

University of Vermont
OF HEALTH & MEDICAL SERVICES
Central Vermont Medical Center

January 30, 2017

Br. 1

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: Central Vermont Medical Center
License # 44-13353-01 *103003292*

Please amend our radioactive materials license to add Sean Reynolds, M.D. as an Authorized User for 35.100 and 35.200 uses. Dr. Reynolds is listed as an Authorized User for 35.100 and 35.200 on the University of Vermont Medical Center license # 44-10187-03.

Please add Russell Meyer, M.D. as an Authorized User for 35.100 and 35.200 uses. Attached is a copy of the Dr. Meyer's preceptor statement signed by Dr. Jay Kikut, Authorized User on the University of Vermont Medical Ctr License # 44-10187-03.

Thank you for your attention to this. If there are any questions, please contact the RSO, Brian Oyadomari, M.S., at (802) 847-3506. If possible, all correspondence should be copied to Brian Oyadomari, M.S., Garden Pavilion, ACC 2, University of Vermont Medical Center, Burlington, VT.

Sincerely,



Nancy Lothian
Chief Operating Officer
Central Vermont Medical Center



Brian Oyadomari, M.S.
Radiation Safety Officer
Central Vermont Medical Center

Central Vermont Medical Center

P.O. Box 547, Barre, VT 05641 | (802) 371-4100 | UVMHealth.org/CVMC

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NRSS/RGNI MATERIALS-002

REC'D IN LAT *02/08/2017*

**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: (05/31/2015)

Name of Proposed Authorized User

Russell Meyer

State or Territory Where Licensed

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) _____

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	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401	see attached summary letter >30	July 2010- June 2014
Radiation protection	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401	see attached summary letter >20	July 2010- June 2014
Mathematics pertaining to the use and measurement of radioactivity	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401	see attached summary letter >10	July 2010- June 2014
Chemistry of byproduct material for medical use (<i>not required for 35.590</i>)	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401	see attached summary letter >10	July 2010- June 2014
Radiation biology	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401	see attached summary letter >20	July 2010- June 2014
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	yes	Total Hours of Experience:	50
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	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401 License 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2012-8/13 see workbook
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401 License 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2012-8/13

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	Fletcher Allen Health Care 111 Colchester Ave Burlington, VT 05401 License 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2012-8/13 see workbook
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Fletcher Allen Health Care License 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2012-8/13
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Fletcher Allen Health Care License 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2012-8/13
Administering dosages of radioactive drugs to patients or human research subjects	Fletcher Allen Health Care License 44-10187-03	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2012-8/13
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	Fletcher Allen Health Care (kit preparation) License 44-10187-03 and also Pharmalogic, LLC (generator elution and testing) License 44-30124-01 MD	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	9/2012-8/13 see workbook

Supervising Individual: Janusz Karol Kikut, M.D.
License/Permit Number listing supervising individual as an authorized user: License 44-10187-02

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 Russell Meyer _____ 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 Russell Meyer _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

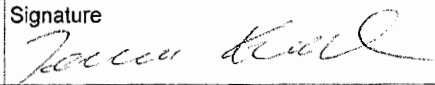
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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	5/27/2014
License/Permit Number/Facility Name			
Fletcher Allen Health Care #44-10187-03			



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Central Vermont Medical Center ATTN: Nancy Lothian, Chief Operating Officer P. O. Box 547 Barre, VT 05641	Date February 17, 2017
	License Number(s) 44-13353-01
	Mail Control Number(s) 593025
	Licensing and/or Technical Reviewer or Branch Medical Branch (Branch 1)

This is to acknowledge receipt of your: Letter and/or Application Dated: 01/30/2017

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 listing 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