

RECEIVED

SEP 24 2010

DNMS

September 21, 2010

US Nuclear Regulatory Commission Region IV
Nuclear Materials Licensing Branch
611 Ryan Plaza Drive
Suite 400
Arlington, Texas 76011-8064

RE: Amendment for Radioactive Materials License #49-29254-01

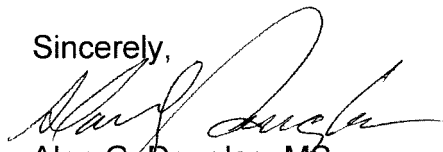
Dear Sir or Madam:

Rocky Mountain Oncology requests that Robert L. Tobin, M.D. be added to the subject license as an authorized user for part 35.600 remote afterloader units. The qualifications for Dr. Tobin are that he has completed training from the manufacturer and has completed three years supervision under Dr. John Purviance, a named authorized user.

Two copies of the current 313A(AUS) are enclosed in support of this request.

For further information, please contact me at: (307) 233-4751 or fax (307) 233-4700.

Sincerely,


Alan G. Douglas, MS
Radiation Safety Officer
Rocky Mountain Oncology
6501 E. 2nd Street
Casper, WY 82609

Attachment: NRC Form 313A(AUS), two copies

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

Robert L. Tobin

State or Territory Where Licensed

WY

Requested

35.400 Manual brachytherapy sources

35.600 Teletherapy unit(s)

Authorization(s)

35.400 Ophthalmic use of strontium-90

35.600 Gamma stereotactic radiosurgery unit(s)

(check all that apply)

☒ 35.600 Remote afterloader unit(s)

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

- Provide a copy of the board certification.
- For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
- Skip to and complete Part II Preceptor Attestation.

☒ **2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**

- Go to the table in section 3.e. to document training for new device.
- Skip to and complete Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

- Classroom and Laboratory Training

35.490

35.491

35.690

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			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

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	
Checking survey meters for proper operation		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Clinical experience in radiation oncology as part of an approved formal training program

Location of Experience/License or
Permit Number of Facility

Dates of
Experience*

Approved by:

Residency Review
Committee for Radiation
Oncology of the ACGME
Royal College of Physicians
and Surgeons of Canada
Committee on Postdoctoral
Training of the American
Osteopathic Association

Supervising Individual

License/Permit Number listing supervising individual as an
Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User		

d. Supervised Work and Clinical Experience for 10 CFR 35.690

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

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*
Reviewing full calibration measurements and periodic spot-checks		Yes No	
Preparing treatment plans and calculating treatment doses and times		Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material		Yes No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		Yes No	
Checking and using survey meters		Yes No	
Selecting the proper dose and how it is to be administered		Yes No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <div style="display: flex; justify-content: space-between;"> <div> Residency Review Committee for Radiation Oncology of the ACGME Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral Training of the American Osteopathic Association </div> <div> </div> </div>		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	8-23-07 & 8-24-07 On-Site Operation Class from manufacturer.		
Safety procedures for the device use	4-18-08 UCSD Med Ctr class 8-24-07 Emergency & Safety Operations		
Clinical use of the device	4-18-08 UCSD MC SAVI Applicator Training 8-24-07 Applications & Accessories Training 4-18-08 UCSD SAVI Applicator		
Supervising Individual. If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.) John Purviance, M.D. / JP		License/Permit Number listing supervising individual as an Authorized User 49-29254-01	

Authorized for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed 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.

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 35.490:

Board Certification

I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 200 hours of

Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of

Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

X I attest that Robert L. Tobin, M.D. has satisfactorily completed 200 hours of classroom

Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

☒ I attest that Robert L. Tobin, M.D. has received training required in 35.690(c) for device
Name of Proposed Authorized User
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as
checked below.

