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401	see attached summary >30	June 2014-June 2018
Radiation protection	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401	see attached summary >20	June 2014-June 2018
Mathematics pertaining to the use and measurement of radioactivity	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401	see attached summary >10	June 2014-June 2018
Chemistry of byproduct material for medical use	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401	see attached summary >10	June 2014-June 2018
Radiation biology	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401	see attached summary >20	June 2014-June 2018
Total Hours of Training:		90	

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: 200

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 Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401 Lic.# 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014-June 2018
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401 Lic.# 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014-June 2018
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401 Lic.# 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014-June 2018
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401 Lic.# 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014-June 2018
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401 Lic.# 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014-June 2018

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

Janusz Karol Kikut, M.D.

Lic.# 44-10187-03

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)	3	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401 Lic.# 44-10187-03	6/3/15, 1/20/16, 9/29/17
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	University of Vermont Medical Center 111 Colchester Avenue, Burlington, VT 05401 Lic.# 44-10187-03	1/20/16, 1/20/16, 7/19/17
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			
<div style="border: 1px solid black; height: 40px; width: 100%;"></div> <p>(List 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

Janusz Karol Kikut, M.D.

Lic.# 44-10187-03

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.

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 _____ 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 Naiim Ali, M.D. 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 Naiim Ali, M.D. 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 Naiim Ali, 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 Naiim Ali, 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 _____ 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

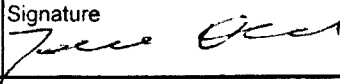
Complete the following for preceptor attestation and signature:

☒ 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 Janusz Karol Kikut, M.D.	Signature 	Telephone Number 8028473593	Date 11/7/18
License/Permit Number/Facility Name Lic# 44-10187-03 / University of Vermont Medical Center			

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.190, 35.290, and 35.590]APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Authorized User

Naiim Ali, M.D.

State or Territory Where Licensed

Vermont

Requested Authorization(s) (check all that apply)

- ☒ 35.100 Uptake, dilution, and excretion studies
- ☒ 35.200 Imaging and localization studies
- ☒ 35.500 Sealed sources for diagnosis (specify device) SPECT System with Gd-153 line source

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 obtained 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. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

☐ 2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

- a. Authorized user on Materials License meeting 10 CFR 35.390 or equivalent Agreement
State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- ☐ 35.290 ☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☒ 3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401	see attached summary letter >30	June 2014-June 2018
Radiation protection	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401	see attached summary letter >20	June 2014-June 2018
Mathematics pertaining to the use and measurement of radioactivity	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401	see attached summary letter >10	June 2014-June 2018
Chemistry of byproduct material for medical use (not required for 35.590)	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401	see attached summary letter >10	June 2014-June 2018
Radiation biology	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401	see attached summary letter >20	June 2014-June 2018

Total Hours of Training: 90

- b. Supervised Work Experience (completion of this table is not required for 35.590).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience	Location of Experience/License or Permit Number of Facility	Total Hours of Experience:	Confirm	Dates of Experience*
Description of Experience Must Include:				
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401 (Lic.# 44-10187-03)	>200	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014-June 2018
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401 (Lic.# 44-10187-03)		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014-June 2018

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

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401 (Lic.# 44-10187-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014- June 2018
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401 (Lic.# 44-10187-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014- June 2018
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401 (Lic.# 44-10187-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014- June 2018
Administering dosages of radioactive drugs to patients or human research subjects	University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401 (Lic.# 44-10187-03)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014- June 2018
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	(kit preparation) University of Vermont Medical Center 111 Colchester Avenue Burlington, VT 05401 (Lic.# 44-10187-03) and also (generator elution and testing) Pharmalogic, LLC (Lic.# 44-30124-01 MD)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	June 2014- June 2018

License/Permit Number listing supervising individual as an authorized user

License 44-10187-03

☐ 35.190 ☐ 35.290 ☐ 35.390 ☒ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

[illegible]

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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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. (Not required to meet training requirements in 35.590)

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 use requested:

For 35.190

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

☒ I attest that Naiim Ali, M.D. has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

☒ I attest that Naiim Ali, M.D. has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

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

☒ 35.190 ☒ 35.290 ☐ 35.390 ☒ 35.390 + generator experience

Name of Preceptor

Signature

Telephone Number

Date

Janusz Karol Kikut, M.D.

