



11/29/2012

ATTN:
Nuclear Regulatory Commission
Region III, Materials Licensing Branch
2443 Warrenville Rd., Ste. #210
Lisle, IL 60532-4352

RE: Amendment to NRC License No. 21-04177-01, Lakeland Medical Center.

Please amend the following items:

Please add Joel VanderLugt, M.D. to our license as an Authorized User for 10 CFR 35.100, 10 CFR 35.200 and 10 CFR 35.300. A copy of his Board certification and preceptor training records are included for your reference.

If there are any questions, please contact me at 269-985-4593, or by fax at 269-982-4937.

Sincerely,

David E. Sieffert, M.S., DABR
Medical Physicist
Radiation Safety Officer
Lakeland Medical Center
1234 Napier Ave.
St. Joseph, MI 49085
e-mail: dsieffert@lakelandregional.org

NRC FORM 313A (AUD) (3-2009)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
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]		

Name of Proposed Authorized User Joel Vanderlugt, M.D.	State or Territory Where Licensed Michigan
Requested Authorization(s) (check all that apply)	
<input checked="" type="checkbox"/> 35.100 Uptake, dilution, and excretion studies	
<input checked="" type="checkbox"/> 35.200 Imaging and localization studies	
<input type="checkbox"/> 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)

NRC FORM 313A (AUD)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation biology			
Total Hours of Training:			

**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:	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

NRC FORM 313A (AUD) **U.S. NUCLEAR REGULATORY COMMISSION**
(3-2009) **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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual _____ License/Permit Number listing supervising individual as an authorized user _____

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.

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(1-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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 Joel Vanderlugt, M.D. 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 _____ 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 Joel Vanderlugt, M.D. 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 _____ 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.

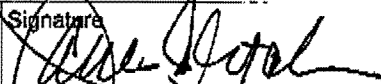
Second Section

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
James W. Fletcher, M.D.

Signature


Telephone Number
(317) 944-1800

Date
09/19/2012

License/Permit Number/Facility Name
NRC License No. 13-02752-03, Permit Nos. UHNM01, RINM01, WDNM01, IU School of Med.

NRC FORM 313A (AUT) (05-2012)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: (05/31/2015)
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]		

Name of Proposed Authorized User <i>Joel Vanderlugt, M.D.</i>	State or Territory Where Licensed <i>Michigan</i>
--	--

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.

NRC FORM 313A (AUT)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. 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	Indiana University School of Medicine License No. 13-02752-03, Radionuclide Permit Nos. UHBM01, R2BM01 + W01M01	30	7/2006 - 6/2011
Radiation protection	Indiana University School of Medicine	20	7/2006 - 6/2011
Mathematics pertaining to the use and measurement of radioactivity	Indiana University School of Medicine	15	7/2006 - 6/2011
Chemistry of byproduct material for medical use	Indiana University School of Medicine	15	7/2006 - 6/2011
Radiation biology	Indiana University School of Medicine	20	7/2006 - 6/2011
Total Hours of Training:		100	

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: 100	
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	Indiana University School of Medicine License No. 13-02720-03 Radionuclide Permit Nos. UHBM01, R2BM01, W01M01	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006 - 6/2011
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Indiana University School of Medicine	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006 - 6/2011
Calculating, measuring, and safely preparing patient or human research subject dosages	Indiana University School of Medicine	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006 - 6/2011
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Indiana University School of Medicine	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006 - 6/2011
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Indiana University School of Medicine	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/2006 - 6/2011

NRC FORM 313A (AUT)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

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: James W. Fletcher, M.D.
License/Permit Number listing supervising individual as an authorized user: UHM01, R21M01, W01M01
13-02752-03

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)	73	Indiana University School of Medicine, NRC license no. 13-02752-03 Radionuclide use permit nos. UHM01, R21M01, + W01M01	7/2006-6/2011
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	73	Indiana University School of Medicine, NRC license no. 13-02752-03 Radionuclide permit nos. UHM01, R21M01, + W01M01	7/2006-6/2011
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)	---	---	---

NRC FORM 313A (AUT)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

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 James W. Fletcher, M.D.	License/Permit Number listing supervising individual as an authorized user 13-02752-03, URM01, RISM01, + WDR01
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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"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) |
| <input checked="" type="checkbox"/> 35.392 | | <input checked="" type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) |
| <input checked="" type="checkbox"/> 35.394 | | <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"/> 35.396 | | <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 _____ 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 **Joel Vanderlugt, M.D.** 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

NRC FORM 313A (AUT)
(05-2012)

U.S. NUCLEAR REGULATORY COMMISSION

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 Joel Vanderlugt, 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 Joel Vanderlugt, 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 Joel Vanderlugt, 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 Joel Vanderlugt, 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

NRC FORM 313A (AUT)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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 James W. Fletcher, M.D.	Signature 	Telephone Number (317) 944-1800	Date 09/26/2012
License/Permit Number/Facility Name NRC License No. 13-02752-03, Permit Nos. UHNM01, RINM01, & WDNM01, IU School of Med.			

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, and the American Association of Physicists in Medicine

Hereby certifies that

Joel Thomas Vander Lugt, 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 that he is qualified to practice,
and is therefore awarded the Board's certification in the specialty of

Diagnostic Radiology

Effective June 30, 2010

AB Eligible

Gene J. Healey
President

Richard I. Morin
Secretary/Treasurer

Harry Schultz
Executive Director

Certificate No. 59109

Valid through 2020



Lakeland Regional Medical Center
1234 Napier Avenue
St. Joseph, MI 49085-2158

Lakeland Specialty Hospital
6418 Deans Hill Road
Berrion Center, MI 49102-9704

Lakeland Community Hospital
400 Medical Park Drive
Watervliet, MI 49098

Lakeland at Meadowbrook
2550 Meadowbrook Road
Benton Harbor, MI 49022

Lakeland Community Hospital
31 N. St. Joseph Avenue
Niles, MI 49120-2287

Lakeland Continuing Care Center
3425 Lakeshore Drive
St. Joseph, MI 49085-2695

Other:

Fax Cover Sheet

To		From	
Name	NRC Region III	Name	David E. Sieffert, MS
Location	Materials Licensing Branch	Location	Lakeland HealthCare
Phone		Phone	269-985-4593
Fax	630-515-1078	Fax	269-982-4937

Message

ATTN:

Materials Licensing
Branch

Notice

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Transmission

By	Date	Pages (including cover)	13
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