



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

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

04 October 2016

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.

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

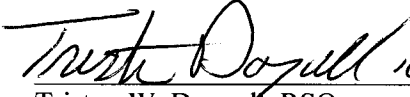
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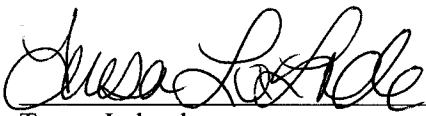
As having delegation of authority for NRC Radioactive Materials License 21-01078-01 (Mercy Health St. Mary's Hospital, Grand Rapids, MI), we are requesting to amend our radioactive materials license as indicated on the following page(s) with supporting documentation included. **We request that these 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
Triston.W.Dougall@mercyhealth.com or 616-685-6744

Sincerely,

 10/4/2016
Triston W. Dougall, RSO
RSO / Medical Physicist


Teresa Lalonde
Director Radiology

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION****Modified for 35.1000 I-125 RSL****Modified for
35.1000
I-125 RSL**

Name of Proposed Authorized User

Adam M. Lenger, M.D.

State or Territory Where Licensed

State of Michigan

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) ☒ 35.1000 I-125 RSL 35.290, training under a 35.490 AU

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 35.290 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

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**3. Training and Experience for Proposed Authorized User (continued)**

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

Supervised Work Experience	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	04 2016 - 06 2016
Checking survey meters for proper operation and performing surveys.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Maintaining running inventories of material on hand	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	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: <input checked="" type="checkbox"/> 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	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 21-01078-01	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**3. Training and Experience for Proposed Authorized User (continued)****c. Supervised Clinical Experience for 10 CFR 35.491**

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690

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

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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			
Safety procedures for the device use			
Clinical use of the device			
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	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.1000: I-125 seed localization

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 Adam M. Lenger, M.D. _____ had satisfactorily completed the training and experience
Name of Proposed Authorized User 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 Adam M. Lenger, M.D. _____ has satisfactorily achieved a level of competency
Name of Proposed Authorized User sufficient to function independently as an authorized user
for 10 CFR 35.1000 I-125 RSL.

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 _____ 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 _____ 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 _____ 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

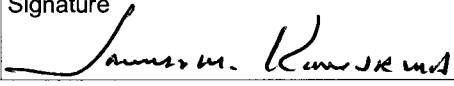
Complete the following for preceptor attestation and signature:

☒ 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
James M. Kane Jr., M.D.		616-685-6672	9/13/2016
License/Permit Number/Facility Name			
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand Rapids MI NRC 21-0708-01			

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION****Modified for 35.1000 I-125 RSL****Modified for
35.1000
I-125 RSL**

Name of Proposed Authorized User

Zdravko Skrtic, MD

State or Territory Where Licensed

State of Michigan

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) ☒ 35.1000 I-125 RSL 35.290, training under a 35.490 AU

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 35.290 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

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Supervised Work Experience	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Maintaining running inventories of material on hand	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	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: <input checked="" type="checkbox"/> 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 individual as an Authorized User Mercy Health St. Mary's NRC 21-01078-01	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690

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

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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			
Safety procedures for the device use			
Clinical use of the device			
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	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.1000: I-125 seed localization

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 Zdravko Skrtic, MD _____ had satisfactorily completed the training and experience
Name of Proposed Authorized User 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 _____ has satisfactorily achieved a level of competency
Name of Proposed Authorized User sufficient to function independently as an authorized user
for 10 CFR 35.1000 I-125 RSL.

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 _____ 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 _____ 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 _____ 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)

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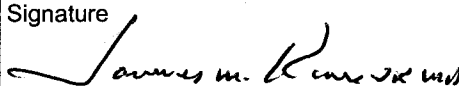
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an authorized user for:

☒ 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
James M. Kane Jr., M.D.		616-685-6672	9/13/2016
License/Permit Number/Facility Name			
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand Rapids MI NRC 21-0708-01			

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION****Modified for 35.1000 I-125 RSL****Modified for
35.1000
I-125 RSL**

Name of Proposed Authorized User

Jennifer Em Rollenhagen, M.D.

State or Territory Where Licensed

State of Michigan

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) ☒ 35.1000 I-125 RSL 35.290, training under a 35.490 AU

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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.
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☒ **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.

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- a. Classroom and Laboratory Training ☐ 35.490 ☐ 35.491 ☐ 35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
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Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Supervised Work Experience	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07 2015 - 01 2016
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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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Maintaining running inventories of material on hand	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	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: <input checked="" type="checkbox"/> 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 individual as an Authorized User Mercy Health St. Mary's NRC 21-01078-01	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690

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

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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			
Safety procedures for the device use			
Clinical use of the device			

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

Authorized for the following types of use:

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

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.1000: I-125 seed localization

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 Jennifer Em Rollenhagen, M.D. _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User 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. _____ has satisfactorily achieved a level of competency
Name of Proposed Authorized User sufficient to function independently as an authorized user
for 10 CFR 35.1000 I-125 RSL.