(802) 847-3593

11/7/18

License/Permit Number/Facility Name

Lic.# 44-10187-03 / University of Vermont Medical Center

May 31, 2018

To whom it may concern:

This letter is to summarize the classroom and laboratory training and specific hands on experience required in the Radiology residency program of the University of Vermont Larner College of Medicine, conducted at the University of Vermont Medical Center. This training is conducted to fulfill the requirements of the Nuclear Regulatory Commission found in 10 CFR Part 35.290(c)(1)(i and ii) or equivalent agreement state requirements and to support the information provided on Form 313A(AUD) and 313A(AUT). The approximate hours given below document that greater than 80 hours of classroom and laboratory training is experienced during the residency.

In fulfillment of the classroom and laboratory training residents participate in:

First year:

- Completion of a series of introductory readings, discussion groups, and basic radiation safety exercises as outlined in Attachment 1. (5 hours)
- Completion of the Radiation Biology modules found in the RSNA/AAPM physics modules and available on line to all radiology residents. (10 hours)
- Attendance at a series of lectures which focus on non Nuclear Medicine modalities, but which introduce basic physics concepts (5 hours)

Second year:

- Attendance at a series of Nuclear Medicine lectures. The syllabus for this is found as Attachment 2. Readings are required for each lecture, which is 2 hours in length. (3 hours per class including readings x 15 classes =45 hours)
- In addition to formal presentations on radiation biology, completion of the online radiation biology material by Eric Hall found at <http://www.columbia.edu/~ejh1/web-rad-train/index.html> (5 to 10 hours)

Third year:

- Completion of the Nuclear Medicine notebook. A pdf of the completed notebook is maintained by the applicant. This activity requires at least 40 hours of time in the FAHC Nuclear Medicine department, observing and performing tasks with both single photon and PET radiopharmaceuticals. It also includes observations and tasks performed at the local commercial radiopharmacy, during which a Mo99/Tc99m generator is eluted under the supervision of one of the authorized nuclear pharmacists. Further, there are readings and required questions related to regulations and radiation safety in nuclear medicine. (40 hours)
- Review sessions on radiation safety and regulations conducted by the medical physics. (6 hours)

Fourth year:

- Review of requirements for unsealed source I-131 therapies and documentation for these.
Review of release requirements for patients receiving therapeutic unsealed source materials. (4 hours)

Naiim Ali, M.D. has successfully completed this classroom and laboratory training.

If further documentation or clarification is necessary, please contact me via email or phone as given below.



Brian Oyadomari, MS, DABR
ABR Certified Medical Nuclear Physicist
Radiation Safety Officer
University of Vermont Medical Center
Department of Radiology
University of Vermont Larner College of Medicine

111 Colchester Ave
Burlington, VT 05401
Brian.Oyadomari@uvmhealth.org
(802) 847-3506

ABR
AMERICAN
BOARD OF RADIOLOGY
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Rev.09/2013

Form B

I-131 Therapy Experience Log

Naim Ali

Resident Name

University of Vermont
Medical Center
Diagnostic Radiology, 47-01-01-2

Program & Number

<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor (AU) Print & Sign Name</u>
≤ 33 mCi		
1. <u>6/3/15</u>	<u>15 mCi</u>	Dr. Janusz K. Kut Print Name <u>Janusz K. Kut</u> Sign Name
2. <u>1/20/16</u>	<u>11.9 mCi</u>	Dr. Timothy Higgins Print Name <u>Timothy Higgins</u> Sign Name
3. <u>9/29/17</u>	<u>18.04 mCi</u>	Dr. Janusz K. Kut Print Name <u>Janusz K. Kut</u> Sign Name

<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor (AU) Print & Sign Name</u>
>33 mCi		
1. <u>1/20/16</u>	<u>50.3 mCi</u>	Dr. Timothy Higgins Print Name <u>Timothy Higgins</u> Sign Name
2. <u>1/20/16</u>	<u>46.3 mCi</u>	Dr. Timothy Higgins Print Name <u>Timothy Higgins</u> Sign Name
3. <u>7/4/17</u>	<u>175 mCi</u>	Dr. Timothy Higgins Print Name <u>Timothy Higgins</u> Sign Name



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

MAY 17 2018

St. Peter's Hospital
317 South Manning Boulevard
Albany, New York 12208

Attention: Andrew Stewart Hawkins, M.D.
Radiation Safety Officer

RE: NYS Dept. of Health Radioactive
Materials License No. 1073-2
DH No. 18-295

Dear Dr. Hawkins:

Enclosed is Amendment No. 113 to New York State Department of Health Radioactive Materials License No. 1073-2, which adds Caitlin Merrow, M.S. as an Authorized Medical Physicist and removes Alex Zaharakis, M.S., as such.

If I may be of assistance, please contact this office at (518) 402-7590 or:

New York State Department of Health
Bureau of Environmental Radiation Protection
Radioactive Materials Section
ESP, Corning Tower, Room 1245
Albany, New York 12237

Sincerely,

A handwritten signature in black ink, reading "Ashley McDermott".

