

### Amendment Request NRC License # 21-01078-01

04 October 2016

Jennifer Dalzell Bishop United States Nuclear Commission Region III, Materials Licensing Section 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

Ms. Bishop:

We request to make the following (3) amendments to our materials license 21-01078-01. This is in addition to the expedited amendment request faxed on 10/3/2016. The original material that was faxed is included in this letter.

- 1) Change for Authorized Users:
  - a. Add 35.1000 for I-125 RSL for,
    - i. Michael Paciorek, M.D.
    - ii. Mark Malnor
    - iii. Chad Williams, M.D.
    - iv. Zdravko Skrtic, M.D.
    - v. Jennifer Rollenhagen, M.D.
    - vi. Adam Lenger, M.D.
  - b. NRC 313a (AUS) modified for 35.1000 attached for each AU
- 2) Remove Authorized User: Francis Verde, M.D.
- 3) Change Condition 8 I: Maximum amount for Iodine 125 permitted by 10 CFR 35.1000
  - a. Increase to 30 millicuries
    - i. Patient volumes will be increasing and are higher than initially expected. Therefore, ordering amounts and DIS amounts awaiting return to IsoAid have increased.
    - ii. 30 millicuries will allow us to order 50 seeds at a time and have 100 seeds in decay-in-storage before shipping back to IsoAid.

As having delegation of authority for NRC Radioactive Materials License 21-01078-01 (Mercy Health St. Mary's Hospital, Grand Rapids, MI), we are requesting to amend our radioactive materials license as indicated on the following page(s) with supporting documentation included. We request that these changes to go into effect immediately.

On behalf of Mercy Health St. Mary's Hospital, licensee on NRC RAM license 21-01078-01, we certify that all information contained in this change request, including any supplements attached hereto, is true and correct to the best of our knowledge.

If you have any questions regarding the application please contact me at <u>Triston.W.Dougall@mercyhealth.com</u> or 616-685-6744

Sincerely,

ull 10/4/2016

Triston W. Dougal, RSO RSO / Medical Physicist

Teresa Lalonde Director Radiology

Mercy Health St. Mary's Campus 200 Jefferson Avenue SE Grand Rapids, MI 49503 (616) 685-5000

	U.S. NUCLEAR REGULATORY COMMISSION D USER TRAINING AND EXPERIENCE PRECEPTOR ATTESTATION ed for 35.1000 I-125 RSL	Modif 35.10 I-125	
Name of Proposed Authorized User	State or Territory Where License	ed	
Adam M. Lenger, M.D.	State of Michigan		
Authorization(s) 35.400 Op		stereotactic rac	liosurgery unit(s)
	emote afterloader unit(s)	5.290, training u	under a 35.490 AU
• · · · · · · · · · · · · · · · · · · ·	PART I TRAINING AND EXPERIENCE Select one of the three methods below)		
date of application or the individu	g Board Certification, must have been obtained wi al must have obtained related continuing education was completed. Provide dates, duration, and desc as checked above.	and experience	e since the
1. Board Certification			
a. Provide a copy of the board ce	rtification.		
<li>b. For 35.600, go to the table in 3 which authorization is sought.</li>	3.e. and describe training provider and dates of tra	ining for each t	ype of use for
c. Skip to and complete Part II Pr	eceptor Attestation.		
✓ 2. Current 35.290 Authorized Us	er Requesting Additional Authorization for 35.1	000 use as cho	ecked above
	o document training for new device.		
b. Skip to and complete Part II Pr	-		
3. <u>Training and Experience for</u>			
a. Classroom and Laboratory Tra	aining 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:	1	

I

#### 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	3 cases supervised 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	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	<ul><li>✓ Yes</li><li>No</li></ul>	04 2016 - 06 2016
Checking survey meters for proper operation and performing surveys.	See above	✓ Yes □ No	See above
Preparing, implanting, and removing RSL, including safe use of tools and shielding. Monitoring before, during, and after to ensure identification and remediation of a broken or leaking source.	See above	<pre>✓ Yes</pre> No	See above
Maintaining running inventories of material on hand	See above	<pre>✓ Yes</pre> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<pre>✓ Yes</pre> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<pre>✓ Yes</pre> No	See above

Clinical experience in I-125 RSL as part of an approved formal training program		on of Experience/License or ermit Number of Facility	Dates of Experience*
Approved by: ✓ The Radiation Safety Committee at Mercy Health	3 cases Mercy Health St. Mary Condition 10.B Lack C 250 Cherry St. SE Gran	ancer Center	04 2016 - 06 2016
Supervising Individual James M. Kane, Jr. M.D.		License/Permit Number listing supervising individual as an Authorized User Mercy Health St. Mary's NRC 21-01078-	

NRC FORM 313A (AUS) (06-2016)

016)	FORM 313A (AUS) <sup>6)</sup> AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)				
Training and Experience for Propo	sed 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 listi Authorized User	ing supervising ind	ividual as an		
d Supervised Work and Clinical Exp	origing for 10 CER 35 690				
d. Supervised Work and Clinical Exp Remote afterloader unit(s)		na stereotactic ra	diosurgery uni		
			unosurgery un		
Supervised Work Experience Total Hours of Ex		xperience:	perience:		
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		Yes			

FORM 313A (AUS) <sup>16)</sup> U.S. NUCLEAR REGULATORY COMMISS AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
Supervised Work and Clinical Experience	e for 10 CFR 35.690 (continued)		
inical experience in radiation icology as part of an approved rmal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience	
pproved 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			
upervising Individual	License/Permit Number listing supervisin Authorized User	g individual as an	
pervising Individual		g individi	

Description of Training		Training Provider and Dates			
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery		
Device operation					
Safety procedures for the device use					
Clinical use of the device					
Individual (If more than	Jal. (If training provided by Supervising one supervising individual is necessary work experience, provide multiple		ervising individual as an		
Authorized for the f	ollowing types of use:	rapy unit(s) 🛛 Gamma ste	ereotactic radiosurgery unit(s)		
f. Provide complete	ed Part II Preceptor Attestation.				