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 _____ 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 _____ 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 _____ 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
James M. Kane Jr., M.D.	<i>James M. Kane Jr.</i>	616-685-6672	9/13/2016
License/Permit Number/Facility Name			
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand Rapids MI NRC 21-0708-01			

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION****Modified for 35.1000 I-125 RSL****Modified for
35.1000
I-125 RSL**

Name of Proposed Authorized User

Chad R. Williams, MD

State or Territory Where Licensed

State of Michigan

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) ☒ 35.1000 I-125 RSL 35.290, training under a 35.490 AU

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 35.290 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

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Supervised Work Experience	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Maintaining running inventories of material on hand	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	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: <input checked="" type="checkbox"/> 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 individual as an Authorized User Mercy Health St. Mary's NRC 21-01078-01	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690

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

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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			
Safety procedures for the device use			
Clinical use of the device			
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	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.1000: I-125 seed localization

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 Chad R. Williams, MD _____ has satisfactorily completed the training and experience
Name of Proposed Authorized User 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 _____ has satisfactorily achieved a level of competency
Name of Proposed Authorized User sufficient to function independently as an authorized user
for 10 CFR 35.1000 I-125 RSL.

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 _____ 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 _____ 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 _____ 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

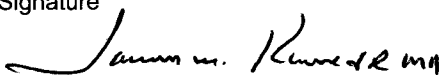
Complete the following for preceptor attestation and signature:

☒ 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
James M. Kane Jr., M.D.		616-685-6672	9/13/2016
License/Permit Number/Facility Name			
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand Rapids MI NRC 21-0708-01			

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION****Modified for 35.1000 I-125 RSL****Modified for
35.1000
I-125 RSL**

Name of Proposed Authorized User

Mark A. Malnor, MD

State or Territory Where Licensed

State of Michigan

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) ☒ 35.1000 I-125 RSL 35.290, training under a 35.490 AU

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 35.290 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

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Supervised Work Experience	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Maintaining running inventories of material on hand	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	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: <input checked="" type="checkbox"/> 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 individual as an Authorized User Mercy Health St. Mary's NRC 21-01078-01	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690

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

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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			
Safety procedures for the device use			
Clinical use of the device			
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	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.1000: I-125 seed localization

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 Mark A. Malnor, MD has satisfactorily completed the training and experience
Name of Proposed Authorized User 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 has satisfactorily achieved a level of competency
Name of Proposed Authorized User sufficient to function independently as an authorized user
for 10 CFR 35.1000 I-125 RSL.

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 _____ 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 _____ 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 _____ 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

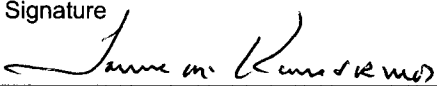
Complete the following for preceptor attestation and signature:

☒ 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
James M. Kane Jr., M.D.		616-685-6672	9/13/2016
License/Permit Number/Facility Name			
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand Rapids MI NRC 21-0708-01			



**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**

Modified for 35.1000 I-125 RSL

**Modified for
35.1000
I-125 RSL**

Name of Proposed Authorized User

Michael Paciorek, MD

State or Territory Where Licensed

State of Michigan

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) ☒ 35.1000 I-125 RSL 35.290, training under a 35.490 AU

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 35.290 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

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Supervised Work Experience	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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07 2015 - 01 2016
Checking survey meters for proper operation and performing surveys.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Maintaining running inventories of material on hand	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using administrative controls to prevent a medical event involving the use of byproduct material	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	See above
Using emergency procedures to control byproduct material, such as procedures regarding a broken or leaking seed.	See above	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	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: <input checked="" type="checkbox"/> 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 individual as an Authorized User Mercy Health St. Mary's NRC 21-01078-01	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690

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

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

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

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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			
Safety procedures for the device use			
Clinical use of the device			
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			
Authorized for the following types of use:			
<input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.1000: I-125 seed localization

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 Michael Paciorek, M.D. _____ had satisfactorily completed the training and experience
Name of Proposed Authorized User 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 user
for 10 CFR 35.1000 I-125 RSL.

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 _____ 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 _____ 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 _____ 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
James M. Kane Jr., M.D.	<i>James M. Kane Jr. M.D.</i>	616-685-6672	9/13/2016
License/Permit Number/Facility Name			
Mercy Health St. Mary's 200 Jefferson Ave. SE Grand Rapids MI NRC 21-0708-01			

FedEx Express

RT 493 1 16:30 D 4526 10:06
FZ

ORIGIN ID: GRRR (616) 605-6118
ANNETTE KING
MERCY HEALTH SAINT MARY'S
200 JEFFERSON AVE SE
GRAND RAPIDS, MI 49503
UNITED STATES US

SHIP DATE: 04OCT16
ACTWTG: 1.0 LB MAN
CRD: 0277725/CAFE2912
BILL SENDER

TO JENNIFER BISHOP
UNITED STATES NUCLEAR COMMISSION
2443 WARRENVILLE RD # 210
REGION 3, MATERIALS LICENSING SECTI
LISLE IL 60532

REF: NUCLEAR MED(TRISTON D.)



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