

**Torres, RobertoJ**

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**From:** Chris <chrisfitz65@hotmail.com>  
**Sent:** Monday, January 06, 2014 6:55 PM  
**To:** Torres, RobertoJ  
**Subject:** Request for Additional Information for Billings Clinic  
**Attachments:** proper\_nrc\_amendment111113.pdf; Michelle Proper, NRC313A, 400 and 600 Varisource IX, 1-6-14.pdf

Good Evening Roberto,

Please find attached a copy of 313A(AUS) for Dr. Proper and a copy of the signed letter dated 11/11/13. Please let me know if this copy is signed. Not sure what happened with the first one.

Thank you for your help with this request.

Chris



November 11, 2013

Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV  
612 East Lamar Blvd., Suite 400  
Arlington, TX 76011-4125  
817-860-8188

Re: Amendment Request for Billings Clinic License Number 25-01051-01

Dear Mr. Torres:

We wish to amend the above referenced license to add Michelle A. Proper, MD as an authorized user for 10 CFR 35.400 and 600 uses. Dr. Proper has completed the necessary training and experience to function as an authorized user for manual brachytherapy sources and remote afterloader uses. Dr. Proper was previously authorized for these uses at Virginia Commonwealth University (VCU). VCU's broadscope license is 760-215-1. Please find attached the following documents for Dr. Proper: training and experience forms from Virginia, ABR Board certification, and a copy of approval from VCU's RSO.

Dr. Proper will receive device specific training from our chief medical physicist, Dennis Check, Ph.D., prior to operating the HDR unit. Users with approval for these use categories will be considered authorized users for the appropriate categories.

We also wish to increase our possession limit for I-131. Please increase our limit to 900 mCi.

Please contact me at 925-550-7720 or [cfitz@billingsclinic.org](mailto:cfitz@billingsclinic.org) should you require further information concerning this amendment request.

Sincerely,

Christopher K. Fitz, J.D., M.S.  
Radiation Safety Officer

Cc: Peggy Wharton, Vice President  
John Schallenkamp, M.D.  
Michelle A. Proper, M.D.

**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: (05/31/2015)

Name of Proposed Authorized User

Michelle A. Proper, M.D.

State or Territory Where Licensed

MT

**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*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> 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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<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	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> 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*
<b>Approved by:</b> <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> 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		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	Billings Clinic AMP D. Cheek, provided device specific on VariSource™ iX system 01/06/14		
Safety procedures for the device use	Billings Clinic AMP D. Cheek, provided device specific on VariSource™ iX system 01/06/14		
Clinical use of the device	Participated with AU's on device specific on VariSource™ iX system 10/13 to 12/13		
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.)		License/Permit Number listing supervising individual as an Authorized User	
John M. Schallenkamp, M.D.		25-01051-01 Billings Clinic	
Authorized for the following types of use:			
<input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> 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 Michelle A. Proper, M.D. 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 Michelle A. Proper, M.D. has satisfactorily completed the requirements in  
Name of Proposed Authorized User

35.690(a)(1).

**OR**

**Training and Experience**

☐ I attest that \_\_\_\_\_ 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 Michelle A. Proper, 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 Michelle A. Proper, 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**

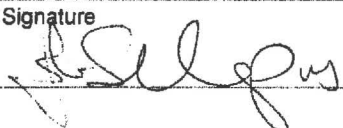
**Complete the following for preceptor attestation and signature:**

☒ 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	Signature	Telephone Number	Date
John M. Schallenkamp, M.D.		(406) 435-7150	01/06/2014
License/Permit Number/Facility Name			
25-01051-01/Billings Clinic			



**Torres, RobertoJ**

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**From:** Torres, RobertoJ  
**Sent:** Tuesday, December 31, 2013 12:17 PM  
**To:** 'cfitz@billingsclinic.org'  
**Subject:** NRC request for additional information  
**Attachments:** ML13329A952.pdf; NRC Form 313A(aus).pdf

Dr. Fitz:

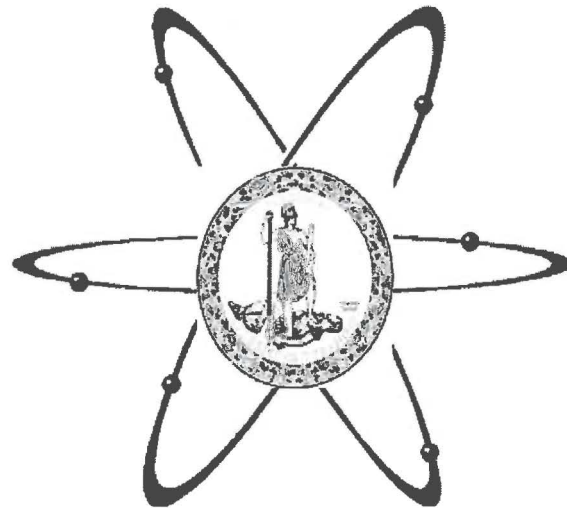
The NRC has completed the technical review of the attached amendment request letter dated November 11, 2013. Please provide the following additional information.