NRC FORM 313A (AUS)	·····	U.S. NUCLEAR REGULATORY COMMISSION
(06-2016)		
AUTHORIZED 05		E AND PRECEPTOR ATTESTATION (continued)
	PART II – PRECEPT	OR ATTESTATION
individual as long a	is the preceptor provides, directs, o	eptor. The preceptor does not have to be the supervising or verifies training and experience required. If more than obtain a separate preceptor statement from each.
	exes below, the preceptor is attesting and not attesting to the individual	ng that the individual has knowledge to fulfill the duties of 's "general clinical competency."
First Section Check one of the followin	ig for each requested authorizat	ion:
For 35.1000: I-125 seed lo	ocalization	
<b>Board Certification</b>		
I attest that		has satisfactorily completed the requirements in
	Name of Proposed Authorized User	_
		ency sufficient to function independently as an s for the medical uses authorized under 10 CFR 35.400.
	OI	R
Training and Experie		
I attest that A	dam M. Lenger, M.D. Name of Proposed Authorized User	had satisfactorily completed the training and experience required for 10 CFR 35.1000 I-125 RSL for a
	Name of Proposed Authorized Oser	10 CFR 35.290 authorized user trained under a 10 CFR 35.490 authorized user.
✓ I attest that A	dam M. Lenger, M.D.	has satisfactorily achieved a level of competency — sufficient to function independently as an authorized user
	Name of Proposed Authorized User	for 10 35.1000 I-125 RSL.
Second Section		
For 35.690:		
<b>Board Certification</b>		
I attest that		has satisfactorily completed the requirements in
35.690(a)(1).	Name of Proposed Authorized User	
Training and Even	Ol	R
Training and Exper	ience	has satisfactorily completed 200 hours of classroom
I attest that	Name of Proposed Authorized User	
		work experience, and 3 years of supervised clinical 10 CFR 35.690(b)(1) and (b)(2).
	AN	ID

NRC FORM 313A (AUS)	U.S. NUCLEAR REGULAT	ORY COMMISSION
(06-2016) AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPT	OR ATTESTATION (con	tinued)
Preceptor Attestation (continued)		
Third Section		
<u>For 35.690:</u> (continued)		
	ining 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 the checked below.	or which authorization is	sought, as
Remote afterloader unit(s) Teletherapy unit(s) Gamm	na stereotactic radiosurge	ery unit(s)
AND		
Fourth Section		
I attest that has achieved a	level of competency suffic	cient to
Name of Proposed Authorized User		
achieve a level of competency sufficient to function independently as		
Remote afterloader unit(s) Teletherapy unit(s) Gamm	na stereotactic radiosurge	ry 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 equiv an authorized user for:	alent Agreement State re	quirements, as
🖌 35.400 Manual brachytherapy sources 🗌 35.600 Teletherapy u	unit(s)	
🔄 35.400 Ophthalmic use of strontium-90 🔲 35.600 Gamma stere	eotactic radiosurgery unit	(s)
✓ 35.600 Remote afterloader unit(s)		
Name of Preceptor Signature	Telephone Number	Date
James M. Kane Jr., M.D.	616-685-6672	9/13/2016
License/Permit Number/Facility Name		115100.0
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand Rapids MI NRC 21-0708-01		

AND	U.S. NUCLEA USER TRAINING PRECEPTOR AT d for 35.10	TESTATION	NCE	Modif 35.10 I-125	
Name of Proposed Authorized User	S	tate or Territory Where	Licensed	ł	
Zdravko Skrtic, MD	S	tate of Michigan			
Authorization(s) 35.400 Oph	nual brachytherapy so thalmic use of strontion note afterloader unit(s	um-90 🔲 35.600 G	amma s	tereotactic rad	•••
	ART I TRAINING A elect one of the thre				
<ul> <li>Training and Experience, including date of application or the individual required training and experience w and experience related to the uses</li> </ul>	must have obtained as completed. Provid	related continuing ec	lucation	and experience	e since the
1. Board Certification					
a. Provide a copy of the board cert	ification.				
b. For 35.600, go to the table in 3. which authorization is sought.	e. and describe trainin	ng provider and date	s of trair	ning for each ty	/pe of use for
c. Skip to and complete Part II Pred	ceptor Attestation.				
<ul> <li>2. <u>Current 35.290 Authorized User</u></li> <li>a. Go to the table in section 3.b to</li> <li>b. Skip to and complete Part II Pred</li> <li>3. <u>Training and Experience for P</u></li> </ul>	document training for ceptor Attestation.	new device.	or 35.10	000 use as che	ecked above
a. Classroom and Laboratory Train	ning 🗌 35.490	35.491	35.6	90	
Description of Training	Locatio	n 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 o	f Training:	l.		

#### 3. <u>Training and Experience for Proposed Authorized User (continued)</u>

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	3 cases supervised <b>Total Hours of</b> 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	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	✓ Yes No	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	✓ Yes □ No	See above
Preparing, implanting, and removing RSL, including safe use of tools and shielding. Monitoring before, during, and after to ensure identification and remediation of a broken or leaking source.	See above	✓ Yes □ No	See above
Maintaining running inventories of material on hand	See above	<pre>✓ Yes</pre> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<ul><li>✓ Yes</li><li>No</li></ul>	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	✓ Yes No	See above

Clinical experience in I-125 RSL as part of an approved formal training program		on of Experience/License or ermit Number of Facility	Dates of Experience*
Approved by: ✓ The Radiation Safety Committee at Mercy Health	3 cases Mercy Health St. Mary Condition 10.B Lack Ca 250 Cherry St. SE Gran	ancer Center	07 2015 - 01 2016
Supervising Individual James M. Kane, Jr. M.D.		License/Permit Number listing supervising individual as a Authorized User Mercy Health St. Mary's NRC 21-01078	

NRC FORM 313A (AUS) (06-2016)

	S AND EXPERIENCE AND PRECEPTOR AT	TESTATION (co	ontinued)	
Training and Experience for Propo c. Supervised Clinical Experience for				
c. Supervised Clinical Experience for			1	
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 list Authorized User	ing supervising ind	ividual as an	
d. Supervised Work and Clinical Exp			diegungen	
Remote afterloader unit(s)	Teletherapy unit(s)     Gamn	na stereotactic ra	idiosurgery un	
Supervised Work Experience	Total Hours of E	xperience:	perience:	
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		

Training and Experience for Proposed	d Authorized User (continued)	
d. Supervised Work and Clinical Experie		
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 supervisir Authorized User	ng individual as an

Description of Training		Training Provider and Dates	
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Individual (If more than o	Ial. (If training provided by Supervising one supervising individual is necessary work experience, provide multiple		upervising individual as an
Authorized for the fe	ollowing types of use:	.i	
Remote afterloa	der unit(s)	rapy unit(s) 🛛 🗌 Gamma s	stereotactic radiosurgery unit(s)
f. Provide complete	d Part II Preceptor Attestation.		