Ashley M. McDermott
Associate Radiological Health Specialist

DJS/AMM:ks

Enclosure: Amendment No. 113

cc: Celeste Des Champs,
CNO/VP of Operations



NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

Pursuant to the Public Health Law, Part 16 of the New York State Sanitary Code, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing radioactive material(s) for the purpose(s), and at the place(s) designated below. The license is subject to all applicable rules, regulations, and orders now or hereafter in effect of all appropriate regulatory agencies and to any conditions specified below.

1. NAME OF LICENSEE St. Peter's Hospital Phone (518) 525-1812	3. LICENSE NUMBER 1073-2 4. EXPIRATION DATE June 17, 2023		
2. ADDRESS OF LICENSEE 317 South Manning Boulevard Albany, New York 12208	<table border="1"><tr><td data-bbox="954 835 1222 1022">5a. REFERENCE DH 18-295</td><td data-bbox="1222 835 1500 1022">b. AMENDMENT N.O. 113</td></tr></table>	5a. REFERENCE DH 18-295	b. AMENDMENT N.O. 113
5a. REFERENCE DH 18-295	b. AMENDMENT N.O. 113		

This license is subject to the following conditions:

Conditions 6 through 9 – Authorized Materials, Form, Possession Limits and Uses
Condition 10 – Authorized Users, Radiation Safety Officer, and Medical Physicists
Condition 11 – Documents Incorporated by Reference
Conditions 12 and beyond – License Conditions

In accordance with the request dated April 18, 2018, signed by Wayne Holmen, A. Stewart Hawkins, M.D., and Matthew Wojtecki, New York State Department of Health Radioactive Materials License No. 1073-2 is hereby amended.

Only the amended sections are included, with specific changes indicated in bold type. All previous license conditions not specifically addressed in this amendment shall remain valid and enforceable.



NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

3. License Number 1073-2

5a. Reference DH 18-295

b. Amendment No. 113

AUTHORIZED USERS, RADIATION SAFETY OFFICER, AND MEDICAL PHYSICISTS

10. A. Medical use of byproduct material shall be used by, or under the supervision of, the following individuals for the specified uses approved under New York State Sanitary Code, Chapter 1, Part 16, "Ionizing Radiation", Section 123:
- | | |
|---------------------------|--|
| Smbat Amirbekian, M.D. | 16.123(c)(1), 16.123(c)(2), 16.123(c)(3) limited to oral administration of iodine 131 in quantities less than or equal to 33 millicuries, and 16.123(c)(7) limited to Yttrium 90 Sirtex Medical Limited SIR-Spheres microspheres |
| Vardan Amirbekian, M.D. | 16.123(c)(1) and 16.123(c)(2) |
| Christopher S. Bang, D.O. | 16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) |
| Martin L. Banson, M.D. | 16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries |
| Richard Cavoli, M.D. | 16.123(c)(1) and 16.123(c)(2) |
| Kirsten K. Cestaro, M.D. | 16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries |
| Kyle A. Denniston, M.D. | 16.123(c)(6) limited to remote afterloader units |
| David A. Ellis, M.D. | 16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) |
| Christian A. Gasson, M.D. | 16.123(c)(6) limited to remote afterloader units |
| A. Stewart Hawkins, M.D. | 16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) |
| Stephen A. Hughes, M.D. | 16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries |
| Christine M. Iseman, M.D. | 16.123(c)(1) and 16.123(c)(2) |
| Jennifer McOsker, M.D. | 16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries |
| Jonathan D. Mishkin, M.D. | 16.123(c)(1) and 16.123(c)(2) |



NEW YORK STATE DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS LICENSE

3. License Number 1073-2

5a. Reference DH 18-295

b. Amendment No. 113

10. A. (Continued)

Nicola Petitti, M.D.	16.123(c)(1) and 16.123(c)(2)
Robert J. Rappoport, M.D.	16.123(c)(1) and 16.123(c)(2)
Lee Ratner, M.D.	16.123(c)(1) and 16.123(c)(2)
Richard F. Rowley, M.D.	16.123(c)(1) and 16.123(c)(2)
Duncan E. Savage, M.D.	16.123(c)(6) limited to remote afterloader units
Steven P. Smith, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries
Mark Usow, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries
Douglas Walled, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3)
Andrew C. Warheit, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries
Brian Weiss, M.D.	16.123(c)(1), 16.123(c)(2), and 16.123(c)(3) limited to oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries

B. Radioactive material listed in Item 6 shall be used by Andrew Stewart Hawkins, M.D., as appropriate to fulfill the responsibilities of the Radiation Safety Officer.