1. Resubmit the letter dated November 11, 2013 to include your signature.
2. Complete the sections highlighted in yellow of the attached NRC Form 313A(aus) and have the form signed by a 10 CFR 35.400 and 35.600 (HDR) authorized user. The need for this form is mainly to document Dr. Proper specific training in the HDR unit at your facility (Varian Varisource iX HDR).

You can provide your response by reply email as a pdf file. Thank you.

Roberto J. Torres  
Senior Health Physicist  
U.S. Nuclear Regulatory Commission, Region IV  
1600 East Lamar Boulevard  
Arlington, TX 76011-4511  
817-200-1189

# COMMONWEALTH of VIRGINIA



## RADIATION PROTECTION REGULATIONS

109 Governor Street, Room 730  
Richmond, VA 23219  
804-864-8150

Reviewer  
Internet Search

## Manual Brachytherapy

10 CFR  
35.400

### **12VAC5-481-2010. Manual Brachytherapy.**

The following regulations, Use of sources for manual brachytherapy (10 CFR 35.400), Surveys after source implant and removal (10 CFR 35.404), Brachytherapy sources accountability (10 CFR 35.406), Safety instruction (10 CFR 35.410), Safety precautions (10 CFR 35.415), Calibration measurements of brachytherapy sources (10 CFR 35.432), Decay of strontium-90 sources for ophthalmic treatment (10 CFR 35.433), Therapy-related computer systems (10 CFR 35.457), Training for use of manual brachytherapy sources (10 CFR 35.490), and Training for ophthalmic use of strontium-90 (10 CFR 35.491) are applicable in the Commonwealth of Virginia.

## Article 8

### Sealed Sources for Diagnosis

#### **12VAC5-481-2020. Use of sealed sources for diagnosis.**

The following regulation, Use of sealed sources for diagnosis (10 CFR 35.500) is applicable in the Commonwealth of Virginia.

#### **12VAC5-481-2030. Training for use of sealed sources for diagnosis.**

The following regulation, Training for use of sealed sources for diagnosis (10 CFR 35.590) is applicable in the Commonwealth of Virginia.

## Article 9

### Photon Emitting Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery

Units

→ = 10 CFR 35.600

#### **12VAC5-481-2040. Photon Emitting Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units.**

The following regulations, Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit (10 CFR 35.600), Surveys of patients and human

research subjects treated with a remote afterloader unit (10 CFR 35.604), Installation, maintenance, adjustment, and repair (10 CFR 35.605), Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (10 CFR 35.610), Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (10 CFR 35.615), Dosimetry equipment (10 CFR 35.630), Full calibration measurements on teletherapy units (10 CFR 35.632), Full calibration measurements on remote afterloader units, (10 CFR 35.633), Full calibration measurements on gamma stereotactic radiosurgery units (10 CFR 35.635), Periodic spot-checks for teletherapy units (10 CFR 35.642), Periodic spot-checks for remote afterloader units (10 CFR 35.643), Periodic spot-checks for gamma stereotactic radiosurgery units (10 CFR 35.645), Additional technical requirements for mobile remote afterloader units (10 CFR 35.647), Radiation surveys, (10 CFR 35.652), Five-year inspection for teletherapy and gamma stereotactic radiosurgery units (10 CFR 35.655), Therapy-related computer systems (10 CFR 35.657), and Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (10 CFR 35.690) are applicable in the Commonwealth of Virginia.

#### Article 10

##### Training and Experience Requirements

#### **12VAC5-481-2050. (Repealed.)**

#### Article 11

##### Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

#### **12VAC5-481-2060. Other medical uses of byproduct material or radiation from byproduct materials.**

The following regulation, Other medical uses of byproduct material or radiation from byproduct materials (10 CFR 35.1000) is applicable in the Commonwealth of Virginia.

#### Article 12

##### Records