NRC FORM 313A (AUS) (06-2016)	U.S. NUCLEAR REGULATORY COMMISSION
	ENCE AND PRECEPTOR ATTESTATION (continued)
PART II – PRECE	EPTOR ATTESTATION
individual as long as the preceptor provides, direc	receptor. The preceptor does not have to be the supervising ets, or verifies training and experience required. If more than ce, obtain a separate preceptor statement from each.
By checking the boxes below, the preceptor is atte the position sought and not attesting to the individ	esting that the individual has knowledge to fulfill the duties of lual's "general clinical competency."
First Section Check one of the following for each requested author	ization:
For 35.1000: I-125 seed localization	
Board Certification	
I attest that     Name of Proposed Authorized User	has satisfactorily completed the requirements in
	petency sufficient to function independently as an rces for the medical uses authorized under 10 CFR 35.400.
	OR
Training and Experience	
✓ I attest that Zdravko Skrtic, MD Name of Proposed Authorized User	had satisfactorily completed the training and experience required for 10 CFR 35.1000 I-125 RSL for a 10 CFR 35.290 authorized user trained under a 10 CFR 35.490 authorized user.
✓ I attest that Zdravko Skrtic, MD Name of Proposed Authorized User	has satisfactorily achieved a level of competency sufficient to function independently as an authorized user for 10 CFR 35.1000 I-125 RSL.
Second Section	
<u>For 35.690:</u>	
Board Certification	
I attest that	has satisfactorily completed the requirements in
Name of Proposed Authorized User 35.690(a)(1).	
Training and Experience	OR
I attest that	has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User and laboratory training, 500 hours of supervise experience in radiation therapy, as required	sed work experience, and 3 years of supervised clinical
	AND

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)         Preceptor Attestation (continued)         Third Section         For 35.690: (continued)	NRC FORM 313A (AUS)	····	U.S. NUCLEAR REGULA	ATORY COMMISSION
Third Section         For 35.690: (continued)           attest that			ID PRECEPTOR ATTESTATION (co	ontinued)
For 35.690: (continued)       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)         Fourth Section       AND         I attest that       has achieved a level of competency sufficient to nachieve 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       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 Ophthalmic use of strontium-90       35.600 Teletherapy unit(s)         35.600 Remote afterloader unit(s)       Telephone Number         Name of Preceptor       Signature         Jamms M. Kane Jr., M.D.       Jamms M. Kane Jr., M.D.         Jenses M. Kane Jr., M.D.       Jamms M. Kane Jr., M.D.	Preceptor Attestation (continu	ued)		
I attest that       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)         Fourth Section       AND         Name of Proposed Authorized User       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:       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:         3 5.400 Manual brachytherapy sources       35.600 Teletherapy unit(s)         3 5.400 Ophthalmic use of strontium-90       35.600 Gamma stereotactic radiosurgery unit(s)         3 5.400 Remote afterloader unit(s)       Telephone Number       Date         Authorized User for:       Signature       Telephone Number       Date         3 5.600 Remote afterloader unit(s)       Signature       Telephone Number       Date         Authorized User for:       Signature       Telephone Number       Date         3 35.600 Remote afterloader unit(s)       Signat	Third Section			
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         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)         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:         I meet the requirements in 10 CFR 35.490, 35.600 Teletherapy unit(s)         35.400 Qhthalmic use of strontium-90       35.600 Gamma stereotactic radiosurgery unit(s)         I 35.400 Qhthalmic use of strontium-90       35.600 Gamma stereotactic radiosurgery unit(s)         I 35.600 Remote afterloader unit(s)       Telephone Number         Name of Preceptor       Signature         Iames M. Kane Jr., M.D.       Signature         Jammas M. Kane Jr., M.D.       Signature         Jammas M. Kane Jr., M.D.       Signature         Jammas M. Kane Jr., M.D.       Signature         J	For 35.690: (continued)			
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)    Fourth Section    I attest that   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)    Fifth Section  Complete the following for preceptor attestation and signature:    I neet 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   35.400 Ophthalmic use of strontium-90   35.600 Remote afterloader unit(s)    Ame of Preceptor  Ame of Preceptor  Signature  Ame of Preceptor  Ame of Preceptor  Signature  Ame of Preceptor  Ame o		· · · · · · · · · · · · · · · · · · ·	s received training required in 35.690	(c) for device
AND         Fourth Section <ul> <li>I attest that</li> <li>Mame of Proposed Authorized User</li> <li>achieve a level of competency sufficient to function independently as an authorized user for:</li> <li>Remote afterloader unit(s)</li> <li>Teletherapy unit(s)</li> <li>Gamma stereotactic radiosurgery unit(s)</li> </ul> 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:           I meet the requirements in 10 CFR 35.490, 35.600 Teletherapy unit(s)           I sto 400 Ophthalmic use of strontium-90           35.400 Ophthalmic use of strontium-90         35.600 Gamma stereotactic radiosurgery unit(s)           I sto 500 Remote afterloader unit(s)         Telephone Number         Date         9/13/2016           Names M. Kane Jr., M.D.         January m. Kuns Jr. m.         6/16-6.855-6.66.72         9/13/2016           Leense/Permit Number/Facility Name         Signature         Telephone Number         Date	operation, safety proc	•	pe(s) of use for which authorization is	s sought, as
Fourth Section         I attest that	Remote afterload	er unit(s) Teletherapy unit(s)	) 🗌 Gamma stereotactic radiosurg	gery unit(s)
□ I attest that		AND		
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)       Telephone Number         Name of Preceptor       Signature         James M. Kane Jr., M.D.       Signature         License/Permit Number/Facility Name       Signature	Fourth Section			
achieve a level of competency sufficient to function independently as an authorized user for:   Remote afterloader unit(s)   Teletherapy 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 35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s) 35.600 Remote afterloader unit(s) Name of Preceptor Signature James M. Kane Jr., M.D. License/Permit Number/Facility Name			s achieved a level of competency suf	ficient to
Fifth Section         Complete the following for preceptor attestation and signature:         Image:		•	ependently as an authorized user for	:
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:         I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:         I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:         I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:         I a state of the requirement				
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:         I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:         I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:         I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:         I a state user for: <td></td> <td></td> <td></td> <td></td>				
✓ 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         James M. Kane Jr., M.D.       ✓         License/Permit Number/Facility Name       Telephone Number	Fifth Section			
✓ 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         James M. Kane Jr., M.D.       ✓         License/Permit Number/Facility Name       Telephone Number	Complete the following for pr	receptor attestation and signatu	ire:	
□ 35.400 Ophthalmic use of strontium-90       □ 35.600 Gamma stereotactic radiosurgery unit(s)         ☑ 35.600 Remote afterloader unit(s)         Name of Preceptor       Signature         James M. Kane Jr., M.D.       Signature         License/Permit Number/Facility Name       Output			.690, or equivalent Agreement State	requirements, as
Image: Signature James M. Kane Jr., M.D.       Signature James M. Kane Jr., M.D.       Telephone Number       Date         License/Permit Number/Facility Name       Date       9/13/2016	✓ 35.400 Manual br	rachytherapy sources 🔲 35.600	Teletherapy unit(s)	
Image: Signature of Preceptor       Signature of Preceptor       Telephone Number       Date         James M. Kane Jr., M.D.       Image: Signature of Comments m. Kome Signature of Co	35.400 Ophthalm	ic use of strontium-90 🔲 35.600	Gamma stereotactic radiosurgery un	iit(s)
James M. Kane Jr., M.D. Cons. J. Kons. James M. Kane Jr. M.D. G16-685-6672 9/13/2016 License/Permit Number/Facility Name				
James M. Kane Jr., M.D. License/Permit Number/Facility Name	Name of Preceptor	Signature 🧳	Telephone Number	Date
License/Permit Number/Facility Name	•			alistant
	· · · · · · · · · · · · · · · · · · ·		MUNKMU GOODDUNDUIL	7/15/2010
	•		21-0708-01	
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NRC FORM 313A (AUS) (06-2016)	U.S. NUCLEAR REGULATORY COMMISSION	Madi	ad for
A BEA.	D USER TRAINING AND EXPERIENCE		fied for
	PRECEPTOR ATTESTATION	35.10	000
Modifie	ed for 35.1000 I-125 RSL	I-125	RSL
Name of Proposed Authorized User	State or Territory Where Licensed	d	
Jennifer Em Rollenhagen, M.D.	State of Michigan		
	inual brachytherapy sources 🔲 35.600 Telethera	py unit(s)	
(check all that apply)	hthalmic use of strontium-90 🔲 35.600 Gamma s		
(oncon un inst spp.), 35.600 Re	mote afterloader unit(s)	.290, training ι	under a 35.490 AU
	PART I TRAINING AND EXPERIENCE Select one of the three methods below)		
date of application or the individua	g Board Certification, must have been obtained with al must have obtained related continuing education was completed. Provide dates, duration, and descr s checked above.	and experience	e since the
1. Board Certification			
a. Provide a copy of the board cer	tification.		
<ul> <li>b. For 35.600, go to the table in 3 which authorization is sought.</li> </ul>	3.e. and describe training provider and dates of train	ning for each ty	pe of use for
c. Skip to and complete Part II Pre	eceptor Attestation.		
✓ 2. Current 35.290 Authorized Use	er Requesting Additional Authorization for 35.10	000 use as che	ecked above
	o document training for new device.		
b. Skip to and complete Part II Pre	•		
3. Training and Experience for I	•		
a. Classroom and Laboratory Tra		200	
-	ining 35.490 35.491 35.6		Dates of
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			
L	Total Hours of Training:		<u> </u>

