



West Michigan Cancer Center
Together, we win.

November 6, 2012

Colleen Carol Casey
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Rd.
Lisle, IL 60532-4352

Re: *Amendment requests for license number 21-32501-01*

This is a request of The West Michigan Cancer Center for the following amendment to its materials license no. 21-32501-01.

Request to add Dr. Jeffrey Radawski as an authorized user for 10 CFR 35.600, use of Iridium-192 in a remote after-loading brachytherapy device. Enclosed is a copy of NRC Form 313A (AUS).

If there are any questions, please do not hesitate to contact me at (269) 373-7407.

Thank you.

A handwritten signature in cursive script, reading "Paul Jursinic".

Paul Jursinic, Ph.D.
Radiation Safety Officer

Enclosure

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**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

Jeffrey Daniel Radawski, M.D.

State or Territory Where Licensed

Michigan, USA

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	Ohio State University - Dept. of Radiation Oncology 300 W. 10th Ave. Columbus, OH 43210	120	07/01/2008 - 06/30/2012
Radiation protection	Same as above	8	Same as above
Mathematics pertaining to the use and measurement of radioactivity	Same as above	8	Same as above
Radiation biology	Same as above	70	Same as above

Total Hours of Training: 214

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	Ohio State University - Dept. of Radiation Oncology 300 W. 10th Ave. Columbus, OH 43210	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2008 - 06/30/2012
Checking survey meters for proper operation	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Preparing, implanting, and safely removing brachytherapy sources	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Maintaining running inventories of material on hand	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Using administrative controls to prevent a medical event involving the use of byproduct material	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Using emergency procedures to control byproduct material	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above

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 checked="" 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	Ohio State University - Dept. of Radiation Oncology 300 W. 10th Ave. Columbus, OH 43210	07/01/2008 - 06/30/2012
Supervising Individual Christopher E. Pelloski, MD	License/Permit Number listing supervising individual as an Authorized User 02110250037	

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 02110250037	

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	Ohio State University - Dept. of Radiation Oncology 300 W. 10th Ave. Columbus, OH 43210	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/2008 - 06/30/2012
Preparing treatment plans and calculating treatment doses and times	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Using administrative controls to prevent a medical event involving the use of byproduct material	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Checking and using survey meters	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above
Selecting the proper dose and how it is to be administered	Same as above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Same as above

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 checked="" 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	Ohio State University - Dept. of Radiation Oncology 300 W. 10th Ave. Columbus, OH 43210	07/01/2008 - 06/30/2012
Supervising Individual Christopher E. Pelloski, MD		License/Permit Number listing supervising individual as an Authorized User 02110250037

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	Ohio State University - Dept. of Radiation Oncology	Ohio State University - Dept. of Radiation Oncology	Ohio State University - Dept. of Radiation Oncology
Safety procedures for the device use	300 W. 10th Ave Columbus, OH 43210 07/01/2008 - 06/30/2012	300 W. 10th Ave Columbus, OH 43210 07/01/2008 - 06/30/2012	300 W. 10th Ave Columbus, OH 43210 07/01/2008 - 06/30/2012
Clinical use of the device	Same as above	Same as above	Same as above
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 02110250037	
Authorized for the following types of use:			
<input checked="" type="checkbox"/> Remote afterloader unit(s) <input checked="" type="checkbox"/> Teletherapy unit(s) <input checked="" 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 _____ 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 Jeffrey Daniel Radawski, M.D. 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

☒ I attest that Jeffrey Daniel Radawski, 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 Jeffrey Daniel Radawski, 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 Jeffrey Daniel Radawski, 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

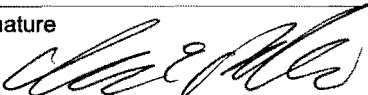
Complete the following for preceptor attestation and signature:

☒ 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)

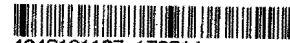
☒ 35.600 Remote afterloader unit(s)

Name of Preceptor	Signature	Telephone Number	Date
Christopher E. Pelloski, MD		(614) 366-2729	10/22/2012
License/Permit Number/Facility Name			
The Ohio State University - Radiation Oncology Residency Program			

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200 North Park Street Kalamazoo, MI 49007-3731 www.wmcc.org

Colleen Carol Casey
Materials Licensing Section
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III
2443 Warrenville Rd.
Lisle, IL 60532-4352