

THE
University of Vermont
MEDICAL CENTER

January 25, 2019

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

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

This letter is in response to your written request dated December 26, 2018 for further information regarding the total supervised work experience for Naiim Ali, M.D. We realized that a typographical error was made on the second page of NRC Form 313 (AUD), which was submitted for Dr. Ali. The Total Hours of Supervised Work Experience should have been entered as > 700. Dr. Ali acquired the necessary training and work experience, as specified in 10 CFR 35.290(c), during his successful completion of the Radiology residency program of the Vermont Larner College of Medicine.

Please find attached the corrected Form 313 (AUD) for Dr. Ali. If you have questions please contact me at (802) 847-4897. All correspondence should be copied to Brian Oyadomari, M.S., Garden Pavilion, ACC 2, The University of Vermont Medical Center. Thank you.

Sincerely,



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

610700

NMSS/RGN1 MATERIALS-002

**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		Total Hours of Experience: > 700	
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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (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

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

Janusz Kaor Kikut, M.D.

License 44-10187-03

Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).

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

c. For 35.590 only, provide documentation of training on use of the device.

Device

Type of Training

Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

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