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#### 3. <u>Training and Experience for Proposed Authorized User (continued)</u>

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	3 cases supervised 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	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	<ul><li>✓ Yes</li><li>No</li></ul>	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	✓ Yes No	See above
Preparing, implanting, and removing RSL, including safe use of tools and shielding. Monitoring before, during, and after to ensure identification and remediation of a broken or leaking source.	See above	<pre>✓ Yes</pre> No	See above
Maintaining running inventories of material on hand	See above	✓ Yes □ No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<pre>✓ Yes</pre> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<ul><li>✓ Yes</li><li>✓ No</li></ul>	See above

Clinical experience in I-125 RSL as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ✓ The Radiation Safety Committee at Mercy Health	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	07 2015 - 01 2016
Supervising Individual James M. Kane, Jr. M.D.	License/Permit Number listing supervising indiv Authorized User Mercy Health St. Mary's NRC	

NRC FORM 313A (AUS) (06-2016)

Training and Experience for Propo	esed Authorized User (continued)		
c. Supervised Clinical Experience for			
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 list Authorized User	ting supervising ind	ividual as an
d. Supervised Work and Clinical Exp	erience for 10 CFR 35.690		
Remote afterloader unit(s)		ma stereotactic ra	idiosurgery uni
Supervised Work Experience	Total Hours of E	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		☐ Yes	

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#### 3. <u>Training and Experience for Proposed Authorized User</u> (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:		
<ul> <li>Residency Review</li> <li>Committee for Radiation</li> <li>Oncology of the ACGME</li> <li>Royal College of Physicians and Surgeons of Canada</li> </ul>		
Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising Authorized User	g individual as an

Description of Training		Training Provider and Dates	
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Individual (If more than	ual. (If training provided by Supervising one supervising individual is necessary I work experience, provide multiple		ervising individual as an
Authorized for the	following types of use: ader unit(s)	apy unit(s) 🗌 Gamma ste	reotactic radiosurgery unit(s)
f. Provide complet	ed Part II Preceptor Attestation.		

