

Hill, Carol

From: Chris Fitz <chrisfitz65@hotmail.com>
Sent: Tuesday, May 24, 2016 2:30 PM
To: Torres, RobertoJ; Hill, Carol
Subject: [External_Sender] Amendment Request for Billings Clinic 25-01051-01
Attachments: NRC_letter_052316_signed.pdf; terakedisGKsigned.pdf; Breanne Terakedis Training GK.pdf

Please find attached an amendment request to add an authorized user to the above referenced license.

Thank you,

Chris Fitz, RSO
Billings Clinic
Billings, MT

PUBLIC

- ☒ Immediate Release
☒ Normal Release

NON-PUBLIC

- ☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____

Reviewer: mf Date: 6/6/16



May 23, 2016

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

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

Dear Mr. Torres:

Please amend the above referenced license to include the following:

1. Please add Breanne Terakedis, M.D., as an authorized user for 10 CFR 25.600 Gamma stereotactic radiosurgery uses. Dr. Terakedis is currently authorized on our license for 10 CFR 300, 400 and 600 uses.

The following documentation in support of Dr. Terakedis's training and experience is included:

- NRC 313A AUT
- Training on Sterotactic unit uses and emergency procedures.

If you have questions or require additional information, please contact me at 925-550-7720.
Thank you for your assistance with this request.

Christopher Fitz, JD, MS, ABSNM
Radiation Safety Officer
Billings Clinic

**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: 05/31/2016

Name of Proposed Authorized User

Breanne Terakedis, M.D.

State or Territory Where Licensed

MT

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**
- a. Provide a copy of the board certification.
- b. 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.
- c. Skip to and complete Part II Preceptor Attestation.
- ☒ 2. **Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**
- a. Go to the table in section 3.e. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation.
- ☐ 3. **Training and Experience for Proposed Authorized User**
- a. 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)

a. 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	

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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: <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)

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: <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			07/31/15 - 04/16/16
Safety procedures for the device use			07/31/15 - 04/16/16
Clinical use of the device			7/31/15, 9/6/15, 10/7/15, 10/8/15, 10/30/15, and 2/12/16
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 Schallenkamp, M.D.		License/Permit Number listing supervising individual as an Authorized User	
Authorized for the following types of use: <input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input checked="" type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

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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 Breanne Terakodis, 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 Breanne Terakedis, 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 Breanne Terakedis, 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

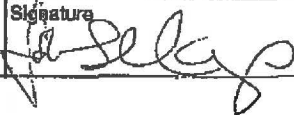
Complete the following for preceptor attestation and signature:

☒ 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 Schallenkamp, M.D.		406-435-71	5/19/2016
License/Permit Number/Facility Name			
Billings Clinic, 25-01051-01			

On 04-08-2016 I performed training with Breanne Terakedis MD on radiation safety, regulatory issues, device operation, safety/emergency procedures, and clinical procedures for 35.1000 Gamma Knife Perfexion. Dr. Terakedis was given a copy of "Emergency na Knife Perfexion stereotactic unit" and the policy was copy of the presentation by Michael Sheetz, "Regulatory ts for use of a Gamma Knife" and reviewed it with her.

35.1000
or 35.600?

Breanne Terakedis MD


Ed Slowey MS DABR