Torres, RobertoJ

From: Alan Douglas [adouglas@RockyMountainOncology.com]
Sent: Tuesday, September 22, 2009 4:40 PM
To: Torres, RobertoJ
Subject: 49-29254-01 amendment request
Attachments: NRC Form 313A DrT.xls.pdf; NRC Form 313A DrP.xls.pdf

Mr. Torres,

Attached are the copies of the NRC Form 313A (AUD)s for Dr. Tobin and for Dr. Purviance. Dr. Fleckenstein is the RSO for PET Imaging of Tulsa. He also oversees the reading of the majority of the PET Images generated by the 14 facilities operated by our parent organization, e+CancerCare.

I believe this addresses the last of your concerns. If I can supply any further information, please do not hesitate to contact me.

Thank you for your attention to our amendment request.

Alan Douglas, MS DABR
Rocky Mountain Oncology
6501 E. 2nd Street
Casper, WY 82609
307.233.4751

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

U.S. NUCLEAR REGULATORY COMMISSION

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: 3/31/2012

Name of Proposed Authorized User	State or Territory Where Licensed
Robert L. Tobin	WY

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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.

[x] 2. **Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License 49-00152-02 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	Rocky Mountain Oncology 49-00152-02		1992-Present

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
James L. Fleckenstein M.D.	7819A

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

- [x] 35.290
- [x] 35.390 + generator experience in 32.290(c)(1)(ii)(G)

R. Tobin N/A

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		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

R. Tobin N/A

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		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ 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		☐ Yes ☐ 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.

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 Robert L. Tobin 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 Robert L. Tobin 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 ☐ 35.690 ☑ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
James L. Fleckenstein MD		(918) 693-7092	9-22-09

License/Permit Number/Facility Name
7819A

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

U.S. NUCLEAR REGULATORY COMMISSION

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: 3/31/2012

Name of Proposed Authorized User	State or Territory Where Licensed
John D. Purviance M.D	

Requested Authorization(s) *(check all that apply)*

- [x] 35.100 Uptake, dilution, and excretion studies
- [x] 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	Tufts, New England Medical CTR, Radiation Oncology Program	720	7/2003 thru 7/2007
Radiation protection	Tufts, New England Med CTR, Radiation Oncology Program	720	7/2003 thru 7/2007
Mathematics pertaining to the use and measurement of radioactivity	Tufts, New England MED CTR, Radiation Oncology Program	720	7/2003 thru 7/2007
Chemistry of byproduct material for medical use *(not required for 35.590)*	Tufts, New England MED CTR, Radiation Oncology Program	720	7/2003 thru 7/2007
Radiation biology	Tufts, New England MED CTR Radiation Oncology Program	720	7/2003 thru 7/2007
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	Rocky Mountain Oncology 49-00152-02	☑ Yes ☐ No	7/07 - Present
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	Rocky Mountain Oncology 49-00152-02	☑ Yes ☐ No	7/07 - Present

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	Rocky Mountain Oncology 49-00152-02	☑ Yes ☐ No	7/07 - Present
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	Rocky Mountain Oncology 49-00152-02	☑ Yes ☐ No	7/07 - Present
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	Rocky Mountain Oncology 49-00152-02	☑ Yes ☐ No	7/07 - Present
Administering dosages of radioactive drugs to patients or human research subjects	Rocky Mountain Oncology 49-00152-02	☑ Yes ☐ No	7/07 - Present
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	Rocky Mountain Oncology 49-00152-02	☑ Yes ☐ No	7/07 - Present

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Robert Tobin MD	49-00152-02

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
NA		

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 John D. Purviance 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 John D. Purviance 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
James L. Fleckenstein MD	[signature]	(918) 693-1092	9-22-09

License/Permit Number/Facility Name
7819A

Torres, RobertoJ

From: Alan Douglas [adouglas@RockyMountainOncology.com]
Sent: Tuesday, September 22, 2009 1:10 PM
To: Torres, RobertoJ
Subject: 49-29254-01 amendment request

Mr. Torres,

Further regarding your question about our supplier for the FDG utilized by the new PET/CT unit. Rocky Mountain Oncology will be receiving its doses from PETNET Solutions, Inc., in Aurora, CO. Their license number is 990-02, Expiration date: July 31, 2014. We do have a copy of their license through amendment 10.

Thank you,

Alan Douglas, MS DABR
Rocky Mountain Oncology
6501 E. 2nd Street
Casper, WY 82609
307.233.4751

Torres, RobertoJ

From: Alan Douglas [adouglas@RockyMountainOncology.com]
Sent: Saturday, September 19, 2009 10:29 AM
To: Torres, RobertoJ
Cc: Chris Burgess
Subject: RE: Request for additional information

Mr. Torres;

In response to your email of 9/8/09 here are the answers to your questions.

1. We will be using F-18 for cancer staging, localization and for therapy response.

2. We will be getting the F-18 from PET-NET radiopharmacy. I am waiting for a response from the suppliers with the license number(s) of the facilities that will be shipping the f-18 to us. I will forward that along just as soon as I receive it.

3. We will be using lead blocks and face shields in the area where the doses are stored and handled prior to injection. The dose calibrator will be located near to the shielded area to minimize the handling that is needed. In addition, large syringe shields that are suitable for F-18 (at 511 keV) will be available for use during the injection. Finger rings and whole body badges will be closely monitor during the initial clinic setup with modifications to the use and handling of the isotopes depending on the exposure levels compared with the patient loads.