NRC FOF	RM 313A (AUS)		U.S. NUCLEAR REGULATORY COMMISSIC
00-2010)	AUTHORIZED	USER TRAINING AND EXPERIEN	NCE AND PRECEPTOR ATTESTATION (continued)
		PART II – PRECEI	PTOR ATTESTATION
Note:	individual as long	g as the preceptor provides, directs	ceptor. The preceptor does not have to be the supervising s, or verifies training and experience required. If more than e, obtain a separate preceptor statement from each.
		boxes below, the preceptor is attes ght and not attesting to the individu	sting that the individual has knowledge to fulfill the duties of al's "general clinical competency."
First So Check		ving for each requested authoriz	ation:
F <u>or 35</u> .	1000: I-125 see	d localization	
B	oard Certificatio	<u>n</u>	
	I attest that	Name of Proposed Authorized User	has satisfactorily completed the requirements in
			etency sufficient to function independently as an ses for the medical uses authorized under 10 CFR 35.400.
			OR
<u>Tra</u>	aining and Expe	rience	
	✓ I attest that	Jennifer Em Rollenhagen, M.D. Name of Proposed Authorized User	had satisfactorily completed the training and experience required for 10 CFR 35.1000 I-125 RSL for a 10 CFR 35.290 authorized user trained under a 10 CFR 35.490 authorized user.
	✓ I attest that	Jennifer Em Rollenhagen, M.D. Name of Proposed Authorized User	has satisfactorily achieved a level of competency sufficient to function independently as an authorized u for 10 CFR 35.1000 I-125 RSL.
	nd Section		
	<u>5.690:</u> 	_	
<u>B</u>	oard Certificatio	<u>11</u>	has satisfactorily completed the requirements in
	I attest that	Name of Proposed Authorized User	
	35.690(a)(1)		
г	raining and Exp		OR
÷	I attest that		has satisfactorily completed 200 hours of classroom
		Name of Proposed Authorized User	
		tory training, 500 hours of supervise in radiation therapy, as required by	ed work experience, and 3 years of supervised clinical y 10 CFR 35.690(b)(1) and (b)(2).
		A	ND

ATTESTATION (con required in 35.690(c hich authorization is ereotactic radiosurge of competency suffi authorized user for: ereotactic radiosurge	c) for device sought, as ery unit(s)
hich authorization is ereotactic radiosurge of competency suffi authorized user for: ereotactic radiosurge	sought, as ery unit(s)
hich authorization is ereotactic radiosurge of competency suffi authorized user for: ereotactic radiosurge	sought, as ery unit(s)
hich authorization is ereotactic radiosurge of competency suffi authorized user for: ereotactic radiosurge	sought, as ery unit(s)
hich authorization is ereotactic radiosurge of competency suffi authorized user for: ereotactic radiosurge	sought, as ery unit(s)
hich authorization is ereotactic radiosurge of competency suffi authorized user for: ereotactic radiosurge	sought, as ery unit(s)
ereotactic radiosurge of competency suffi authorized user for: ereotactic radiosurge	ery unit(s)
of competency suffice authorized user for: ereotactic radiosurge	cient to
authorized user for: ereotactic radiosurge	
authorized user for: ereotactic radiosurge	
authorized user for: ereotactic radiosurge	
ereotactic radiosurge	əry unit(s)
	ery unit(s)
Agreement State re	
	quirements, a
tic radiosurgery unit	(s)
ephone Number	Date
6-685-6672	4/13/2016

<b>{</b> 06-2016	AUTHORIZE ANI ANI ANI ANI ANI	D USER TRAINI	000 I-125 RSL	35.10 I-125	
Chad	R. Williams, MD		State of Michigan		
Auth	orization(s) 35.400 Op	ohthalmic use of strop	ntium-90 🔲 35.600 Gamma s	tereotactic rad	
				2	
	Training and Experience, includir date of application or the individu required training and experience and experience related to the use	ng Board Certification al must have obtaine was completed. Prov	, must have been obtained with d related continuing education	and experience	e since the
	I. Board Certification				
	a. Provide a copy of the board ce	rtification.			
	<li>b. For 35.600, go to the table in which authorization is sought.</li>		ning provider and dates of trair	ning for each ty	pe of use for
	c. Skip to and complete Part II Pr	eceptor Attestation.			
<b>√</b> 2	. Current 35.290 Authorized Us	er Requesting Addi	tional Authorization for 35.10	000 use as che	ecked above
	a. Go to the table in section 3.b t	o document training	for new device.		
	b. Skip to and complete Part II Pr	eceptor Attestation.			
□ :	<ol><li>Training and Experience for</li></ol>	Proposed Authorize	ed User		
	a. Classroom and Laboratory Tra	aining 🗌 35.490	35.491 35.6	90	
	Description of Training	Loca	tion of Training	Clock Hours	Dates of Training*
	Radiation protection				
	AND PRECEPTOR ATTESTATION Modified for 35.1000 I-125 RSL       35.1000 I-125 RSL         me of Proposed Authorized User ad R. Williams, MD       State or Territory Where Licensed State of Michigan         requested thorization(s) back all that apply       35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s) 35.600 Remote afterloader unit(s) √35.1000 I-125 RSL 35.290, training under a 35.490 or 35.600 Remote afterloader unit(s) √35.1000 I-125 RSL 35.290, training under a 35.490 or 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 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 35.290 Authorized User Requesting Additional Authorization for 35.1000 use as checked above         a. Go to the table in section 3.b 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				
		Total Hours	s of Training:		L

#### 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	3 cases supervised 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	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	<ul><li>✓ Yes</li><li>□ No</li></ul>	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	<pre>✓ Yes</pre> No	See above
Preparing, implanting, and removing RSL, including safe use of tools and shielding. Monitoring before, during, and after to ensure identification and remediation of a broken or leaking source.	See above	<pre>✓ Yes</pre> No	See above
Maintaining running inventories of material on hand	See above	✓ Yes □ No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<pre>✓ Yes</pre> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<pre>✓ Yes</pre> No	See above

Clinical experience in I-125 RSL as part of an approved formal training program		on of Experience/License or rmit Number of Facility	Dates of Experience*
Approved by: ✓ The Radiation Safety Committee at Mercy Health	3 cases Mercy Health St. Mary' Condition 10.B Lack Ca 250 Cherry St. SE Gran	ncer Center	07 2015 - 01 2016
Supervising Individual James M. Kane, Jr. M.D.		License/Permit Number listing supervising individual as an Authorized User Mercy Health St. Mary's NRC 21-01078-01	

FORM 313A (AUS) AUTHORIZED USER TRAINING	GAND EXPERIENCE AND PRECEPTOR A	S. NUCLEAR REGUL			
Training and Experience for Propo	sed 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 list Authorized User	ting supervising ind	ividual as an		
d. Supervised Work and Clinical Exp	erience for 10 CFR 35.690				
Remote afterloader unit(s)	Teletherapy unit(s) Gam	ma stereotactic ra	adiosurgery uni		
Supervised Work Experience	Total Hours of I	Experience:	perience:		
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			