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

☒ I attest that Robert L. Tobin, M.D. has achieved a level of competency sufficient to
Name of Proposed Authorized User
achieve a level of competency sufficient to function independently as an authorized user for:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

☒ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as
an authorized user for:

☐ 35.400 Manual brachytherapy sources ☐ 35.600 Teletherapy unit(s)

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

☒ 35.600 Remote afterloader unit(s)

Name of Preceptor

John Purviance

Signature

[Signature]

Telephone Number

Date

License/Permit Number/Facility Name

Rocky Mountain Oncology

49-29254-01

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User

Robert L. Tobin

State or Territory Where Licensed

WY

Requested**Authorization(s)**

(check all that apply)

35.400 Manual brachytherapy sources

35.600 Teletherapy unit(s)

35.400 Ophthalmic use of strontium-90

35.600 Gamma stereotactic radiosurgery unit(s)

☒ 35.600 Remote afterloader unit(s)**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

- Provide a copy of the board certification.
- For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
- Skip to and complete Part II Preceptor Attestation.

☒ **2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**

- Go to the table in section 3.e. to document training for new device.
- Skip to and complete Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

- Classroom and Laboratory Training

35.490

35.491

35.690

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			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work and Clinical Experience for 10 CFR 35.490 *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*

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	
Checking survey meters for proper operation		Yes No	
Preparing, implanting, and safely removing brachytherapy sources		Yes No	
Maintaining running inventories of material on hand		Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material		Yes No	
Using emergency procedures to control byproduct material		Yes No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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Approved by:

- Residency Review
Committee for Radiation
Oncology of the ACGME
- Royal College of Physicians
and Surgeons of Canada
- Committee on Postdoctoral
Training of the American
Osteopathic Association

Supervising Individual

License/Permit Number listing supervising individual as an
Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User		

d. Supervised Work and Clinical Experience for 10 CFR 35.690

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

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*
Reviewing full calibration measurements and periodic spot-checks		Yes No	
Preparing treatment plans and calculating treatment doses and times		Yes No	
Using administrative controls to prevent a medical event involving the use of byproduct material		Yes No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		Yes No	
Checking and using survey meters		Yes No	
Selecting the proper dose and how it is to be administered		Yes No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: Residency Review Committee for Radiation Oncology of the ACGME Royal College of Physicians and Surgeons of Canada Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
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Device operation	8-23-07 & 8-24-07 On-Site Operation Class from manufacturer. 4-18-08 UCSD Med Ctr class		
Safety procedures for the device use	8-24-07 Emergency & Safety Operations 4-18-08 UCSD MC SAVI Applicator Training		
Clinical use of the device	8-24-07 Applications & Accessories Training 4-18-08 UCSD SAVI applicator		
Supervising Individual. If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.) John Purviance, M.D. JP		License/Permit Number listing supervising individual as an Authorized User 49-29254-01	

Authorized for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed 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.

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 35.490:

Board Certification

I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 200 hours of

Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of

Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

I attest that _____ has satisfactorily completed the requirements in

Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

X I attest that Robert L. Tobin, M.D. has satisfactorily completed 200 hours of classroom

Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

☒ I attest that Robert L. Tobin, M.D. has received training required in 35.690(c) for device
Name of Proposed Authorized User
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as
checked below.

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

☒ I attest that Robert L. Tobin, M.D. has achieved a level of competency sufficient to
Name of Proposed Authorized User
achieve a level of competency sufficient to function independently as an authorized user for:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

☒ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as
an authorized user for:

☐ 35.400 Manual brachytherapy sources ☐ 35.600 Teletherapy unit(s)

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

☒ 35.600 Remote afterloader unit(s)

Name of Preceptor

John Purviance

Signature

[Signature]

Telephone Number

Date

License/Permit Number/Facility Name

Rocky Mountain Oncology

49-29254-01

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM LTS

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date:
Fee Comments:
Decom Fin Assur Req'd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ROCKY MOUNTAIN ONCOLOGY
Received Date: 09/24/2010
Docket Number: 3037415
Mail Control Number: 573613
License Number: 49-29254-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Colleen Murnahan

Date: _____

9-29-2010

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____