4. There should be no sources greater than 30 mCi. The rod source in the scanner is 1.5 mCi and the sources for the dose calibrators are 5 mCi or less. Perhaps in the future we'll get a solid Ge-68 cylinder for normalization, but that is typically 10-15 mCi total.

5. The physician 313's will be coming under separate cover. You will understand that getting the signatures necessary require the use of snail-mail and we are somewhat at the mercy to other people's schedules in getting this completed. Rest assured that we are moving forward with all possible speed.

Alan Douglas, MS DABR
Rocky Mountain Oncology
6501 E. 2nd Street
Casper, WY 82609
307.233.4751

From: Torres, RobertoJ [mailto:RobertoJ.Torres@nrc.gov]
Sent: Tuesday, September 08, 2009 10:28 AM
To: Alan Douglas
Subject: Request for additional information

Mr. Douglas:

Please provide the following information in support of license amendment request dated June 6, 2009 to add 35.100 and 35.200 authorization (and authorized users) to license 49-29254-01, Rocky Mountain Oncology. Thank you.

1. As a clarification, please describe what type of radioactive materials will be used under 35.100 and 35.200 uses (Tc-99m, Tl-201, Ga-67, F-18, etc.) and what type of diagnostic procedures will be perfomed (bone scans, lungs scans, heart scans, etc.) for each radionuclide.

2. Describe if a Mo-99/Tc-99m generator will be used on site or if a radiopharmacy will be used to prepare and deliver 35.100 and 35.200 material, or if a combination of both will be used. Provide radiopharmacy name and license number.

3. Describe methods and equipment that will be used for protecting handlers when using Tc-99m (140 keV) and when using F-18 (0.511 MeV).

4. Provide manufacturer's name and model number of radioactive sealed sources used for calibration, transmission or as a reference source for the gamma camera or PET camera, that exceeds 30 millicuries each. If you have such sealed sources they will be line listed (authorized) in the license. If the sources are below 30 mCi each, they are authorized by regulation (35.65) and will not be line listed in the license. See link.

http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0065.html

5. In order to authorize Dr. Tobin and Dr. Purviance as 35.100 and 35.200 authorized users we need that the attached NRC Form 313A (AUD) be completed by each physician. The board certifications provided for both of them are good for "Radiation Oncology" (35.400 and 35.600) but not for "Diagnostic Radiology" (35.100 and 35.200). Therefore the physicians need to document their training and experience in the attached Form 313A (AUD) and have a preceptor sign it. I have also included physician-specific samples of NRC Form 313s to guide them on how to correctly fill out the form depending on their specific authorizations on other NRC licenses.

The list of Board Certifications recognized by NRC for training and experience purposes can be found at: http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

Please provide the requested information by close of business on 9/18/09 (about two weeks from now). Call me if you have any questions. Thank you.

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission - Region IV
Division of Nuclear Materials Safety
Nuclear Materials Safety Branch B
612 East Lamar Boulevard, Suite 400
Arlington, Texas 76011-4125
Telephone 817-860-8189
Facsimile 817-860-8263
robertoj.torres@nrc.gov

Torres, RobertoJ

From: Torres, RobertoJ
Sent: Tuesday, September 08, 2009 11:28 AM
To: 'adouglas@rockymountainoncology.com'
Subject: Request for additional information
Attachments: nrc313a(aud).pdf; SCAN4767.pdf

Mr. Douglas:

Please provide the following information in support of license amendment request dated June 6, 2009 to add 35.100 and 35.200 authorization (and authorized users) to license 49-29254-01, Rocky Mountain Oncology. Thank you.

1. As a clarification, please describe what type of radioactive materials will be used under 35.100 and 35.200 uses (Tc-99m, Tl-201, Ga-67, F-18, etc.) and what type of diagnostic procedures will be perfomed (bone scans, lungs scans, heart scans, etc.) for each radionuclide.

2. Describe if a Mo-99/Tc-99m generator will be used on site or if a radiopharmacy will be used to prepare and deliver 35.100 and 35.200 material, or if a combination of both will be used. Provide radiopharmacy name and license number.

3. Describe methods and equipment that will be used for protecting handlers when using Tc-99m (140 keV) and when using F-18 (0.511 MeV).

4. Provide manufacturer's name and model number of radioactive sealed sources used for calibration, transmission or as a reference source for the gamma camera or PET camera, that exceeds 30 millicuries each. If you have such sealed sources they will be line listed (authorized) in the license. If the sources are below 30 mCi each, they are authorized by regulation (35.65) and will not be line listed in the license. See link.

http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0065.html

5. In order to authorize Dr. Tobin and Dr. Purviance as 35.100 and 35.200 authorized users we need that the attached NRC Form 313A (AUD) be completed by each physician. The board certifications provided for both of them are good for "Radiation Oncology" (35.400 and 35.600) but not for "Diagnostic Radiology" (35.100 and 35.200). Therefore the physicians need to document their training and experience in the attached Form 313A (AUD) and have a preceptor sign it. I have also included physician-specific samples of NRC Form 313s to guide them on how to correctly fill out the form depending on their specific authorizations on other NRC licenses.

The list of Board Certifications recognized by NRC for training and experience purposes can be found at: http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

Please provide the requested information by close of business on 9/18/09 (about two weeks from now). Call me if you have any questions. Thank you.

Roberto J. Torres
Senior Health Physicist
U.S. Nuclear Regulatory Commission - Region IV
Division of Nuclear Materials Safety
Nuclear Materials Safety Branch B
612 East Lamar Boulevard, Suite 400
Arlington, Texas 76011-4125
Telephone 817-860-8189

Facsimile 817-860-8263
robertoj.torres@nrc.gov