#### NRC FORM 313A (AUS) (06-2016)

#### U.S. NUCLEAR REGULATORY COMMISSION

#### AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

#### 3. <u>Training and Experience for Proposed Authorized User</u> (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 supervisin Authorized User	ig individual as an

Description of Training		Training Provider and Dates				
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery			
Device operation						
Safety procedures for the device use						
Clinical use of the device						
Individual (If more than	ual. (If training provided by Supervising one supervising individual is necessary work experience, provide multiple	License/Permit Number listing supe Authorized User	rvising individual as an			
Remote afterloa	following types of use: ader unit(s)	apy unit(s) 🗌 Gamma ste	reotactic radiosurgery unit(s)			

NRC FORM 313A (AUS) (06-2016)	U.S. NUCLEAR REGULATORY COMMISSION
	NCE AND PRECEPTOR ATTESTATION (continued)
PART II – PRECE	PTOR ATTESTATION
individual as long as the preceptor provides, direct	eceptor. The preceptor does not have to be the supervising ts, or verifies training and experience required. If more than the ce, obtain a separate preceptor statement from each.
By checking the boxes below, the preceptor is atte the position sought and not attesting to the individu	esting that the individual has knowledge to fulfill the duties of ual's "general clinical competency."
First Section Check one of the following for each requested authoriz	zation:
For 35.1000 I-125 seed localization	
Board Certification	
I attest that     Name of Proposed Authorized User	has satisfactorily completed the requirements in
	petency sufficient to function independently as an ces for the medical uses authorized under 10 CFR 35.400.
	OR
Training and Experience	
✓ I attest that Chad R. Williams, MD Name of Proposed Authorized User	had satisfactorily completed the training and experience required for 10 CFR 35.1000 I-125 RSL for a 10 CFR 35.290 authorized user trained under a 10 CFR 35.490 authorized user.
✓ I attest that Chad R. Williams, MD Name of Proposed Authorized User	has satisfactorily achieved a level of competency sufficient to function independently as an authorized user for 10 CFR 35.1000 I-125 RSL.
Second Section	
<u>For 35.690:</u>	
Board Certification	
I attest that	has satisfactorily completed the requirements in
Name of Proposed Authorized User 35.690(a)(1).	
Training and Experience	OR
I attest that	has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User and laboratory training, 500 hours of supervis experience in radiation therapy, as required b	sed work experience, and 3 years of supervised clinical
	AND

s.

IRC FORM 313A (AUS)			U.S. NUCLEAR REGULAT	ORY COMMISSION
AUTHORIZED USER TRAINING AND E		PRECEPT	OR ATTESTATION (con	ntinued)
Preceptor Attestation (continued)				
Third Section				
For 35.690: (continued)				
I attest that		received trai	ning required in 35.690(c	c) for device
operation, safety procedures, and clir checked below.		e(s) of use f	or which authorization is	sought, as
Remote afterloader unit(s)	eletherapy unit(s)	🗌 Gamm	na stereotactic radiosurge	ery unit(s)
	AND			
Fourth Section				
I attest that	has	achieved a l	level of competency suffi	cient to
Name of Proposed Author achieve a level of competency sufficie		nondently as	an outhorized user for:	
	ent to function indep eletherapy unit(s)		na stereotactic radiosurge	on unit(e)
				= = = = = = = =
Fifth Section				
Complete the following for preceptor attesta	ation and signatur	e:		
✓ I meet the requirements in 10 CFR 38 an authorized user for:	-		alent Agreement State re	equirements, as
✓ 35.400 Manual brachytherapy sou	Jrces 🗌 35.600 T	eletherapy ι	unit(s)	
35.400 Ophthalmic use of strontiu	m-90 🗌 35.600 C	3amma stere	otactic radiosurgery unit	(s)
✓ 35.600 Remote afterloader unit(s)				
lame of Preceptor Signature	÷,		Telephone Number	Date
ames M. Kane Jr., M.D.		med R mg	616-685-6672	9/13/2016
icense/Permit Number/Facility Name	·	<u> </u>		<u>  ••••</u>
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand	1 Rapids MI NRC 2	21-0708-01		

ANI Modifie Name of Proposed Authorized User Mark A. Malnor, MD Requested Authorization(s) (check all that apply) ANI Modifie 35.400 M 35.400 O	D PRECEPTOR ATTESTATION ed for 35.1000 I-125 RS State or Territory Where Lice State of Michigan anual brachytherapy sources 35.600 Teleth ohthalmic use of strontium-90 35.600 Gamm	E Mod 35.1 L I-12 ensed	5 RSL		
<ul> <li>* 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.</li> </ul>					
1. Board Certification					
		training for each	type of use for		
-					
✓ 2. Current 35.290 Authorized Us	er Requesting Additional Authorization for 3	<b>5.</b> 1000 use as c	necked above		
b. Skip to and complete Part II P	receptor Attestation.				
3. <u>Training and Experience for</u>	Proposed Authorized User				
a. Classroom and Laboratory Tr	aining 35.490 35.491	35.690			
Description of Training	Location of Training	Clock Hours	Dates of Training*		
Radiation physics and instrumentation					
Radiation protection	AuthorizeD USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION Modified for 35.1000 I-125 RSL       35.1000 I-125 RSL         If Proposed Authorized User       State or Territory Where Licensed         A. Mation, MD       State of Michigan         ested       35.400 Manual brachytherapy sources       35.600 Teletherapy unit(s)         rization(s)       35.400 Ophthalmic use of strontum-00       35.600 Gamma stereotactic radiosurgery unit(s)         rization(s)       35.400 Ophthalmic use of strontum-00       35.600 Gamma stereotactic radiosurgery unit(s)         rianing and Experience, including Board Certification, must have been obtained within the 7 years preceding the late of application or the individual must have obtained related continuing education and experience since the equired training and experience was completed. Provide dates, duration, and description of continuing education in dexperience related to the uses checked above.         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.         Current 35.290 Authorized User Requesting Additional Authorization for 35.1000 use as checked above         . Go to the table in section 3.b to document training for new device.         . Skip to and complete Part II Preceptor Attestation.         Training and Experience for Pr				
Mathematics pertaining to the use and measurement of radioactivity					
Radiation biology					
L	Total Hours of Training:	I	l		