C. The Authorized Medical Physicists for this license are Amanda Dyess, M.S., Caitlin Merrow, M.S., Lawrence Reinstein, Ph.D., and Matthew R. Wojtecki, M.S.

FOR THE NEW YORK STATE DEPARTMENT OF HEALTH

Date: MAY 17 2018

DJS/AMM:ks

cc: Celeste Des Champs,
CNO/VP of Operations

By Daniel J. Samson
Daniel J. Samson, CHP, Chief
Radioactive Materials Section
Bureau of Environmental Radiation Protection



Verification of Certification and Maintenance of Certification (MOC)

November 15, 2018

Name: Mr. Matthew Robert Wojtecki

Practice Locations: Delmar, NY

Participating in MOC

Certificate	Status	Valid Through	Maintenance	MOC Requirements
Therapeutic Medical Physics	Valid	03/01/2020	Maintained	Meeting

The information provided in this letter is considered the primary source verification. The most current certificate and MOC public reporting status information can be accessed at any time for Mr. Matthew Robert Wojtecki by entering the required information in the 'Verify board certification status' search on the ABR website at www.theabr.org.

For questions regarding the ABR MOC Program or its participation requirements, please contact the board office at (520) 519-2152 or information@theabr.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Valerie B. Jackson", with a stylized flourish at the end.

Valerie Jackson, MD
Executive Director
American Board of Radiology

RETURN PACKING LIST / DISPOSAL RECEIPT

All information must be provided to ensure proper handling of your return

B

FROM:

Company Name PharmaLogic LTD
 Address 1191 S. Brownell Rd Ste 40
 City Williston State VT ZIP 05425
 RSO / Contact Name* Zonker White
 *Person responsible for Disposal Receipt Records
 Telephone (570) 423-9495 Fax
 Email (BEST OPTION) Zonker White@pharmacologic.info

SEND TO:

 **Eckert & Ziegler**
Isotope Products

Attention: Receiving
1800 North Keystone Street
Burbank, CA 91504
 Telephone - (661) 309-1010
 Fax - (661) 257-8303
 Email: nucmedsales@ezag.com

Record Your FedEx Tracking # 8075 2399 2257
 From Your Air Waybill:
 Please note that the Shipper is responsible for return freight costs

STOP: Original Sheet B must be affixed to the **OUTSIDE** and a copy of the Return Packing List (this page) placed inside of the package. Each returned source to EZIP must be on a one-to-one exchange basis only. For additional returns, please contact EZIP customer service for additional cost considerations.

RETURN # RA- 297627

Write RA# on outside of box or use provided Return Authorization Label.
 Please allow a minimum of 5 business days for disposal processing.
 EZIP does not accept returns through the US Postal Service.

	Catalog Model#	Source Serial #	Nuclide	Original Activity	Original Reference Date	Source Wipe Test < 5nCi
						<small>*Note: No leak test report required unless damaged.</small>
J 1)	<u>BM06S-685</u> <small>RADUVAL VIAL</small>	<u>BM06068509107103</u>	<u>Ge-68</u>	<u>21.05MBq</u>	<u>4/22/2009</u>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
J 2)	<u>? MMS07-153-1000</u> <small>RADUVAL REP</small>	<u>1245-89-1thru 6</u>	<u>Gd-153</u>	<u>3.7MBq x 6</u>	<u>8/1/2007</u>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3)	<u>BM00-99 (x4)</u>	<u>UM01B + UM04B</u>	<u>Co-57</u>	<u>37MBq (x4)</u>	<u>11/11/2010</u>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
J 4)	<u>? SM</u> <small>RADUVAL</small>	<u>BM03-57L (x3)</u>	<u>Co-57</u>	<u>50.4MBq (x3)</u>	<u>2/9/2007</u>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

*If source is damaged or contaminated, describe condition below and submit a copy of the last leak test.

Keep a copy of this form for your records. It may be requested by your regulatory agency.
 I acknowledge that the above information is true to the best of my knowledge.

Print Name & Sign:

Zonker White 1/30/2017

FOR EZIP USE ONLY

EZIP has received the radioactive sources listed above, except as noted below

Receiver's Name: Isidoro Landeros

Receipt Date: 01 FEB 17

Sources not received:

☒ N/A

E-MAILED FEB 07 2017



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

The University of Vermont Medical Center
ATTN: Eileen Whalen, R.N., President and CEO
111 Colchester Avenue
Burlington, VT 05401

Date

December 6, 2018

License Number(s)

44-10187-03

Mail Control Number(s)

610700

Licensing and/or Technical Reviewer or Branch

Medical Branch

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 11/21/2018

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:

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