#### 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	3 cases supervised 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	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	<pre>✓ Yes</pre> No	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	✓ Yes □ No	See above
Preparing, implanting, and removing RSL, including safe use of tools and shielding. Monitoring before, during, and after to ensure identification and remediation of a broken or leaking source.	See above	<pre>✓ Yes</pre> No	See above
Maintaining running inventories of material on hand	See above	<ul><li>✓ Yes</li><li>No</li></ul>	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<ul><li>✓ Yes</li><li>□ No</li></ul>	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<ul><li>✓ Yes</li><li>No</li></ul>	See above

Clinical experience in I-125 RSL as part of an approved formal training program		on of Experience/License or ermit Number of Facility	Dates of Experience*
Approved by: ✓ The Radiation Safety Committee at Mercy Health	3 cases Mercy Health St. Mary Condition 10.B Lack C 250 Cherry St. SE Gra	ancer Center	07 2015 - 01 2016
Supervising Individual James M. Kane, Jr. M.D.		License/Permit Number listing supervising individual as a Authorized User Mercy Health St. Mary's NRC 21-0107	

CFORM 313A (AUS) AUTHORIZED USER TRAINING	U.S AND EXPERIENCE AND PRECEPTOR AT	NUCLEAR REGUL					
Training and Experience for Propo	sed 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 list Authorized User	ing supervising ind	ividual as an				
d. Supervised Work and Clinical Exp	erience for 10 CEB 35 690						
Remote afterloader unit(s)		na stereotactic ra	diosurgery unit				
Supervised Work Experience	Total Hours of E	(perience:					
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					
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					

#### 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:		
<ul> <li>Residency Review</li> <li>Committee for Radiation</li> <li>Oncology of the ACGME</li> <li>Royal College of Physicians and Surgeons of Canada</li> </ul>		
Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising Authorized User	individual as an

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Individual (If more than	ual. (If training provided by Supervising one supervising individual is necessary work experience, provide multiple	License/Permit Number listing supe Authorized User	rvising individual as an
Authorized for the	following types of use:		
Remote afterloa	ader unit(s)	apy unit(s) Gamma ste	reotactic radiosurgery unit(s)
f. Provide complet	ed Part II Preceptor Attestation.		

NRC FORM 313A (AUS) (06-2016)	U.S. NUCLEAR REGULATORY COMMISSION
	PERIENCE AND PRECEPTOR ATTESTATION (continued)
PART II – P	RECEPTOR ATTESTATION
individual as long as the preceptor provides,	al's preceptor. The preceptor does not have to be the supervising directs, or verifies training and experience required. If more than verience, obtain a separate preceptor statement from each.
By checking the boxes below, the preceptor the position sought and not attesting to the in	is attesting that the individual has knowledge to fulfill the duties of ndividual's "general clinical competency."
First Section Check one of the following for each requested au	ithorization:
For 35.1000: I-125 seed localization	
Board Certification	
I attest that	has satisfactorily completed the requirements in
Name of Proposed Authorized	
	competency sufficient to function independently as an sources for the medical uses authorized under 10 CFR 35.400.
	OR
Training and Experience	
✓ I attest that Mark A. Malnor, MD Name of Proposed Authorized	had satisfactorily completed the training and experience required for 10 CFR 35.1000 I-125 RSL for a 10 CFR 35.290 authorized user trained under a 10 CFR 35.490 authorized user.
✓ I attest that Mark A. Malnor, MD Name of Proposed Authorized	has satisfactorily achieved a level of competency sufficient to function independently as an authorized user for 10 CFR 35.1000 I-125 RSL.
Second Section	
<u>For 35.690:</u>	
Board Certification	
I attest that Name of Proposed Authorized	has satisfactorily completed the requirements in
35.690(a)(1).	
Training and Experience	OR
☐ I attest that	has satisfactorily completed 200 hours of classroom
Name of Proposed Authorize	
	pervised work experience, and 3 years of supervised clinical ired by 10 CFR 35.690(b)(1) and (b)(2).
	<b>AND</b>

NRC FORM 313A (AUS)		U.S. NUCLEAR REGULA	TORY COMMISSION
AUTHORIZED USER TRAIN	ING AND EXPERIENCE AND PRECEPT	OR ATTESTATION (coi	ntinued)
Preceptor Attestation (continued)			-
Third Section			
For 35.690: (continued)			
<u>roros.coc</u> . (continued)			
I attest that		aining required in 35.690(	c) for device
	Proposed Authorized User es, and clinical use for the type(s) of use	for which authorization is	sought, as
Remote afterloader uni	t(s) 🔲 Teletherapy unit(s) 🗌 Gam	na stereotactic radiosurg	ery unit(s)
	AND		
Fourth Section			
I attest that	has achieved a	level of competency suff	icient to
	Proposed Authorized User		
achieve a level of compete	ncy sufficient to function independently a	s an authorized user for:	
Remote afterloader unit	t(s) Teletherapy unit(s) Gam	ma stereotactic radiosurg	ery unit(s)
Fifth Section			
Complete the following for precept	tor attestation and signature:		
✓ I meet the requirements in an authorized user for:	10 CFR 35.490, 35.491, 35.690, or equiv	valent Agreement State re	equirements, as
✓ 35.400 Manual brachyt	herapy sources 🔲 35.600 Teletherapy	unit(s)	
35.400 Ophthalmic use	of strontium-90 🔲 35.600 Gamma ster	eotactic radiosurgery unit	t(s)
✓ 35.600 Remote afterloa	ider unit(s)		
Name of Preceptor	Signature /	Telephone Number	Date
James M. Kane Jr., M.D.		616-685-6672	9/13/2016
License/Permit Number/Facility Name	mine M. C. und Re mos	616-003-6072	115/2016
-	e. SE Grand Rapids MI NRC 21-0708-01		
	· · · · · · · · · · · · · · · · · · ·		
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	U.S. NUCLEAR REGULATORY COMMISSION D USER TRAINING AND EXPERIENCE D PRECEPTOR ATTESTATION Ed for 35.1000 I-125 RSL		_
Name of Proposed Authorized User	State or Territory Where License	ed	
Michael Paciorek, MD	State of Michigan		
Requested 35.400 Ma	anual brachytherapy sources 35.600 Telether	apy unit(s)	
Authorization(s) 35.400 Op	ohthalmic use of strontium-90 🔲 35.600 Gamma	stereotactic rac	liosurgery unit(s)
(check all that apply) 35.600 Re	emote afterloader unit(s)	5.290, training	under a 35.490 AU
	PART I TRAINING AND EXPERIENCE Select one of the three methods below)		
date of application or the individu	ng Board Certification, must have been obtained wi al must have obtained related continuing education was completed. Provide dates, duration, and desc es checked above.	n and experiend	e since the
1. Board Certification			
a. Provide a copy of the board ce	rtification.		
<ul> <li>b. For 35.600, go to the table in which authorization is sought.</li> </ul>	3.e. and describe training provider and dates of tra	ining for each t	ype of use for
c. Skip to and complete Part II Pr	eceptor Attestation.		
2. Current 35.290 Authorized Us	er Requesting Additional Authorization for 35.	1000 use as ch	ecked above
a. Go to the table in section 3.b t	to document training for new device.		
b. Skip to and complete Part II Pr	receptor Attestation.		
3. Training and Experience for	Proposed Authorized User		
a. Classroom and Laboratory Tra		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:		

#### 3. <u>Training and Experience for Proposed Authorized User (continued)</u>

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	3 cases supervised 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	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	✓ Yes □ No	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	✓ Yes □ No	See above
Preparing, implanting, and removing RSL, including safe use of tools and shielding. Monitoring before, during, and after to ensure identification and remediation of a broken or leaking source.	See above	✓ Yes □ No	See above
Maintaining running inventories of material on hand	See above	✓ Yes □ No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	✓ Yes	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<ul><li>✓ Yes</li><li>□ No</li></ul>	See above

Clinical experience in I-125 RSL as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ✓ The Radiation Safety Committee at Mercy Health	3 cases Mercy Health St. Mary's NRC 21-01078-01 Condition 10.B Lack Cancer Center 250 Cherry St. SE Grand Rapids, MI	07 2015 - 01 2016
Supervising Individual James M. Kane, Jr. M.D.	License/Permit Number listing supervising indi Authorized User Mercy Health St. Mary's NR	

NRC FORM 313A (AUS) (06-2016)

Training and Experience for Propo	sed Authorized User (continued)		
c. Supervised Clinical Experience for			
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 Exp	erience for 10 CFR 35,690		
Remote afterloader unit(s)		ma stereotactic ra	adiosurgery uni
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	

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#### 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 supervisin Authorized User	g individual as an

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Individual (If more than	ual. (If training provided by Supervising one supervising individual is necessary work experience, provide multiple	License/Permit Number listing supe Authorized User	ervising individual as an
Authorized for the	following types of use:		
Remote afterloa	ader unit(s)	apy unit(s) 🛛 🗌 Gamma ste	reotactic radiosurgery unit(s)
f. Provide complete	ed Part II Preceptor Attestation.		

NRC FO	RM 313A (AUS)		U.S. NUCLEAR REGULATORY COMMISSIO
	AUTHORIZED	USER TRAINING AND EXPERIEN	CE AND PRECEPTOR ATTESTATION (continued)
		PART II – PRECEP	TOR ATTESTATION
Note:	individual as lon	g as the preceptor provides, directs,	eptor. The preceptor does not have to be the supervising or verifies training and experience required. If more than , obtain a separate preceptor statement from each.
		boxes below, the preceptor is attest ght and not attesting to the individua	ting that the individual has knowledge to fulfill the duties of I's "general clinical competency."
	Section	wing for each requested authoriza	tion.
	.1000: I-125 see	•	
	Board Certificatio		
_	I attest that	-	has satisfactorily completed the requirements in
		Name of Proposed Authorized User	
			tency sufficient to function independently as an s for the medical uses authorized under 10 CFR 35.400.
_			DR
<u>T</u> I	raining and Expe		
	I attest that	Michael Paciorek, M.D. Name of Proposed Authorized User	had satisfactorily completed the training and experienc required for 10 CFR 35.1000 I-125 RSL for a 10 CFR 35.290 authorized user trained under a
			10 CFR 35.490 authorized user.
	✓ I attest that	Michael Paciorek, M.D.	has satisfactorily achieved a level of competency
		Name of Proposed Authorized User	— sufficient to function independently as an authorized us for 10 CFR 35.1000 I-125 RSL.
	ond Section 35.690:		
Ē	Board Certificatio	n	
	I attest that		has satisfactorily completed the requirements in
	35.690(a)(1)	Name of Proposed Authorized User	
			R
	Training and Exp	berience	
	I attest that	Name of Proposed Authorized User	has satisfactorily completed 200 hours of classroom
		,	d work experience, and 3 years of supervised clinical 10 CFR 35.690(b)(1) and (b)(2).
		A	ND

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AUTHORIZED USER TR	AINING AND EXPERIENCE AND	PRECEPTOR ATTESTATION (con	ntinued)
Preceptor Attestation (continue	d)		
Third Section			
For 35.690: (continued)			
I attest that		eceived training required in 35.690(	c) for device
	me of Proposed Authorized User edures, and clinical use for the type	e(s) of use for which authorization is	sought, as
Remote afterloade	r unit(s) 🗌 Teletherapy unit(s)	Gamma stereotactic radiosurg	jery unit(s)
	AND		
Fourth Section			
I attest that		achieved a level of competency suff	icient to
	me of Proposed Authorized User	endently as an authorized user for:	
Remote afterloade	r unit(s)  Teletherapy unit(s)	Gamma stereotactic radiosurg	ery unit(s)
an authorized user for ✓ 35.400 Manual bra	:: achytherapy sources	90, or equivalent Agreement State re eletherapy unit(s) amma stereotactic radiosurgery uni	
Name of Preceptor	Signature	Telephone Number	Date
James M. Kane Jr., M.D.	Janua me. Kum	VEM.1 616-685-6672	9/13/201
James Wi. Kalle Ji., W.D.		· · · · · · · · · · · · · · · · · · ·	
License/Permit Number/Facility Name	<b>;</b>		
License/Permit Number/Facility Name	on Ave. SE Grand Rapids MI NRC 2.	1-0708-01	
License/Permit Number/Facility Name		1-0708-01	
License/Permit Number/Facility Name		1-0708-01	
License/Permit Number/Facility Name		1-0708-01	
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